White Paper

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Importance of Rotational Stability and Tear Film Stability in Toric Contact Lens Wearers

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Introduction

Astigmatism occurs when light entering the eye does not converge at a single focal point in the back of the eye, but instead focuses at two different locations.[1] Visually, this causes images to appear smeared / elongated, due to the distance between these points, and degrades vision at both distance and near. The most common cause is due to a non-uniform corneal surface, where the curvature is greater in one meridian (plane) than the other but can also be caused by the crystalline lens of the eye.[1] Visual correction for patients with astigmatism requires different optical powers in two different meridians (a spherical and a cylindrical component) in order to refocus the two focal points back into one single point.[1] In order to accomplish this effectively, the use of spherocylindrical spectacle glasses, toric contact lenses, refractive surgery, or a toric IOL is required, as these options allow for the correct power at both meridians. Correction using spherical equivalent power, without a discrete cylindrical component (sometimes referred to as "masking" astigmatism) will always result in uncorrected astigmatism and compromised visual quality relative to the magnitude of the astigmatism.[2]

Astigmatism amounts of >0.75D (in at least one eye) occur in 47% of individuals.[3] Of those with astigmatism, who are being corrected, 68% are corrected by eye glasses, 22% by spherical contact lenses, and 10% by toric contact lenses.[4] Modern toric contact lenses have made significant improvements in design and surface technology allowing for exceptional comfort, stabilization, and vision making them an excellent option for astigmatic correction. Additionally, it has been shown that toric contact lenses provide superior visual acuity, visual quality, and functional vision, particularly during digital device use (less need to increase zoom and contrast) compared to spherical equivalent contact lenses even for low to moderate astigmatism making them the ideal choice of soft contact lens correction.[5–9]

Factors Contributing to Stability of Toric Contact Lenses

Rotational Stability

In order for toric contact lenses to work effectively, they must maintain the correcting cylinder at the appropriate axis during wear. The various stabilization methods used to accomplish this are shown in Table 1.[10–13] Of the modern toric lens designs, there is no 'optimal' design for on-eye stability per se. Instead, it is the physical properties of the lens material (i.e. modulus, flexure) in conjunction with the design that determine the best stabilization method for a given material.

Design	Mechanism of Action	Advantages	Disadvantages	Examples
Traditional Prism Ballast 	Base down prism adds thickness to the inferior lens and pressure from the upper lid helps orient the lens. Gravity may help the thicker region to locate inferiorly.	Upper lid pressure keeps the thicker region oriented inferiorly	Inferior lens is thicker causing decreased O2 transmissibility and potentially reduced comfort; prism within optic zone	SofLens Toric SofLens Daily Disposable for Astigmatism
Traditional Peri Ballast 	Inferior peripheral carrier which contains base down prism inferiorly within the carrier only.	Decreased amount of prism within optic zone	Inferior lens is thick causing decreased O2 and potentially reduced comfort	Biotrue OneDay for Astigmatism
Modified Prism Ballast 	Base down prism adds thickness to the inferior lens and pressure from the upper lid helps orient the lens. Gravity may help the thicker region to locate inferiorly.	Prism is restricted to a smaller area inferiorly than in traditional prism ballast designs. Optic zone is larger allowing for minimal prism affect. Can be thinned inferiorly allowing for increased O2 transmissibility and improved comfort	Minimal prism within optic zone	PRECISION1® for Astigmatism AIR OPTIX® plus HydraGlyde® for Astigmatism Ultra for Astigmatism Biofinity toric MyDay toric Avaira toric
Dual Thin Zones  **Thin Zones**  **Accelerated Stabilization**	Thinner zones superior and inferior to fit under lids and allow the lens to align.	Thinner edges at the lid margins may allow for improved comfort	Relies mainly on the lids for stable orientation	DAILIES® AquaComfort Plus® Toric Acuvue Oasys for Astigmatism Acuvue Oasys for Astigmatism 1-Day 1-Day Acuvue Moist for Astigmatism

Table 1: Toric Contact Lens Stabilization Methods

Evaluating the Fit of a Toric Contact Lens

There are two key clinical factors that indicate how stable a toric contact lens is on the eye: 1) rotation (orientation) and 2) oscillation.

