

# PRECISION1™ (verofilcon A) One Day Contact Lenses

Clinical Science Compendium

Summary of presented research



## INTRODUCTION

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At Alcon, our vision care medical device products, such as PRECISION1™ One Day Contact Lenses, are designed, manufactured and marketed with a body of science developed through rigorous bench research and clinical studies. As the body of knowledge behind Alcon's products grows, so does the challenge of making our customers aware of its depth. Our medical affairs organization is thus focused on both high-quality data generation and its communication to the clinical community. High-quality scientific publications are essential to convey the clinical community's knowledge and experience with new technology. This clinical science compendium provides a consolidated view of abstracts / presentations from U.S. and international congresses evaluating the pre-clinical and clinical characteristics of PRECISION1™, a daily disposable contact lens that is the first and only lens with Alcon's proprietary SMARTSURFACE™ Technology. In addition to exploring this compendium, we encourage you to visit Alcon's Medical Affairs website—[AlconScience.com](http://AlconScience.com)—to learn more about how medical science matters to us. Beyond scientific publications relating to Alcon's portfolio, you will find more information on independent medical educational grants, teaching facility equipment placement, and areas of interest for investigator-initiated trials.

## METHODOLOGY

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This compendium includes papers and posters presented at U.S. and international optometry and ophthalmology congresses involving PRECISION1™ One Day Contact Lenses from January 2019 through December 2019. The research included bench studies assessing the material properties and performance of PRECISION1™, as well as clinical studies examining patient outcomes with the lenses. Twelve (12) total studies are included (9 original presentations and 3 encore presentations / subset analyses). Seven (7) posters / presentations reported clinical data, while 5 reported bench data.

All studies were sponsored by Alcon Research, LLC.

# Table of Contents

## Bench Studies

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- Characterization of A Novel Surface Modified Silicone Hydrogel Contact Lens in Fully Hydrated Environments** 1  
Shi C, Cantu-Crouch D, Sharma V, Wu J. Poster presented at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, April 27-May 2, 2019; Vancouver, Canada; Poster B0437.
- Surface characterization methods developed to optimize the “SMARTSURFACE®” chemistry for Precision1™ (One Day Contact Lenses)** 2  
Tucker B. Presented at the BioInterface workshop and symposium of the Surfaces in Biomaterials Foundation. Sept 4-6, 2019; Park City, Utah.
- Characterization of the Surface Properties of a Novel Daily Disposable Silicone Hydrogel Contact Lens** 3  
Tucker B, Leveillee E, Bauman E, Subbaraman L. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida, Poster #62.
- Low Friction and Low Modulus Contact Lens Surfaces Improve Lubricity and Reduce Cell Damage in Corneal Epithelial Cell Models** 4  
Sawyer WG, Pitenis AA, Angelini TE, Levings PP. Presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida.
- Measurement of the Optical Quality of Contact Lens Materials with Dehydration** 5  
Schwiegerling J, Booajari S. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida; Poster #176.

## Clinical Studies

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- Clinical comparison of a new silicone hydrogel daily disposable compared to a HEMA-based daily disposable lens** 6  
Grant T, Cummings S. Presented at the 22nd Asia Pacific Optometric Congress (APOC), June 17-20, 2019; Manila, Philippines.  
*Study also presented as an encore presentation:*  
**Clinical comparison of a new silicone hydrogel daily disposable compared to a HEMA-based daily disposable lens**  
Grant T, Cummings S. Poster presented at the 17th international cornea and Contact Lens Congress (ICCLC), October 11-13, 2019; Noosa, Australia.  
*Subset of the data presented as:*  
**Clinical Assessment of a New Silicone Hydrogel Daily Disposable and a HEMA-Based Daily Disposable Lens**  
Cummings S, Brobst A, I. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida, Poster #58.
- High Patient Satisfaction with a Novel SMARTSURFACE™ Technology Daily Disposable Contact Lens** 7  
Grant T, Tang A. Poster presented at the 22nd Asia Pacific Optometric Congress (APOC), June 17-20, 2019; Manila, Philippines.  
*Subset of the data presented as:*  
**New contact lens wearers and practitioners have high patient satisfaction with a novel SmartSurface™ Technology daily disposable contact lens**  
Grant T, Tang A. Poster presented at the 17th international cornea and Contact Lens Congress (ICCLC), October 11-13, 2019; Noosa, Australia.
- Clinical Performance of a New Daily Disposable Spherical Contact Lens** 8  
Cummings S, Giedd B, Pearson C. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida, Poster #65.
- Clinical Lens Fit Characteristics of a New Silicone Hydrogel Daily Disposable and Two Commercially Available Daily Disposable Contact Lenses** 9  
Gilbert Spear K, Brobst A, Cummings S. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida, Poster #58.

