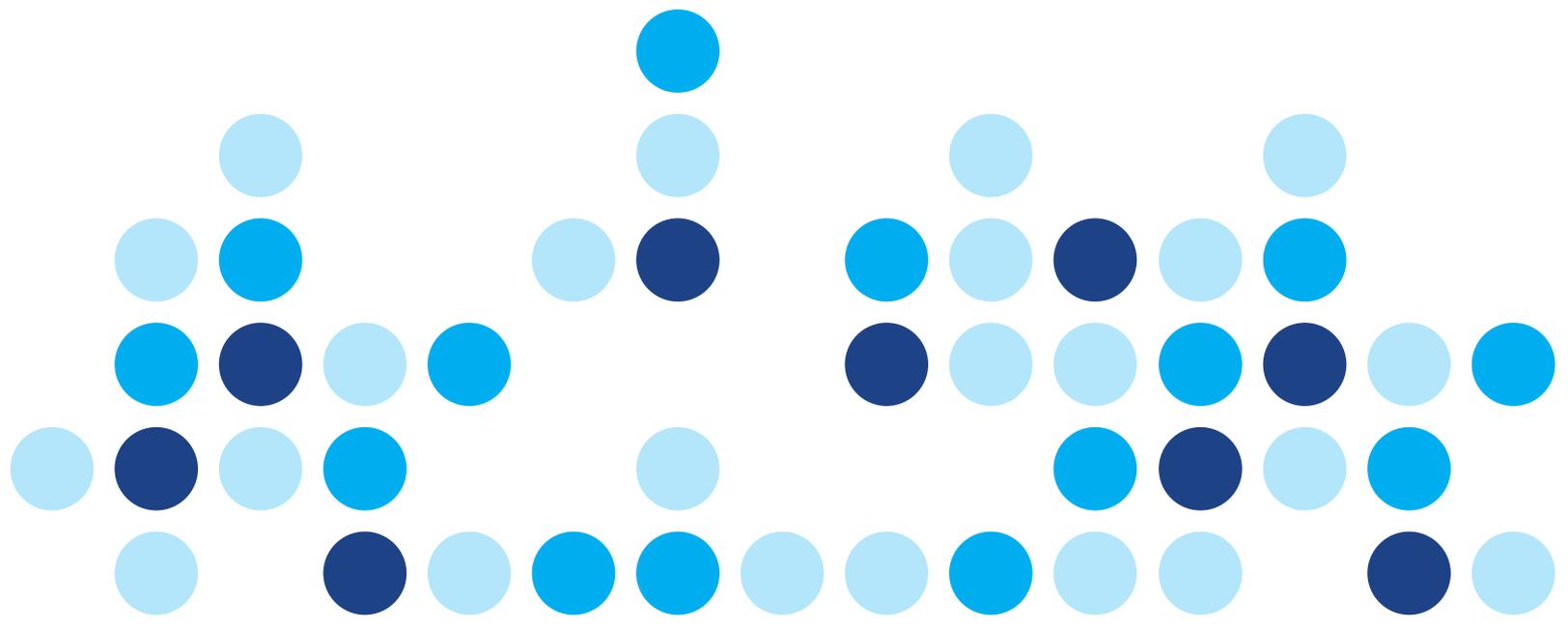


Precision1[®] Contact Lenses With Smartsurface[®] Technology: Material Properties, Surface Wettability and Clinical Performance

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Key Takeaways

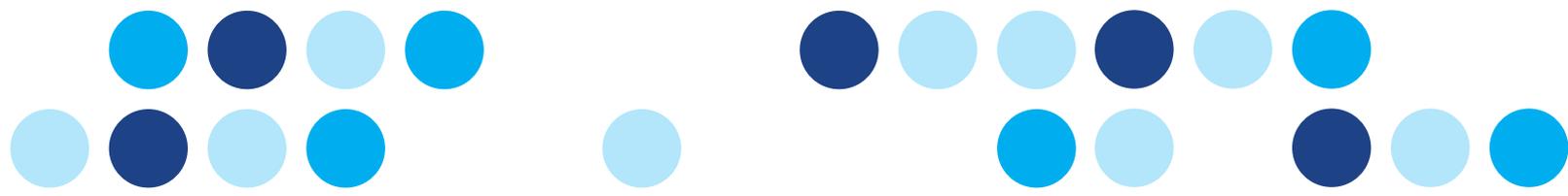
- A wettable contact lens surface is critical for maintaining a smooth and stable tear film.
- PRECISION1® (verofilcon A) contact lenses have a highly breathable silicone hydrogel core with 51% water content surrounded by a permanent moisture layer of hydrogel polymers with >80% water content.
- SMARTSURFACE® Technology is a micro-thin (2-3 microns) layer of moisture, which is permanently anchored to the lens core creating a highly wettable and lubricious surface.
- PRECISION1® contact lenses showed superior in vitro lens surface wettability by 1) maintaining an intact layer of moisture on the surface longer and 2) exhibiting a slower rate of de-wetting when compared to 1-Day Acuvue^ Moist, clariti^ 1 Day and MyDay^ contact lenses.
- PRECISION1® contact lenses achieved high ratings from wearers in overall comfort, overall vision and overall handling.