1. **ROTATION** (orientation) of the lens is where the axis of the lens settles, and this is determined by viewing the angular position of the scribe marks in primary gaze. In a stable lens, this lens position should not change significantly over the wearing period.
2. **OSCILLATION** of the lens is how much the lens rotates with blinks or eye movements before quickly returning back to the original position (orientation). A stable lens will have minimal rotation during blinks and will quickly rotate back to the resting position after a blink.

The final rotation of a contact lens may or may not be aligned to the vertical (6 o'clock) meridian and it is not uncommon for it to settle in a slightly rotated (misaligned) position.[11] Rotation and oscillation are measured at the slit lamp by orienting a slit beam with the appropriate lens axis markings and assessing rotation and oscillation.

A small amount of lens rotation is acceptable if it is stable and visual performance is not affected. It is more important that the amount of lens oscillation is small and consistent over time, such as while blinking or during eye movements. Significant lens oscillation can cause decreased or fluctuating vision. If the rotation is consistent, but does cause a decrease in visual acuity, then it will be necessary to compensate accordingly using the LARS technique (Figure 1).[11]

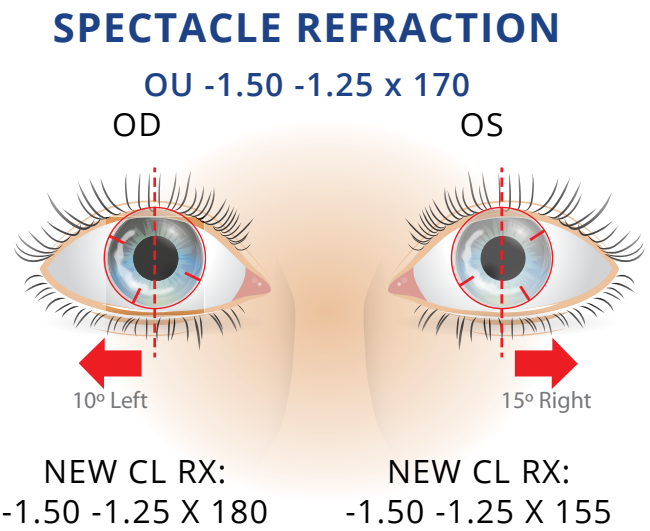

Figure 1: Lars Technique

For clockwise (left) rotation, add the amount of rotation to the axis in the spectacle prescription. For counter-clockwise (right) rotation, subtract the amount from the spectacle prescription.

Note:** Adjusting the axis will allow for the optics of the lens to be aligned with the eye, however, **the final lens will still be rotated by the same amount on the eye and the lens orientation markings will be in the same position.

Tear Film Stability

Two of the main functions of the tear film are 1) to provide a smooth optical surface to allow for clear, undistorted vision, and 2) to lubricate the ocular surface to reduce friction with the eyelids.[14] When a contact lens is placed on the eye it disrupts the structure of the tear film leaving the tears more susceptible to increased tear evaporation, reduced tear break-up time and tear film instability.[15,16] This ultimately can affect the wettability on the surface of the lens and cause reduced visual quality, increased friction with the lids, and decreased comfort.[15,16]

An unstable tear film can also create localized dryness on the surface of the lens where deposits may accumulate and further contribute to tear film disruption.[10,15,16] While both deposits and an unstable tear film can lead to increased lens surface dryness and symptoms of discomfort or decreased vision in any type of contact lens wearer,[15,16] these factors may impact toric contact lens wearers to a greater extent. The dynamics of the lids are one of the main causes of lens axis misalignment, therefore, eyelid anatomy and function are critical to proper orientation. Toric contact lens designs rely on the ability of thinner regions of the lens to tuck easily under one or both eyelids in order to create the appropriate pressure around thicker regions, which helps keep the lens positioned correctly.[10] Increased lens surface dryness, brought on by tear film instability, may increase friction between the lid and lens surface and lead to undesired lens rotation or oscillation and ultimately reduce vision and comfort.[10]

Tear film stability over the lens surface varies for different lens materials depending on the properties of the material itself, specifically wettability of the surface and the propensity for lens deposition. Lens materials that show decreasing tear film stability over the wearing period may also demonstrate increased interactions with the lid over the course of a day, due to friction, and thereby contributing to symptoms of fluctuating vision throughout the day.[16,17]

In order for toric contact lenses to be successful, it is critical that they maintain both rotational stability and tear film stability to provide comfort and good visual outcomes.[10,11,15] Modern toric lenses have incorporated newer stabilization designs and surface technologies to meet these requirements, allowing them to provide consistent patient outcomes.