# Characterization of A Novel Surface Modified Silicone Hydrogel Contact Lens in Fully Hydrated Environments

Shi et al. Poster presented at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, April 27-May 2, 2019; Vancouver, Canada; Poster B0437.\*

## OVERVIEW



### STUDY DESIGN

Environmental Scanning Electron Microscopy (ESEM) and Atomic Force Microscopy (AFM) study of verofilcon A contact lenses (PRECISION1™) in fully hydrated conditions



### STUDY SETTING(S)

Alcon (Fort Worth, TX)



### PATIENTS

N/A



### METHODOLOGY

ESEM was utilized to image different silicone hydrogel (SiHy) contact lenses in a 100% humidity environment. Samples were imaged and characterized in aqueous solutions under AFM using quantitative nanomechanical analysis.



### CONTACT LENS TYPE(S)

Senofilcon A, comifilcon A, stenfilcon A, delefilcon A, and verofilcon A (PRECISION1™)



### KEY ENDPOINT(S)

Lens surface and core properties using both surface and cross-sectional imaging

## ANALYSIS AND CONCLUSIONS

**Characterization of verofilcon A (PRECISION1™) contact lenses demonstrated the presence of a surface gel and difference in modulus between the lens core and surface.**

Surface modification techniques can create novel, ultra-soft surface gels on SiHy core materials. Such unique structures and properties have been successfully characterized by ESEM and AFM in fully hydrated conditions.

## STUDY RESULTS

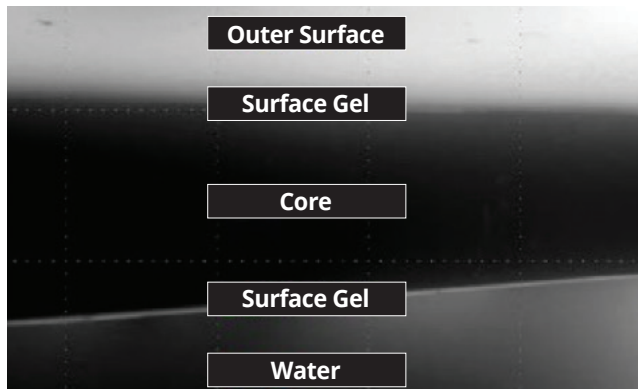
### ENVIRONMENTAL SCANNING ELECTRON MICROSCOPY

- Using the ESEM technique, a surface gel was observed on the top of the modified contact lens core material in 100% relative humidity (Figure 1)

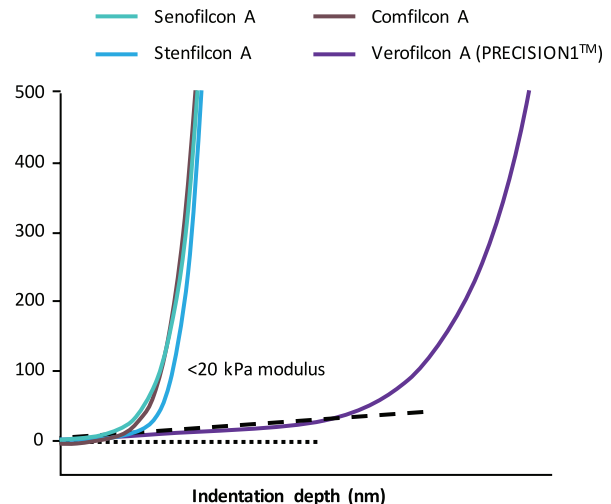
### ATOMIC FORCE MICROSCOPY

- An ultra-soft surface layer on the top of the verofilcon A material (PRECISION1™) was visible using the liquid AFM technique
- Nanoindentation testing demonstrated a different modulus at the core (0.6 MPa) compared to the surface layer on the verofilcon A (PRECISION1™) lens (<20 kPa), resulting from the ultra-soft, high water surface material (Figure 2)
- Such distinctive surface structures and properties were not seen on any other SiHy contact lenses except delefilcon A, which is a water gradient contact lens

**Figure 1.** Environmental Scanning Electron Microscopy (ESEM) image of verofilcon A (PRECISION1™) lens cross-section in 100% relative humidity conditions.



**Figure 2.** Atomic Force Microscopy (AFM) nanoindentation of verofilcon A (PRECISION1™), stenfilcon A, senofilcon A, and comifilcon A lens surfaces in phosphate-buffered saline



\* All authors are employees of Alcon.