New Contact Lens Wearer Satisfaction

It is well known that contact lens dropout is an issue for established contact lens wearers,¹ but a recent U.K. study shows that dropout is also a problem in new wearers (neophytes).² This study showed that new wearers are not completely satisfied with their wearing experience. The main overall issues that the new wearers struggled with are poor vision (41%), poor comfort (36%) and handling (25%). When the new wearers who had dropped out of contact lens wear were asked “what would persuade you to try contact lenses again?”, the top three answers were better vision, better comfort and easier handling.²

Optically Precise Tear Film

The tear film, whether over the cornea or over a contact lens, plays an important role in both comfort and vision.³ Our eyes blink approximately 14,000 times per day, meaning the eyelid slides over the front of the cornea – or a contact lens – about once every six seconds.⁴ Additionally, the tear film, overlying the cornea or a contact lens, is responsible for approximately 70% of the eyes refractive power contributing to vision.^{5,6} Therefore, establishing a tear film that is optically precise (smooth and stable) at the contact lens surface is critical. A wettable and lubricious contact lens surface is key in achieving this and ultimately supports 1) visual quality⁷ and 2) comfort by reducing friction with the eyelid.^{3,8,9}



Evolution of Water Surface Technology

In 2013, Alcon introduced the first soft contact lens with water surface technology – DAILIES TOTAL1® water gradient contact lenses (delefilcon A). The advanced chemistry of this lens was, and is, novel and different than any other soft contact lens on the market. The ultrasoft hydrophilic water surface provides exceptional lubricity,¹⁰ comfort^{8,9} and visual quality.¹¹ However, water gradient technology is exclusive to the delefilcon A material and requires the use of LightStream® Technology on the manufacturing platform for production of these lenses.

Alcon has developed a new daily disposable lens material with water surface benefits. In order to do this, novel surface chemistry was utilized along with a unique manufacturing platform optimized to integrate water to the surface of a new core silicone hydrogel material. PRECISION1® (verofilcon A) daily disposable contact lenses with SMARTSURFACE® Technology are built on the legacy of water surface innovation in combination with Alcon's latest Agilient manufacturing platform.

PRECISION1® contact lenses with SMARTSURFACE® Technology

Verofilcon A is a highly breathable ($Dk/t @ -3.00 = 100$) silicone hydrogel material with 51 percent water content at the core of PRECISION1® contact lenses. The SMARTSURFACE® Technology is a permanent layer of moisture at the lens surface with >80 percent water content and consists of bound hydrogel polymers that completely encapsulate the core of the lens (Figure 1 & 2).¹² The lens core has a modulus of 0.6MPa allowing for easy handling and an ultrasoft lens surface that is several hundred times softer than the core to support on-eye comfort (Figure 2).^{12,13} While the silicone hydrogel core allows for high oxygen permeability and easy handling, the SMARTSURFACE® water layer helps to support lens surface wettability, comfort and an optically precise tear film for visual quality.^{12,13}

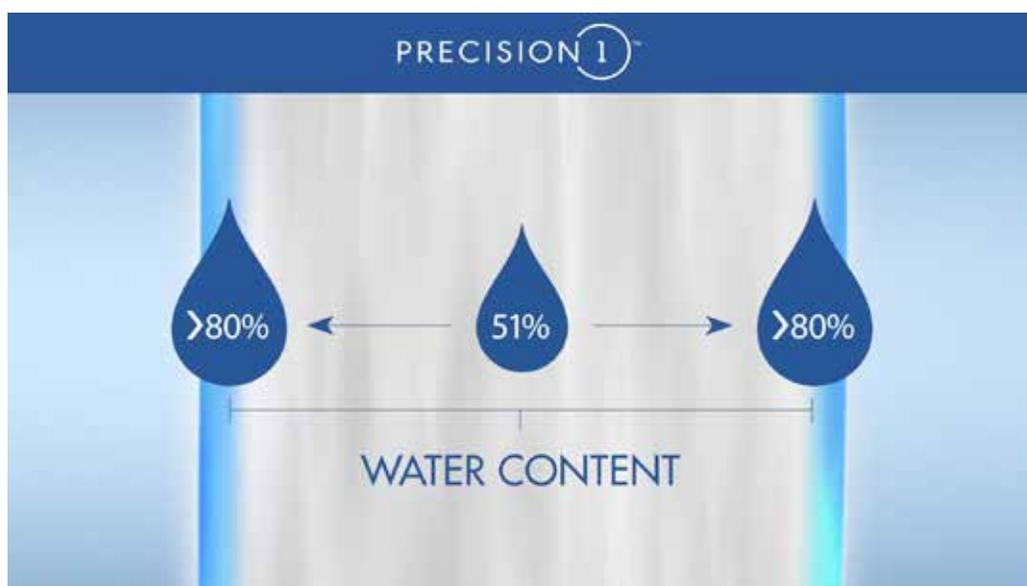
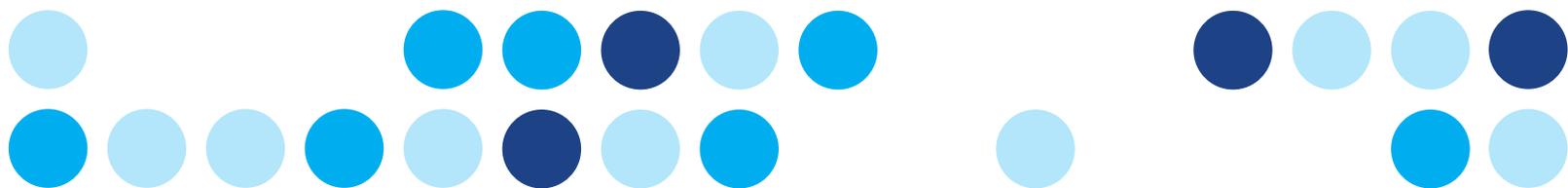