PRECISION1® for Astigmatism contact lenses

PRECISION1® for Astigmatism (verofilcon A) daily disposable contact lenses have a highly breathable silicone hydrogel core with 51% water content surrounded by a permanent moisture layer of hydrogel polymers with >80% water content. This outer layer of moisture, SMARTSURFACE® Technology, is micro-thin (2-3 microns) and is permanently anchored to the lens core creating a highly wettable and lubricious surface.[18] Surface wettability of the verofilcon A material was compared *in vitro* to other lens materials using the iDDrop method to assess the initial water break-up time for each lens. This *in vitro* method is used to show surface wetting properties of each lens material and is not a clinical performance assessment. The *in vitro* study showed that verofilcon A exhibited superior lens surface wettability by maintaining an intact layer of moisture on the surface longer than Biotrue^ ONEday, 1-DAY ACUVUE^ MOIST, clariti^ 1 day and MyDay^ contact lenses ($p<0.001$) (Figure 2). Importantly, this in vitro measure showed that contact lenses with water surface technology hold onto moisture at the surface longer than the other lenses tested.[19,20*]

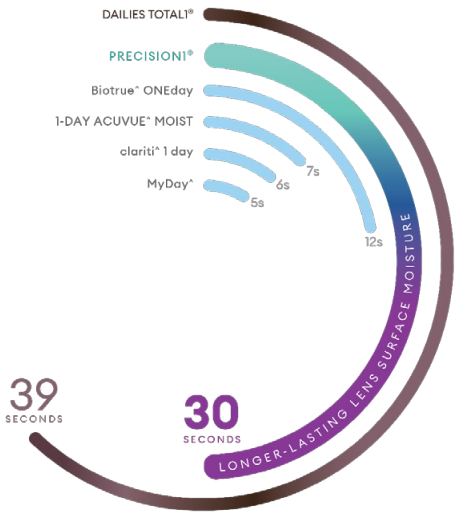

Figure 2: In vitro Lens Surface Wettability with iDDrop method (verofilcon A material vs others). Verofilcon A (PRECISION1®) demonstrated superior moisture stability vs Biotrue^ ONEday, 1-DAY ACUVUE^ MOIST, clariti^ 1 day and MyDay^ contact lenses[19,20]

PRECISION1® for Astigmatism utilizes a modified prism-ballast design called PRECISION BALANCE 8|4® design (Figure 3). Unlike traditional prism-ballasted designs, the thickest regions of the lens are at 8 and 4 o'clock giving the lens two anchor points for stabilization, rather than one. In between these two points, there is minimal prism, creating less inferior lens bulk than traditional prism-ballast designs and therefore a thinner lens inferiorly. This maximizes oxygen transmission and helps provide lower lid comfort. These modifications also allow for a wider optic zone that helps to provide consistent vision during blinking and eye movements. With this design, the upper lid provides pressure on the top of the lens, pushing it down towards the lower lid. The lower lid then keeps the 8 and 4 thick zones balanced for stabilization. The PRECISION1® for Astigmatism contact lenses settle on the eye within 60 seconds. The mean amount of rotation in primary gaze is 3° and remains stable during blinking with <5° of oscillation, helping to provide excellent vision (Figure 3).[21]