# Surface Characterization Methods Developed to Optimize the “SMARTSURFACE®” Chemistry for PRECISION1™ (One Day Contact Lenses)

Tucker B. Presented at the BioInterface workshop and symposium of the Surfaces in Biomaterials Foundation, Sept 4-6, 2019; Park City, Utah.\*

## OVERVIEW



### STUDY DESIGN

Series of in vitro studies to evaluate the surface properties of SMARTSURFACE® technology used in PRECISION1™ (verofilcon A) contact lenses



### STUDY SITE(S)

Alcon (Fort Worth, TX)



### PATIENTS

N/A



### METHODOLOGY

Bench study evaluating surface presence, surface uniformity, surface wettability (contact angle, water break up time [WBUT]), and surface softness (nanoindentation)



### CONTACT LENS TYPE(S)

PRECISION1™ (verofilcon A), 1-Day ACUVUE MOIST (etafilcon A), MyDay™ (Stenfilcon A), clariti 1 day (somofilcon A), and ACUVUE Oasys (senofilcon A)



### KEY ENDPOINT(S)

Surface presence, surface uniformity, surface wettability, and surface softness

## ANALYSIS AND CONCLUSIONS

### SMARTSURFACE® remains uniform at the surface of PRECISION1™ (verofilcon A) contact lenses.

In addition, PRECISION1™ contact lenses were more wettable and softer than comparator lenses under both laboratory and physiologically relevant conditions.

## STUDY RESULTS

### LENS CHARACTERIZATION

- Fluorescent surface staining revealed that SMARTSURFACE® remains at the surface of PRECISION1™ (verofilcon A) contact lenses (Figure 1)
- Sudan Black (blue) staining for hydrophobic compounds revealed that SMARTSURFACE® Technology kept dye from penetrating into verofilcon A (PRECISION1™) lenses, demonstrating a uniform surface over the contact lens

### SURFACE PROPERTIES

- Contact angle can be used to determine wettability in the laboratory; typically, low angles (<40°) indicate a wettable surface
- Verofilcon A (PRECISION1™) contact lenses had a lower contact angle than other materials assessed (Figure 2)
- Using the interfacial dewetting and drainage optical platform (iDDrOP) to assess WBUT, verofilcon A (PRECISION1™) was shown to retain phosphate-buffered saline (PBS) longer than comparator lenses
- Nanoindentation testing using the Piuma Optics 11 Nanoindentation device showed that verofilcon A (PRECISION1™) required a lower force for same indentation than comparator lenses (Figure 3A) and lower modulus values (Figure 3B) than comparator lenses, indicating that verofilcon A will compress more than the comparator lenses under physiologically relevant conditions

Figure 1. Fluorescently stained surface of PRECISION1™ (verofilcon A) contact lens

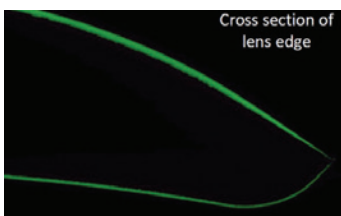


Figure 2. Summary of lens contact angle.

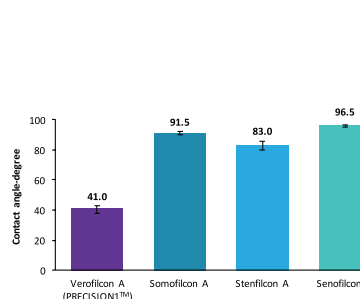
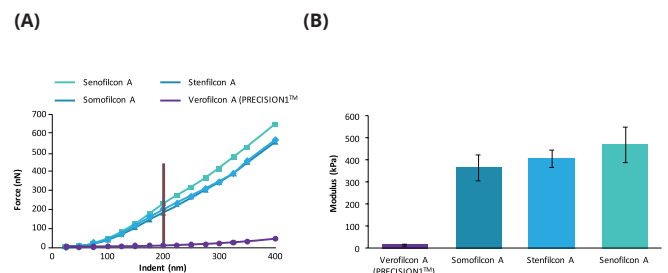


Figure 3. Nanoindentation testing results (Optics11 Piuma 11). Indent distance vs force (A). Modulus at 200 nm indent (B).



# Characterization of the Surface Properties of a Novel Daily Disposable Silicone Hydrogel Contact Lens

Tucker et al. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida, Poster #62.\*

## OVERVIEW



### STUDY DESIGN

*In vitro* study to characterize the aqueous film stability of verofilcon A (PRECISION1™) and comparator contact lenses by evaluating water break up time (WBUT) using the interfacial dewetting and drainage optical platform (iDDrOP)



### STUDY SETTING(S)

Alcon research (Ft Worth, TX)



### PATIENTS

N/A



### METHODOLOGY

Pre-soaked contact lenses were submerged in phosphate buffered saline (PBS) and raised through the air/water interface to determine when and how fast dewetting occurs



### CONTACT LENS TYPE(S)

PRECISION1™ (verofilcon A), 1-Day ACUVUE® MOIST® (etafilcon A), MyDay (stenfilcon A), clariti 1 day (somofilcon A)



### KEY ENDPOINT(S)

WBUT (the time from when the lens is first raised through the air/water interface, to the first time when zero fluid thickness is observed)