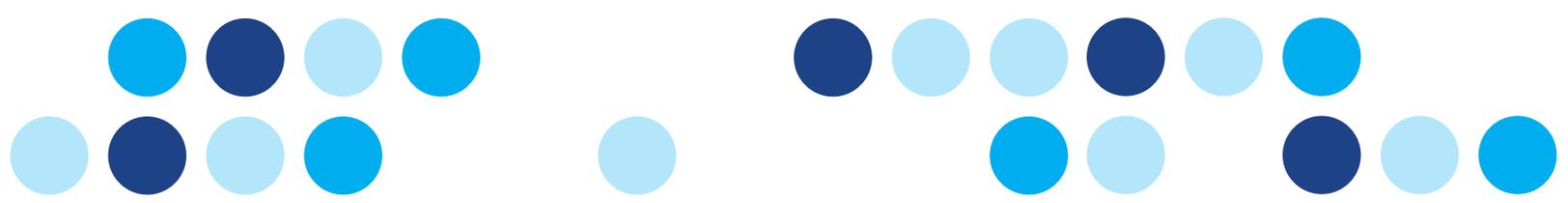
Figure 1: PRECISION1® Contact Lens Core and Surface Water Content



To create the SMARTSURFACE® water layer on PRECISION1® contact lenses, a unique manufacturing process was created for the verofilcon A material. The lenses go through a series of extraction steps, which include a sequence of different baths that contain a hydrogel polymer, polyacrylic acid (PAA). PAA is a very hydrophilic (water-loving) polymer and is a main contributor to the high water content (>80%) on the lens surface. One bath of the series slightly expands the lens material, temporarily opening small pores in the lens surface to allow the PAA to penetrate into the lens surface. The PAA polymers are locked into place when the lens is moved to a subsequent bath in the manufacturing process. Finally, when the lens is in the blister pack, the heat from the autoclave stage completes the formation of the water surface by crosslinking the PAA with wetting agents consisting of copolymers of polyamidoamine (PAE) and polyacrylamide-acrylic acid (PAAm-PAA). The final result is a micro-thin layer of moisture (2-3 microns), which is permanently anchored to the lens creating a highly wettable and lubricious surface (Figure 3).¹²

Material	verofilcon A
Type	Silicon Hydrogel
Group (per ISO 18369-1:2017)	5B (>50% water, nonionic at pH 6-8)
Water content (core)	51%
Water content (surface)	>80%
O ₂ Permeability (dK/t @ -3.00; CT 0.09)	100
Base curve (mm)	8.3
Diameter (mm)	14.2
Modulus (core)	0.6 MPa
UV absorption	Class I UV blocker (≥90% UVA, ≥99% UVB)
Surface technology	SMARTSURFACE®
Handling tint	VISITINT®
Powers	-0.50D to -6.00D (0.25D steps); -6.50D to -12.00D (0.50D steps) +0.50D to +6.00D (0.25D steps); +6.50D to +8.00D (0.50D steps)