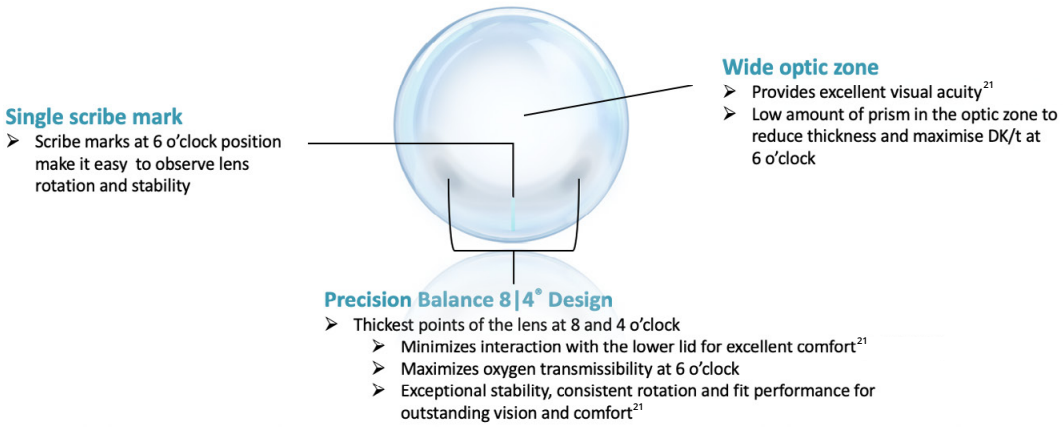

Figure 3: PRECISION1® for Astigmatism with PRECISION BALANCE 8|4® Design

DAILIES® AquaComfort Plus® Toric contact lenses

DAILIES® AquaComfort Plus® Toric (nelfilcon A) contact lenses are hydrogel daily disposable contact lenses made of a material containing a hydrophilic polymer called polyvinyl alcohol (PVA), and 69% water content. This polymer is unique in that bound forms of the PVA permanently crosslink to create a matrix in the lens material, while unbound forms of PVA are able to slowly release from the lens. The unbound PVA is continuously released throughout the day based on the forces of the lid on the lens during blinking and this technology is called Blink-Activated Moisture (Figure 4).[22,23] PVA is a successful tear film stabilizer that is widely used in lubricating eye drops and has been shown to improve tear break up time.[22,24] When compared to the leading daily disposable lens**, DAILIES® AquaComfort Plus® has shown a more stable non-invasive tear break-up time ($p<0.05$) over the surface of the lens (Figure 5).[25]

Two other moisturizing agents, HPMC (hydroxypropyl methylcellulose) and PEG (polyethylene glycol), are added to the blister pack solution to help provide comfort at insertion and early in the day.[23] The Blink-Activated Moisture technology, along with the other moisturizing agents, help to stabilize the tear film and support clear vision, wettability and comfort throughout the day.[24]

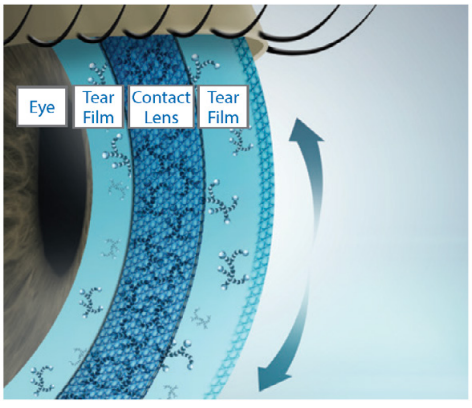

Figure 4: Release of unbound PVA into the tear film during blinking

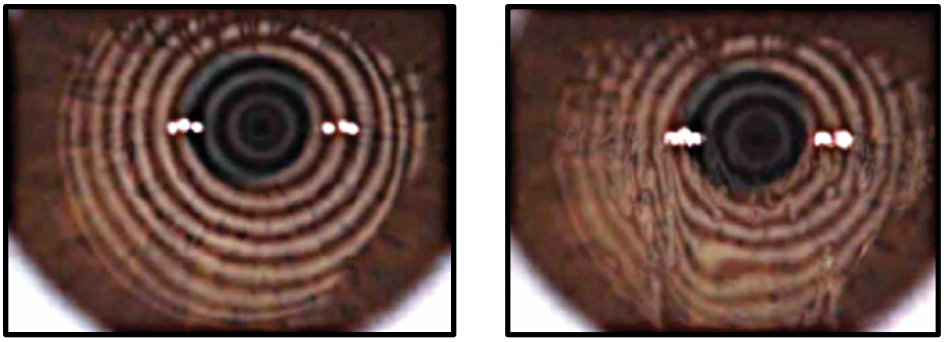

Figure 5: Tear film stability with nelfilcon A contact lens (left) vs. the leading daily disposable contact lens (right) Images from the same patient's eye, 10 seconds post-blink, after wearing each lens for 12 hours**

The stabilization method for DAILIES® AquaComfort Plus® Toric contact lenses is the PRECISION CURVE® lens design, which is a dual thin zones design (Figure 6). The lens is thinner superiorly and inferiorly providing two functions: 1) allows the lens to fit comfortably under the eye lids and 2) allows both lids to align to the thicker portions of the lens and apply equal pressure in order to keep the lens in the correct orientation. 99% of DAILIES® AquaComfort Plus® Toric contact lenses remain stable during blinking with less than 5° of oscillation, helping to provide consistent vision.[26] Once the lens has settled, the average amount of rotation in primary gaze is ~5°, and provides excellent visual acuity.[26]