## ANALYSIS AND CONCLUSIONS

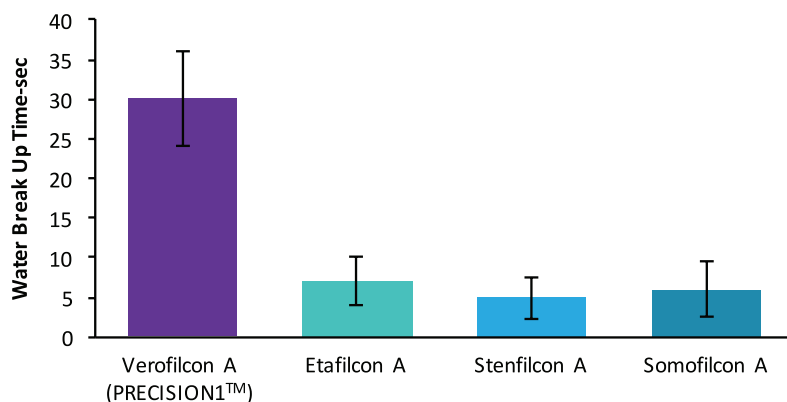
**Verofilcon A (PRECISION1™) contact lenses have a highly wettable surface gel on a silicone hydrogel core material. The surface modification process improved aqueous film stability on verofilcon A contact lenses as demonstrated with a longer WBUT.**

## STUDY RESULTS

### IN VITRO STUDY RESULTS

- The WBUT of verofilcon A (PRECISION1™) was statistically higher than the other lenses ( $p < 0.05$ ; Student's t-test) (Figure 1)

Figure 1. Water Break Up Time (WBUT) of verofilcon A (PRECISION1™) and comparator contact lenses.



\*All authors are employees of Alcon.

# Low Friction and Low Modulus Contact Lens Surfaces Improve Lubricity and Reduce Cell Damage in Corneal Epithelial Cell Models

Sawyer et al. Presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida.\*

## OVERVIEW



### STUDY DESIGN

An in vitro system was developed to evaluate surface shear, friction, and contact pressure of PRECISION1™ (verofilcon A) compared to other contact lens materials on a corneal epithelial cell monolayer and assess the cellular damage under physiologically relevant conditions



### STUDY SETTING(S)

University of Florida, USA



### PATIENTS

N/A



### METHODOLOGY

Sections of contact lenses were mounted onto the surface of a polyacrylamide probe and slid against the cell monolayer for >16 hours (10,000 cycles of sliding)



### CONTACT LENS TYPE(S)

PRECISION1™ (verofilcon A), DAILIES TOTAL1™ (delefilcon A), 1-Day ACUVUE MOIST (etafilcon A), clariti 1 day (somofilcon A), MyDay™ (stenfilcon A)



### KEY ENDPOINT(S)

Contact area, pressure, and friction forces (y axis) versus the track position (x-axis) for each cycle were measured and friction coefficients in the sliding regime were calculated; cell damage, via staining assay, was assessed after 1,000 cycles; pro-inflammatory cytokine production, measured via ELISA

## ANALYSIS AND CONCLUSIONS

**Lenses with a surface gel layer (PRECISION1™ and DAILIES TOTAL1™) showed the lowest levels of cell damage.**

Lenses with surface gel layers demonstrated lower friction and lower shear stress than comparator lenses. Lower shear stress is associated with reduced cell damage and cytokine production. Cytokine production may be a biophysical link between lubricity and comfort.

## STUDY RESULTS

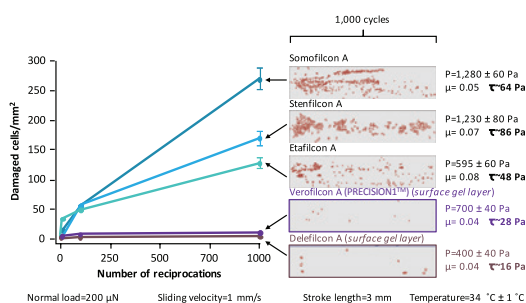
### CELL DAMAGE ASSESSMENT

- Compared to lenses without surface gel layers, both delefilcon A (DAILIES TOTAL1™) and verofilcon A (PRECISION1™) showed the least amount of cell death over time, and damage was largely isolated (Figure 1)
- Comparator lenses (somofilcon A, stenfilcon A, etafilcon A) showed the largest increases in cell damage over time and showed clumps/groups of cells going through the cell death process; these clumps / groups expanded in size (# of cells) and showed increasing