Figure 2: PRECISION1® Contact Lens Parameters



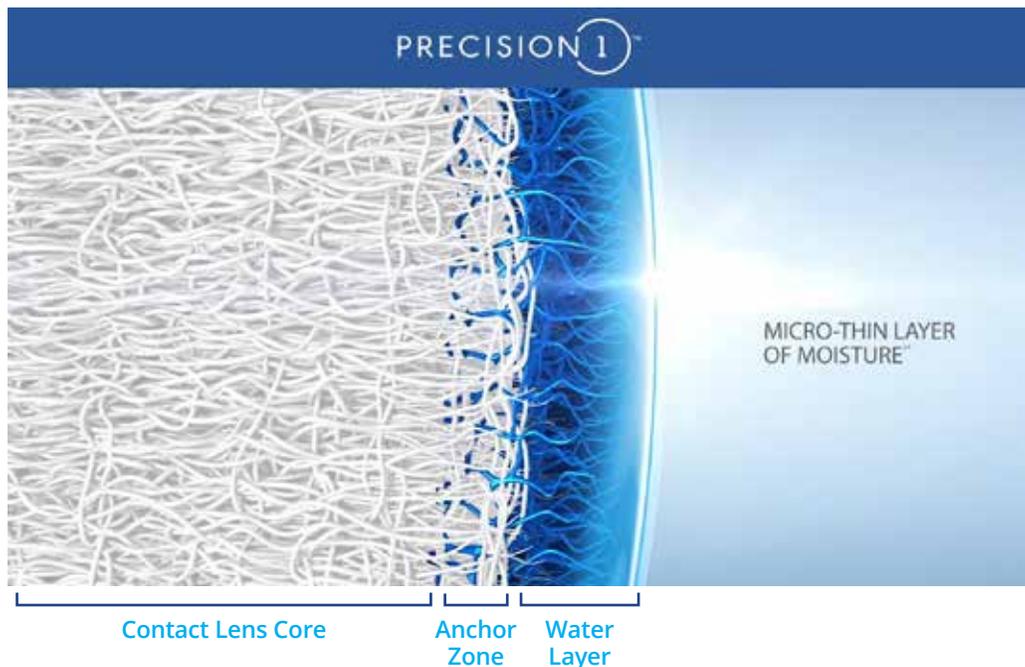


Figure 3: PRECISION1® Contact Lens with SMARTSURFACE® Technology

Permanent, micro-thin water layer (2-3 microns)

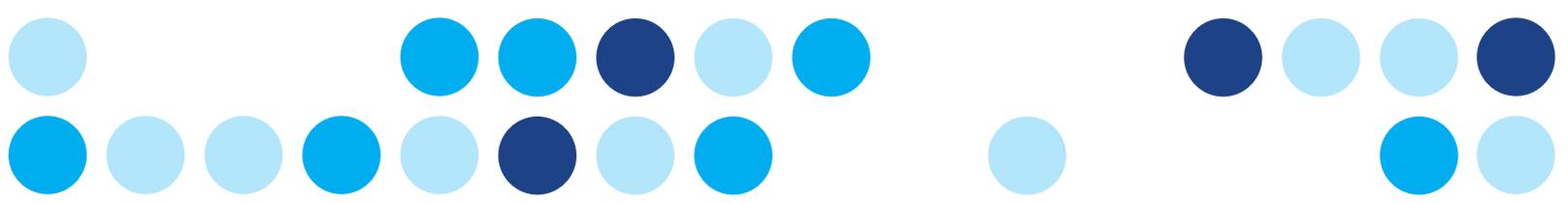
Agilent Manufacturing Platform

The Agilent manufacturing platform was created for the production of PRECISION1® contact lenses, and while it is optimized for these lenses, it is a versatile platform that can be used for other lens materials in the future. In general, the manufacturing process includes the same basic steps as any other platform, however this new system is fully automated, includes precise injection molding, and allows for 100 percent high speed computer-aided visual inspection. Most importantly, this system is modular and easily interchangeable, making it extremely flexible for the production of future lens materials.

The other main benefit is that the Agilent manufacturing process uses thermal curing for PRECISION1® lenses, which allows for the incorporation of UV absorbing agents into the lens material providing Class I UV blocking protection ($\geq 90\%$ of UVA, $\geq 99\%$ of UVB).

In Vitro Surface Wettability

Contact lens wettability was measured *in vitro* using the iDDrop method to assess both initial water break-up time (WBUT) and rate of water break-up (retention time) for PRECISION1®, DAILIES TOTAL1®, 1-Day Acuvue^ Moist, clariti^ 1 Day and MyDay^ lenses.¹⁴ This *in vitro* method is used to show surface wetting properties of each lens material and is not a clinical performance assessment. With this method, lenses were rinsed, then soaked in phosphate buffered saline (PBS) for 16 hours +/- 2 hours to remove any blister pack solution. The lenses were then mounted on a curved surface that maintained the shape of the contact lens and then submerged into a PBS bath. The lenses were then raised above the PBS surface while a video recording was taken of the surface of the lenses in order to visualize the dynamic water break-up at the lens surface. The first instance of a break in the lens surface moisture is reported as the surface moisture break-up time. The retention time and dewetting rate profiles represent the rate at which the moisture break-up spreads across the lens surface. Retention time was reported as the time it took for the surface moisture coverage to go from 100% wetted to 90% wetted. The dewetting rate profiles show the time



it took for the surface moisture coverage to go from 100% wetted to <10% wetted. For each lens type, 10 lenses were tested, with three measurements per lens for a total of 30 measurements. Between the 3 lens measurement recordings, the lens was re-submerged in order to fully wet the lens.