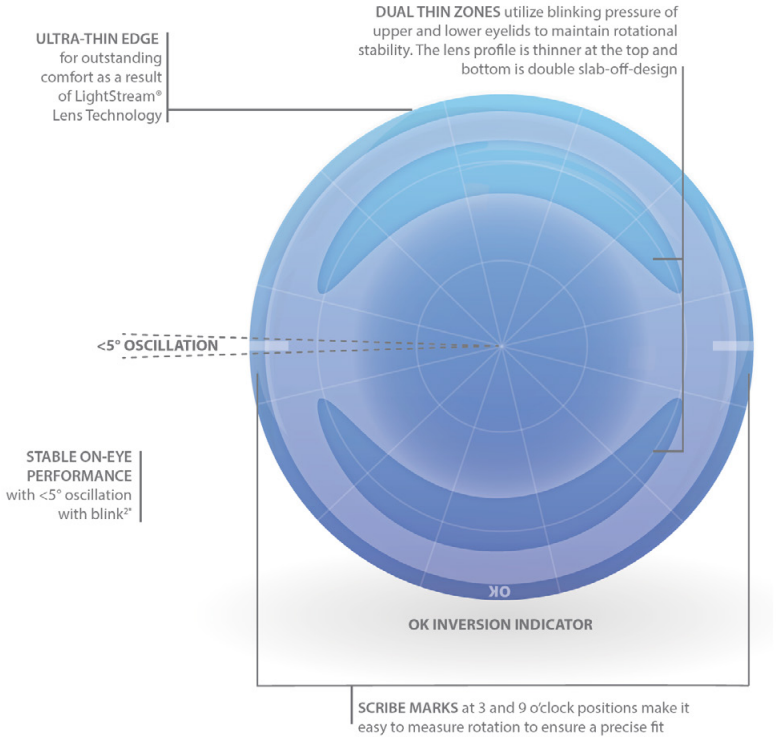

Figure 6: DAILIES® AquaComfort Plus® Toric with PRECISION CURVE® Design

AIR OPTIX® plus HydraGlyde® for Astigmatism contact lenses

AIR OPTIX® plus HydraGlyde® for Astigmatism (lotrafilcon B) contact lenses are silicone hydrogel monthly replacement lenses. They feature both SmartShield® Technology and HydraGlyde® Moisture Matrix. SmartShield® is a permanent plasma treatment to the lens surface that alters the molecules through oxidation, minimizing the amount of exposed silicone. It creates a smooth, hydrophilic barrier that attracts moisture to provide lens surface wettability and also resists deposit build-up, both of which help to provide comfort all day, tear film stability and excellent vision.[27–30] HydraGlyde®

is a surface-active wetting agent that contains a hydrophilic component that attracts and retains moisture at the lens surface.[31,32] When compared to the leading frequent replacement contact lens***, lotrafilcon B contact lenses have shown greater tear film stability ($p<0.05$) based on a higher minimum protected area (MPA), meaning that the lens was covered (protected) by more tear film after holding the eye open and just prior to blinking the eye (Figure 7).[30]