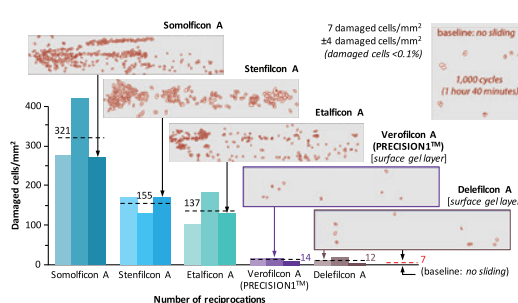
- damage with increasing number of cycles
- The process for verofilcon A and delefilcon A was different in that damage occurred to random isolated cells over time, rather than clumps/groups and the damage was much less over time (Figure 1)
- Surface gel layer lenses also showed lower shear stresses and friction than the comparators (Figure 1)
- As a reference point, blinking and ocular movement shear stresses suggest that the healthy eye is typically experiencing stresses on the order of 20-30 Pa

- Repeating experiments in triplicate demonstrated similar results with respect to cell damage (mean damaged cells/mm<sup>2</sup> = verofilcon A [PRECISION1™]: 14, delefilcon A: 12, etafilcon A: 137, somofilcon A: 321, stenfilcon A: 155); further, the surface gel layer lenses were barely above baseline natural cell death (Figure 2)
- The experimental model also showed that the production of proinflammatory cytokines increases with increasing shear stress (Figure 3)

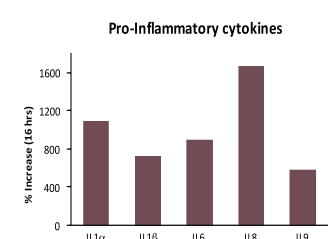
**Figure 1.** Cell damage with different contact lens materials, assessed after 1,000 sliding cycles. (P, pressure (Pa); μ, coefficient of friction; τ, shear stress (Pa))



**Figure 2.** Cell damage intensity with different contact lens materials, assessed after 1,000 sliding cycles. Surface gel layer contact lenses (PRECISION1™ (verofilcon A) and DAILIES TOTAL1™ (delefilcon A)) had damage levels comparable to baseline natural cell death in the experimental model.



**Figure 3.** Cytokine production assessed during 10,000 sliding cycles of friction testing on the cell monolayer.



\* Greg Sawyer is a paid consultant for Alcon.

# Measurement of the Optical Quality of Contact Lens Materials with Dehydration

Schwiegerling and Boojari. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida: Poster #176.\*

## OVERVIEW



### STUDY DESIGN

A novel system was developed to measure of the Point Spread Function (PSF), and tear-film break up on the anterior surface of a PRECISION1™ (verofilcon A) contact lens and analyze how they are linked to corresponding image quality



### STUDY SITE(S)

University of Arizona, USA



### PATIENTS

N/A



### METHODOLOGY

An artificial eye model composed of an achromatic doublet and a 3D printed "sclera" was used in conjunction with a system which enables both the tear film at the anterior contact lens and the image quality transmitted through the eye model to be assessed simultaneously.



### CONTACT LENS TYPE(S)

PRECISION1™ (verofilcon A)



### KEY ENDPOINT(S)

Tear film stability (Placido ring pattern), simulated image quality using PSF

## ANALYSIS AND CONCLUSIONS

A novel system was used to measure the optical performance of PRECISION1™ (verofilcon A) contact lenses and the state of the tear film on the surface of the lens. These factors were then used to relate image quality to irregularity of the tear film. The PRECISION1™ lens maintained Placido ring pattern stability over a 60 second dehydration interval and maintained its image quality.

## STUDY RESULTS

### METHODOLOGICAL DETAILS

- The system used in this study consisted of two separate channels:
- A collimated green LED beam that passes through the eye model assembly and is focused down to a PSF where it is then recorded through a microscope
- An illuminated cone with a Placido ring pattern that reflects from the anterior contact lens surface and is recorded by a second camera; the Placido ring pattern changes as the contact lens dries and these changes can be recorded

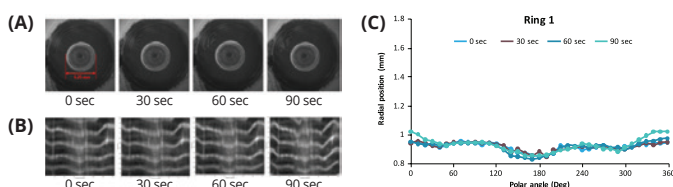
### TEAR FILM BREAKUP ASSESSMENT

- Over 60-90 sec, the Placido ring pattern slowly changes as the tear film evaporates. (Figure 1A)
- The Placido ring pattern was plotted so that their radial position is on the vertical axis and their meridian is on the horizontal axis; here, only the first four rings, corresponding to the central 3.5 mm of the contact lens, are shown (Figure 1B)
- To quantify the tear film dynamics, the variability of the rings was examined across time by looking at the change in ring position; the PSF at each time position was convolved with an optotype to relate tear film variability to image quality
- Observation of Placido ring positions over a 90-second period revealed that the pattern was stable through the first 60 seconds, with most changes occurring in the final 30 seconds along the 0-60° semi chords and the 300-359° semi chords (Figure 1C)
- To quantify the change in the ring positions, the baseline ring was subtracted from the subsequent rings and the standard deviation of the difference was determined; this is a measure of how similar the ring pattern is to the initial ring (Figure 2)