PRECISION1® contact lenses demonstrated significantly longer surface moisture break up time than 1-Day Acuvue^ Moist, clariti^ 1 Day and MyDay^ lenses ($p < 0.001$ for all) (Figure 4) meaning that the surface moisture remained intact longer for PRECISION1®.¹⁴ PRECISION1® contact lenses also showed significantly higher moisture retention times ($p < 0.001$ for all) (Figure 5a) and demonstrated a significantly slower rate of dewetting ($p < 0.001$) (Figure 5b) when compared to 1-Day Acuvue^ Moist, clariti^ 1 Day and MyDay^ lenses.¹⁴ This means that even after a break in the moisture occurred on the lens surface, the moisture layer remained in place significantly longer for PRECISION1® than the comparator lenses.¹⁴

In this *in vitro* study, PRECISION1® contact lenses showed superior lens surface wettability by 1) maintaining an intact layer of moisture on the surface longer and 2) exhibiting a slower rate of dewetting when compared to 1-Day Acuvue^ Moist, clariti^ 1 Day and MyDay^ lenses.¹

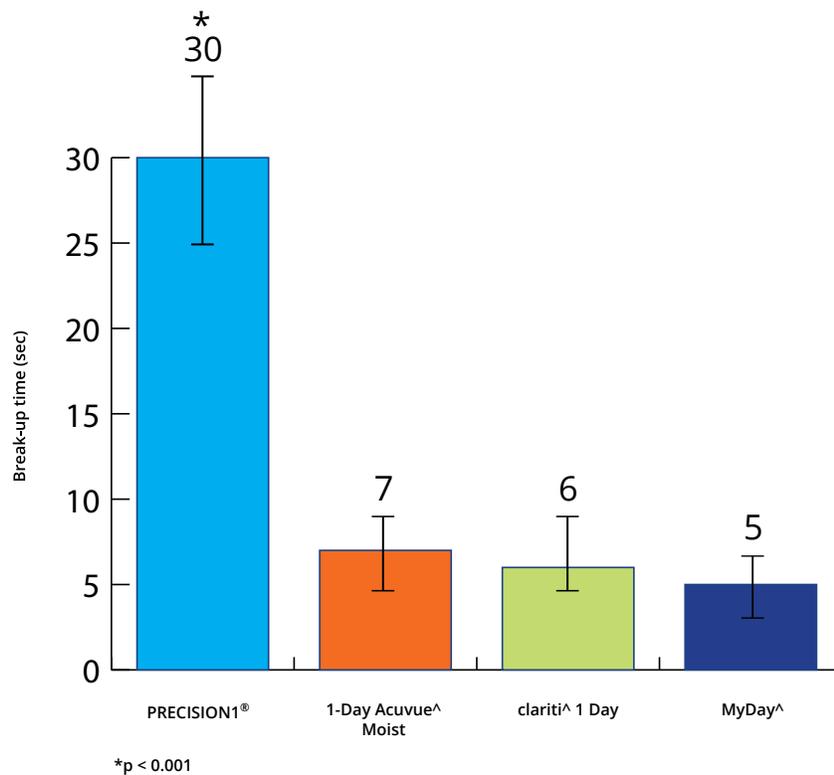
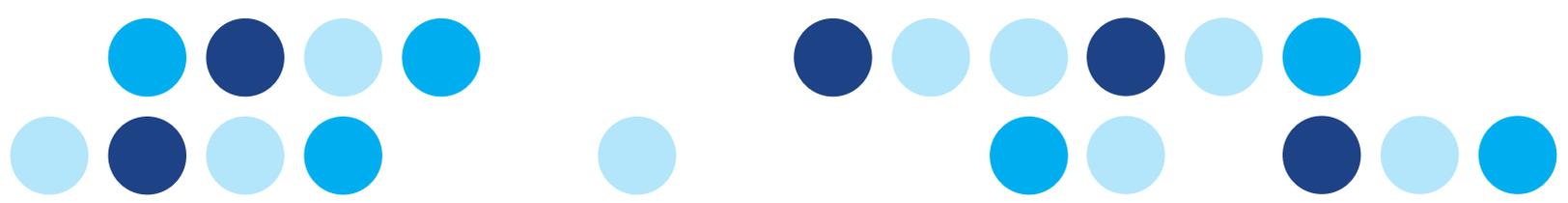


Figure 4: Average surface moisture break-up time per lens brand.

Surface moisture remained intact on the lens surface longer for PRECISION1® contact lenses as shown by a significantly longer surface moisture break-up time compared to 1-Day Acuvue^ Moist, clariti^ 1 Day and MyDay^ lenses ($p < 0.001$).