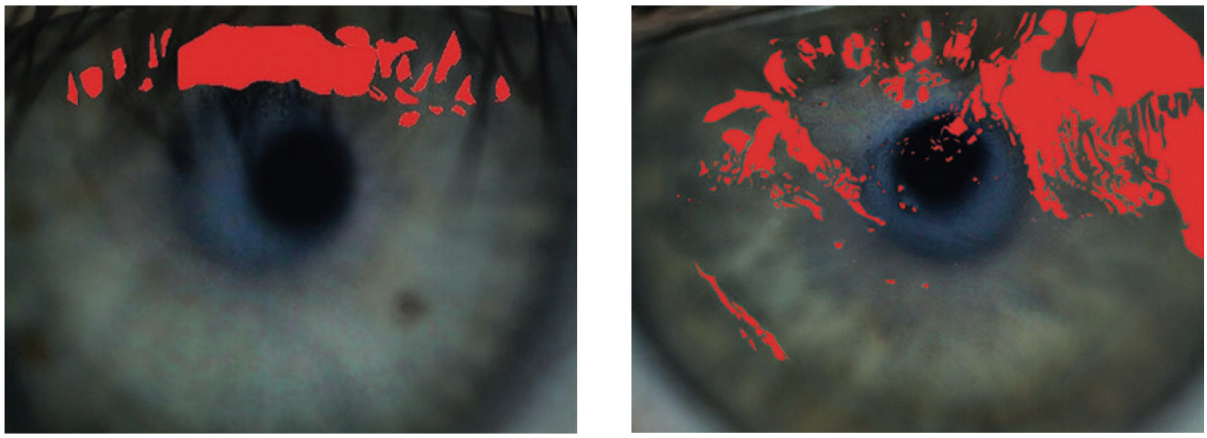

Figure 7: MPA (non-red areas) with lotrafilcon B contact lens (left) vs. the leading frequent replacement contact lens (right)* after 30 days of daily wear and 14 days of daily wear respectively. Minimum Protected Area (MPA): the area (%) of the lens covered by the tear film (non-red areas) after holding the eye open and just prior to blinking; the area is associated with the last image prior to the blink.**

AIR OPTIX® plus HydraGlyde® for Astigmatism also utilizes the PRECISION BALANCE 8|4® design, a modified prism-ballast design for rotational lens stabilization (Figure 8). The AIR OPTIX® plus HydraGlyde® for Astigmatism contact lenses remain stable on the eye during blinking with 98% of lenses having less than 5° of oscillation providing reliable and consistent vision.[33] Once the lenses have settled, 88% of lenses have <5° of rotation while still providing excellent vision.[33]

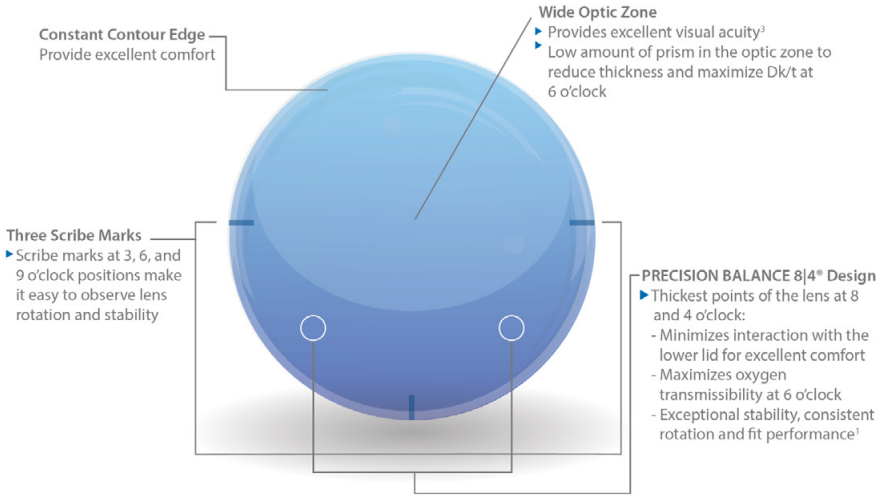

Figure 8: AIR OPTIX® plus HydraGlyde® for Astigmatism with PRECISION BALANCE 8|4® Design

Summary

Toric contact lenses are an excellent vision correction option for patients with astigmatism. Several studies have shown that patients with even small amounts of astigmatism (> 0.75D) have superior vision with a toric versus a spherical contact lens.[5-9] The success of a toric contact lens is dependent on both rotational stability and tear film stability for both comfort and visual acuity. Toric lenses require an effective stabilization method that involves specific interactions with the lids.[10,11] The tear film over the lens surface needs to be stable throughout the day in order to provide a smooth, wettable surface so as not to cause increased friction with the lids and unwanted potential lens rotation.[10,16] This helps to ensure consistent and non-fluctuating vision throughout the day. In order for toric contact lens wear to be successful, it is important to choose a toric contact lens that provides stability on the eye and includes surface wetting technology that supports a stable tear film throughout the day for consistent comfort and vision.[10,11,15]

* Based on an *in vitro* study wherein wettability was measured using the iDDrop System ($p<0.001$). All lenses were tested in an identical manner, soaked in a PBS (phosphate-buffered saline solution) for 16 hours +/- 2 hours.

**etafilcon A material

***senofilcon A material

^Trademarks are the property of their respective owners.

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Important information for AIR OPTIX® for Astigmatism (lotrafilcon B) contact lenses: For daily wear or extended wear up to 6 nights for near / far-sightedness and astigmatism. Risk of serious eye problems (i.e., corneal ulcer) is greater for extended wear. In rare cases, loss of vision may result. Side effects like discomfort, mild burning or stinging may occur.

See product instructions for complete wear, care and safety information. Rx only

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