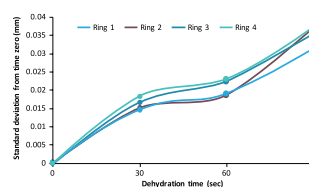
### CHANGE IN IMAGE QUALITY

- In the experimental model, the simulated image quality was maintained over a 60 second interval. (Figure 3)

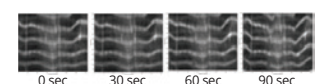
**Figure 1.** Example Placido ring images of a contact lens on the eye model in 30 second intervals following disbursement of contact lens packaging solution (A). Radial views of the Placido ring images allowed for easier assessment of tear film breakup for rings 1 through 4 over (B). Evolution of Placido ring positions over 90 seconds, ring 1 (closest to center). The pattern for all rings was particularly stable through the first 60 seconds.



**Figure 2.** Standard deviation of the ring patterns based on change from baseline as the tear film evaporates.



**Figure 3.** Image quality at the various time points illustrated with the convolution of the PSF with a letter E optotype is related to tear film breakup.



\* Jim Schwiegerling is a paid consultant for Alcon.

# Clinical Comparison of a New Silicone Hydrogel Daily Disposable Compared to a HEMA-Based Daily Disposable Lens

Visual Acuity

Patient-Reported Outcomes

Grant T, Cummings S. Presented at the 22nd Asia Pacific Optometric Congress (APOC), June 17-20, 2019; Manila, Philippines.\*

Study also presented as an encore presentation with the same title:

Grant T, et al. Poster presented at the 17th international cornea and Contact Lens Congress (ICCLC), October 11-13, 2019; Noosa, Australia.\*

A subset of these results was also presented at:

## Clinical Assessment of a New Silicone Hydrogel Daily Disposable and a HEMA-Based Daily Disposable Lens

Cummings et al. Poster presented at the American Academy of Optometry (AAO) annual meeting, October 23-26, 2019; Orlando, Florida, Poster #58.†

### OVERVIEW



#### STUDY DESIGN

Multicenter prospective, randomized, double-masked, two-week cross-over pilot study to evaluate the overall performance of PRECISION1™ daily disposable contact lenses



#### STUDY SETTING(S)

Three (3) sites in the USA



#### PATIENTS

Twenty-two (22) current contact lens wearers; average age 31.0 ± 10.5 years (range: 8-56 years)



#### METHODOLOGY

Subjects wore one of two lens types for ~1 week and then crossed over to the alternate lens type for ~1 week. Lenses were worn bilaterally and daily for ≥5 days/week for ≥8 hours/day



#### CONTACT LENS TYPE(S)

PRECISION1™ (verofilcon A) and 1-Day ACUVUE MOIST (etafilcon A)



#### KEY ENDPOINT(S)

Subject-rated comfort (overall, at insertion, end of day), quality of vision (throughout the day, end of day), and handling (overall) on a 10-point scale (1 = poor, 10 = excellent) at the end of each treatment phase; subject lens preference and reason for preference

### ANALYSIS AND CONCLUSIONS

**Subjects preferred verofilcon A (PRECISION1™) to etafilcon A lenses after wearing both types for ~8 days each. Subjective ratings of overall comfort, overall handling, and overall quality of vision were higher than 9 of 10 for PRECISION1™ lenses.**

Compared to etafilcon A PRECISION1™ (verofilcon A) lenses were rated numerically higher for handling (overall) and comfort (overall, at insertion, and end of day), as well as higher for quality of vision overall and at end of day.

### STUDY RESULTS

#### SUBJECTIVE ASSESSMENT

- After wearing verofilcon A (PRECISION1™) and etafilcon A contact lenses for ~8 days each, subject ratings of overall comfort, overall handling and overall quality of vision were higher for PRECISION1™ (Figure 1)

#### PATIENT PREFERENCE

- 77.3% of subjects preferred verofilcon A (PRECISION1™) (Figure 2), citing comfort (41.2%), handling (35.3%), better vision (17.6%), and other (5.9%) as reasons for their preference
- Of the 22.7% of subjects who preferred etafilcon A (Figure 2), all indicated that this preference was related to comfort

#### KEY LENS PERFORMANCE VARIABLES

- No observation above 1 (0-4 scale) with respect to front surface wettability and deposits was recorded for either test lens
- There was no finding above 1 for verofilcon A (PRECISION1™) with respect to back surface deposits (0-4 scale); one subject wearing etafilcon A had a recording of grade 2 at follow-up
- There was no biomicroscopy finding of 3 or 4 (on a 0-4 scale) for either lens for all corneal and conjunctival variables assessed
- All eyes had visual acuity 6/7.5 or better for both lenses

Figure 1. Patient-reported comfort (A), vision (B), and ease of handling (C) at follow-up.