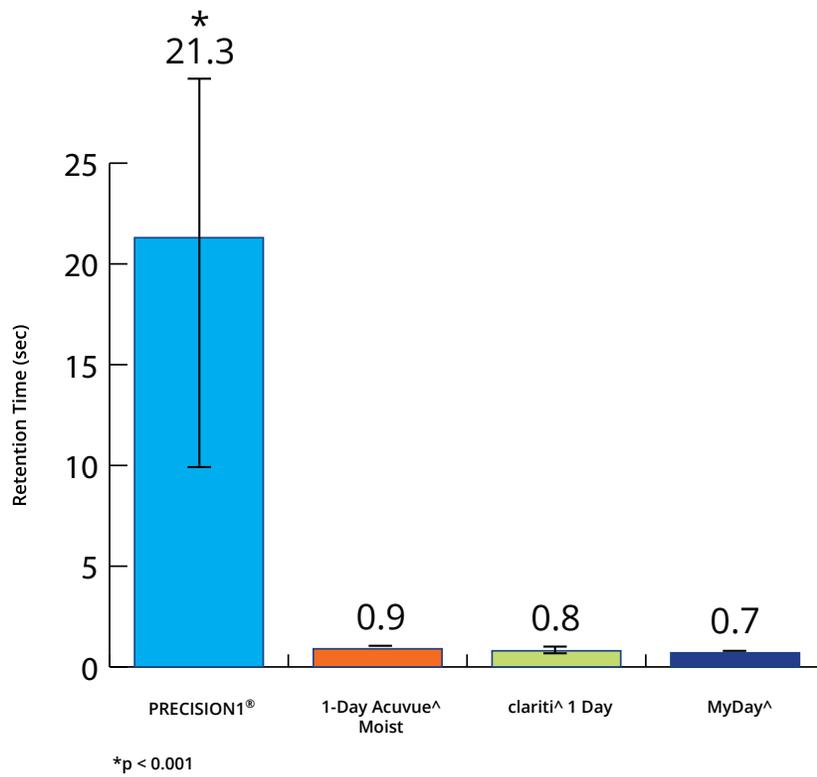


Figure 5a: Average surface moisture retention times defined as the rate at which the moisture break-up spread across the lens surface and shows the time it took for the lens surface moisture coverage to go from 100% wetted to 90% wetted. PRECISION1® lenses maintained moisture on the lens surface better, showing a significantly longer moisture retention time than 1-Day Acuvue^ Moist, clariti^ 1 Day and MyDay^ lenses (p<0.001).

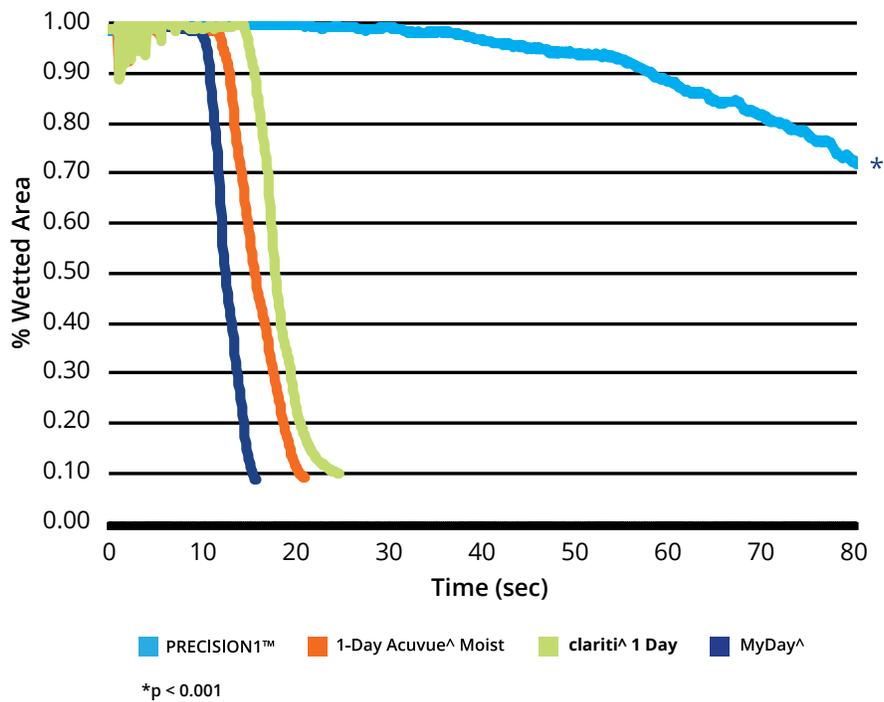
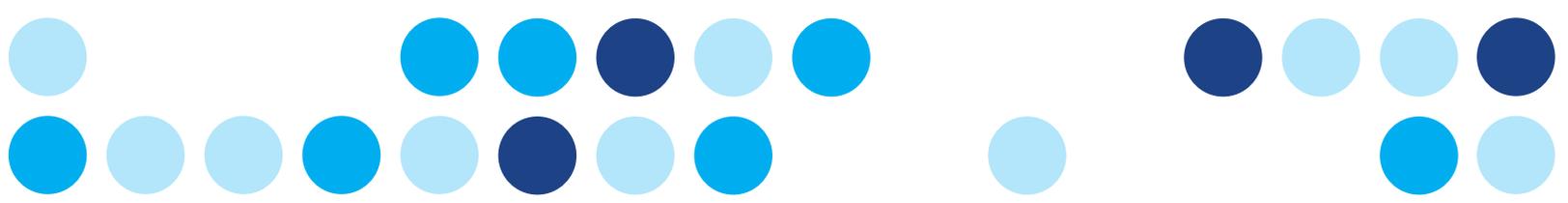


Figure 5b: Surface dewetting rate profiles defined as the rate at which the moisture break-up spread across the lens surface and shows the time it took for the surface moisture coverage to go from 100% wetted to <10% wetted. PRECISION1® lenses maintained moisture on the lens surface better and showed a significantly slower dewetting rate than 1-Day Acuvue^ Moist, clariti^ 1 Day and MyDay^ lenses (p<0.001).