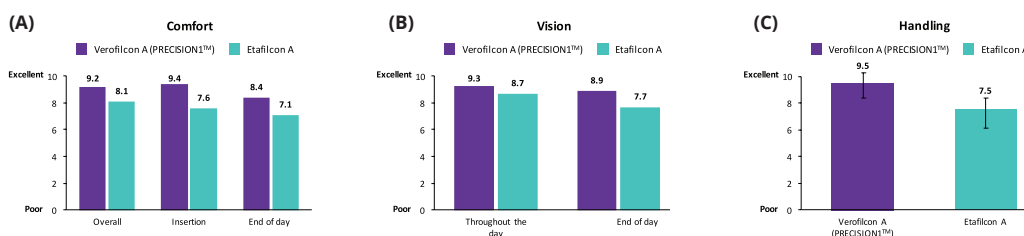
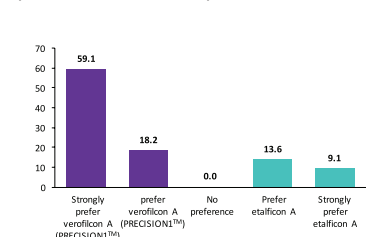


Figure 2. Subject-reported lens preference at follow-up.



\*Tim Grant and Stacie Cummings are employees of Alcon.  
†Stacie Cummings and Anne Brobst are employees of Alcon.

# High Patient Satisfaction with a Novel SMARTSURFACE™ Technology Daily Disposable Contact Lens

Patient-Reported Outcomes

Practitioner-Reported Outcomes

Grant et al. Poster presented at the 22nd Asia Pacific Optometric Congress (APOC), June 17-20, 2019; Manila, Philippines.\*

A subset of the data (new lens wearers) was presented as:

## New contact lens wearers and practitioners have high patient satisfaction with a novel SmartSurface™ Technology daily disposable contact lens

Grant et al. Poster presented at the 17th International Cornea and Contact Lens Congress (ICCLC), October 11-13, 2019; Noosa, Australia.\*

### OVERVIEW



#### STUDY DESIGN

Prospective survey of patient satisfaction with SMARTSURFACE™ daily disposable contact lenses (PRECISION1™ (verofilcon A))



#### STUDY SITE(S)

Australian and New Zealand Product Experience and Consumer Evaluation (PEaCE) survey



#### PATIENTS

Three hundred and forty-seven (347) new and current contact lens wearers; 31 eye care professionals (ECPs)



#### METHODOLOGY

In an ECP's office, patients completed online questionnaires related to their experience and personal preference at baseline and after 1 week of wearing verofilcon A (PRECISION1™) contact lenses; ECPs also completed online questionnaires before and after fitting patients with PRECISION1™



#### CONTACT LENS TYPE(S)

PRECISION1™ (verofilcon A)



#### KEY ENDPOINT(S)

New and current lens wearers reported subjective experience of factors including lens comfort, long-lasting comfort, ease of handling, and sharpness of vision

### ANALYSIS AND CONCLUSIONS

#### Patients preferred PRECISION1™ contact lenses and ECPs agreed that PRECISION1™ provided high levels of patient satisfaction.

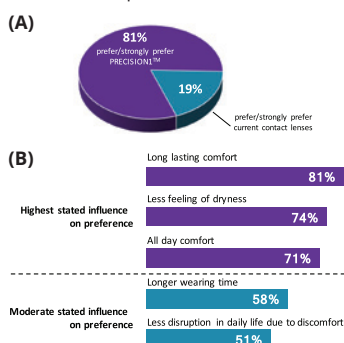
Current wearers cited all-day comfort, longer wearing time, and less disruption in daily life as drivers of success. New wearers cited clear distance vision, comfortable fit, ease of insertion, long lasting comfort, comfort when looking at real life tasks such as mobile phones/computers, spectacle free vision, and handling as factors driving success. ECPs indicated that PRECISION1™ contact lenses are easy to fit and that they would proactively recommended them to new contact lens wearers.

### STUDY RESULTS

#### PATIENT DEMOGRAPHICS

- Patients completing questionnaires had a mean age of 32 years (18 to 55 years). The female: male ratio was 64:36
- Among previous contact lens wearers, the most commonly used lenses were 1-day ACUVUE Oasys (29%), 1-day ACUVUE MOIST (24%), DAILIES® AquaComfort Plus® (15%), and MyDay (14%)

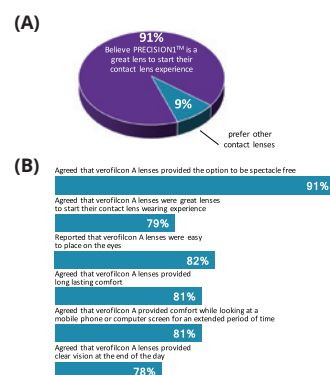
**Figure 1.** Post wearing survey results. Current lens wearer preference for PRECISION1™ or their previous contact lens (A), and primary reasons for PRECISION1™ preference (B).