Clinical Study Results

In a prospective, randomized, double-masked, parallel group clinical study of 105 subjects, lenses were worn as daily disposables over a 3-month period and subjects rated their overall comfort, vision and handling on a 10-point scale (1 = worst; 10 = best) at multiple timepoints. PRECISION1[®] one-day contact lenses achieved high ratings from wearers in overall comfort (9.4, 9.3, 9.5), overall vision (9.4, 9.3, 9.4) and overall handling (9.0, 9.1, 9.2) at 1, 2 and 3 months, respectively. Further, these high ratings were consistent over the 3 months of wear (Figure 6).¹⁵

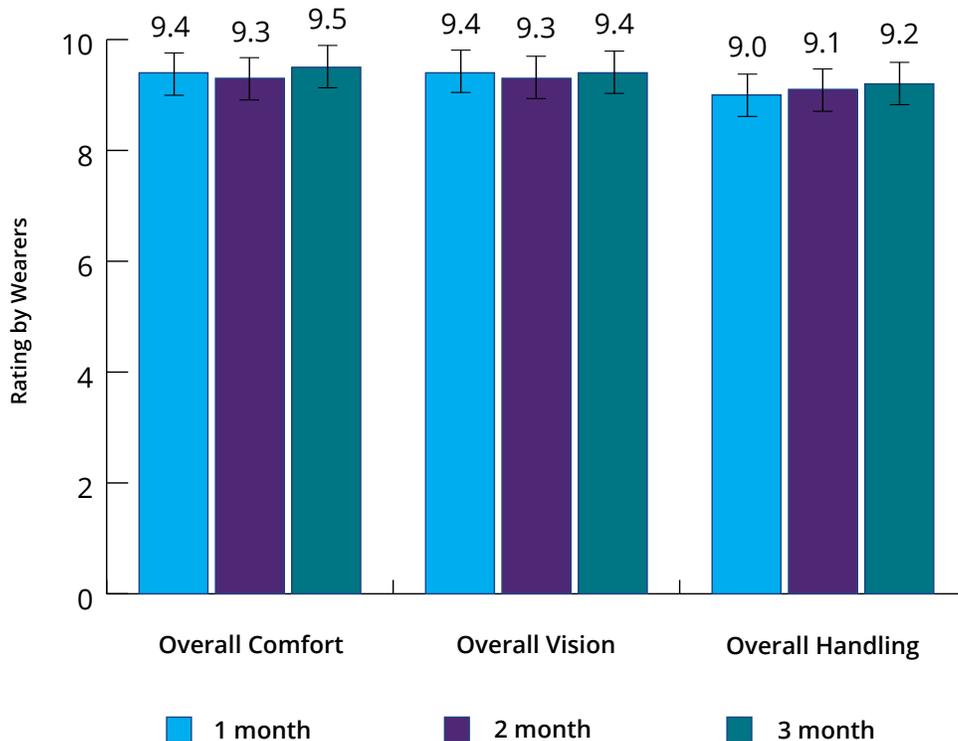


Figure 6: Average subjective ratings over 3 months for comfort, vision and handling.

PRECISION1[®] showed consistently high ratings for all measures over 3 months of daily disposable wear.

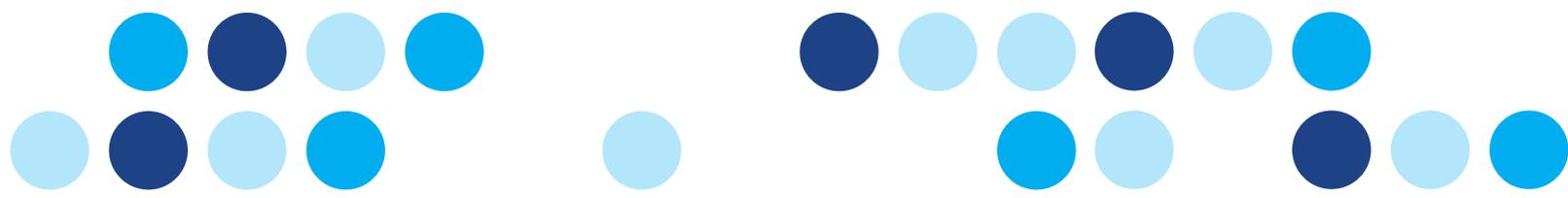
Conclusion

PRECISION1[®] (verofilcon A) daily disposable contact lenses are Alcon's latest lens innovation and feature a unique water surface technology that creates a highly wettable and lubricious lens surface. As demonstrated by *in vitro* and clinical studies, the silicone hydrogel core provides high oxygen permeability and easy handling, while the SMARTSURFACE[®] Technology, consisting of hydrogel polymers and >80% water, provides a soft cushion of moisture that supports a stable tear film and, ultimately, comfort and vision.^{14,15} PRECISION1[®] contact lenses with SMARTSURFACE[®] Technology are designed to meet the needs of new wearers and can help to keep them satisfied and successful with contact lens wear.

Disclosures: Jessica Mathew is an Alcon employee.

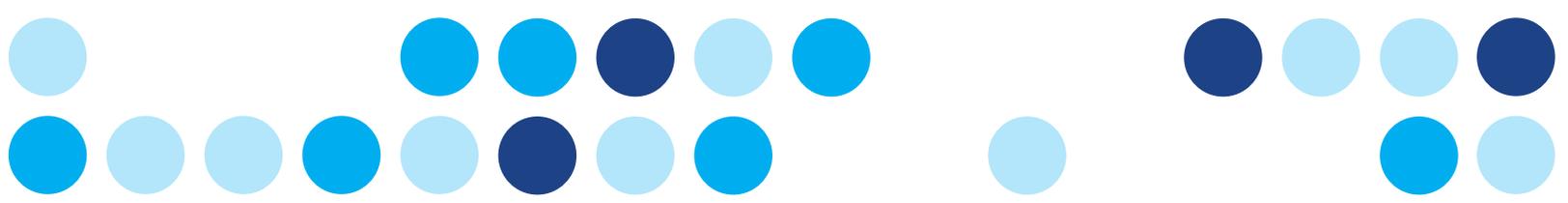
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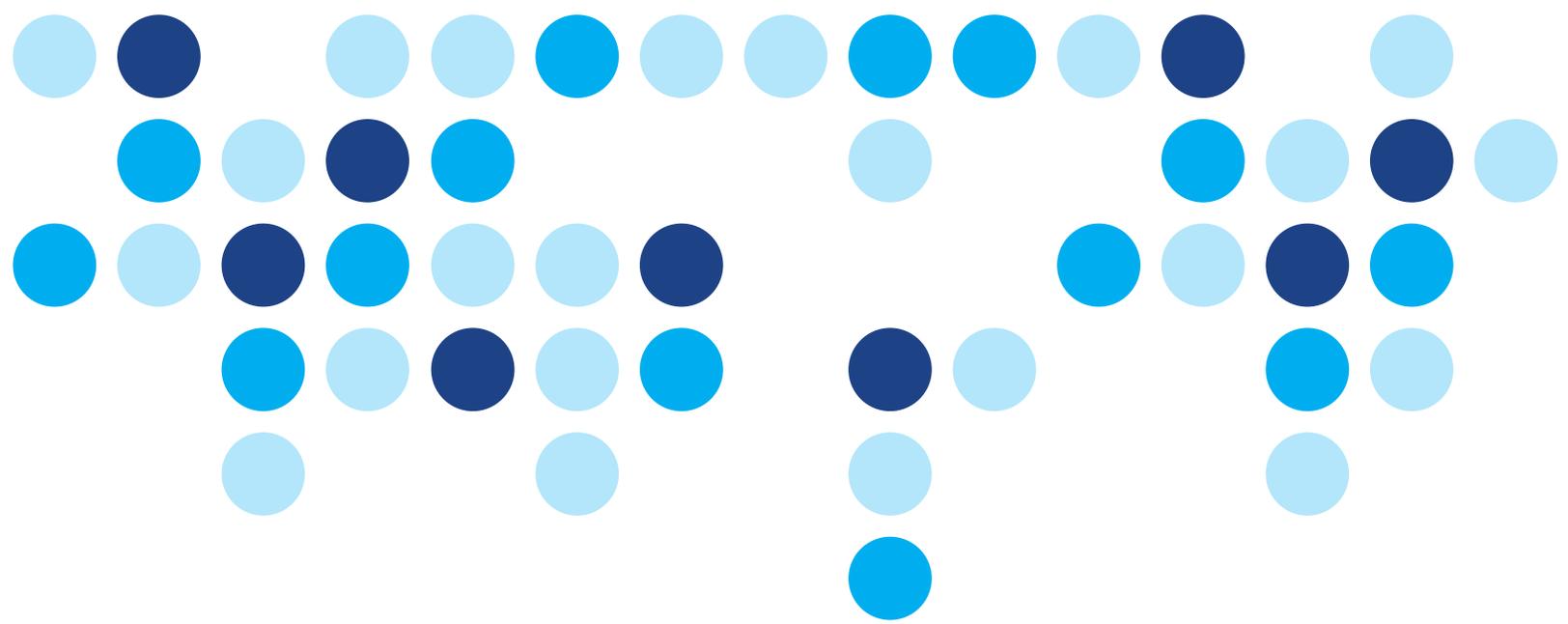
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