#### PATIENT EXPERIENCE

- Current contact lens wearers reported a preference for PRECISION1™ after their trial experience (81% preferred PRECISION1™; **Figure 1A**)
- Primary reasons for current lens wearers' preference for PRECISION1™ lenses include long-lasting comfort, less feeling of dryness, and all-day comfort (**Figure 1B**)
- New contact lens wearers reported high levels of satisfaction with PRECISION1™ lenses (**Figure 2A and 2B**) after their trial experience

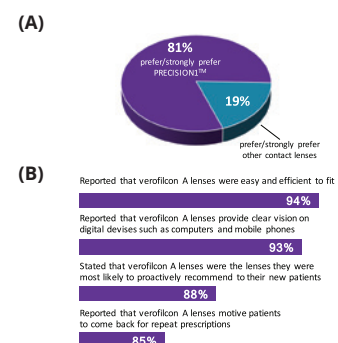
**Figure 2.** Post wearing survey results. New lens wearer satisfaction with PRECISION1™ (A) and new lens wearer experience with PRECISION1™ (B).



#### ECP EXPERIENCE

- Surveyed ECPs agreed that PRECISION1™ contact lenses provided good patient satisfaction; 81% of ECPs indicated that PRECISION1™ was the preferred lens (**Figure 3A**)
- ECPs agreed that these lenses are easy to fit and that they would proactively recommend these lenses to new contact lens wearers (**Figure 3B**)

**Figure 3.** Post wearing ECP survey results. Contact lens preference (A), and ECP experience (B).



\*Tim Grant and Anson Tang are employees of Alcon.



# Clinical Performance of a New Daily Disposable Spherical Contact Lens

Cummings et al. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida, Poster #65.\*

Visual Acuity

Patient-Reported Outcomes

Lens Fit

## OVERVIEW



### STUDY DESIGN

Multicenter, double-masked, prospective, randomized, stratified, parallel-group study to evaluate the overall performance of verofilcon A (PRECISION1™) daily disposable contact lenses



### STUDY SETTING(S)

Six (6) sites in the USA



### PATIENTS

Sixty-nine (69) subjects (72% female), with a mean age of 32.3 ± 6.3 years and no history of eye surgery or eye disease included in the verofilcon A (PRECISION1™) group



### METHODOLOGY

Subjects were randomized 2:1 ratio to bilaterally wear verofilcon A contact lenses (PRECISION1™) or control contact lenses for 3 months. Subjects were stratified by corneal curvature radius range on 7.8±0.22 mm (horizontal and vertical) in at least 1 eye



### CONTACT LENS TYPE(S)

Only PRECISION1™ (verofilcon A) data reported in this presentation



### KEY ENDPOINT(S)

Distance visual acuity (VA), subjective ratings of comfort, vision, and lens handling (10-point scale, with 1 = poor/difficult and 10 = excellent/easy), and lens fit characteristics (centration and overall fit); all evaluated at 1 and 2 weeks and at 1, 2, and 3 months

## ANALYSIS AND CONCLUSIONS

**After 3 months of wear, verofilcon A (PRECISION1™) contact lenses showed excellent VA, overall comfort, overall vision, and overall handling, as well as excellent lens fit/movement and centration.**

The unique material features, advanced surface technology, and optimal lens fitting characteristics of these new lenses contributed to a high level of satisfaction by lens wearers.

## STUDY RESULTS

- Patients completing questionnaires had a mean age of 32.3 ± 6.3 years and 72% of patients were female
- One patient discontinued after lens dispensing (not due to an adverse event)

## VISUAL ACUITY RESULTS

- At the 3-month follow up visit, >95% eyes wearing verofilcon A (PRECISION1™) contact lenses had distance VA of 20/20 or better (Table 1)

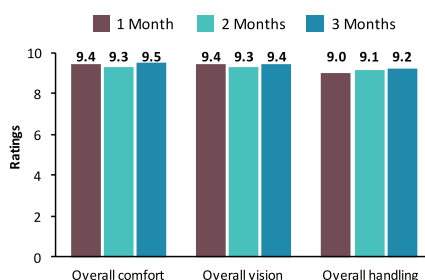
## SUBJECTIVE ASSESSMENT AND LENS FIT

- After 3 months of wear, verofilcon A (PRECISION1™) contact lenses were highly rated with respect to overall comfort, overall vision, and overall handling (Figure 1)
- Lens fit/movement (Figure 2A) and centration (Figure 2B) for verofilcon A (PRECISION1™) contact lenses was considered excellent

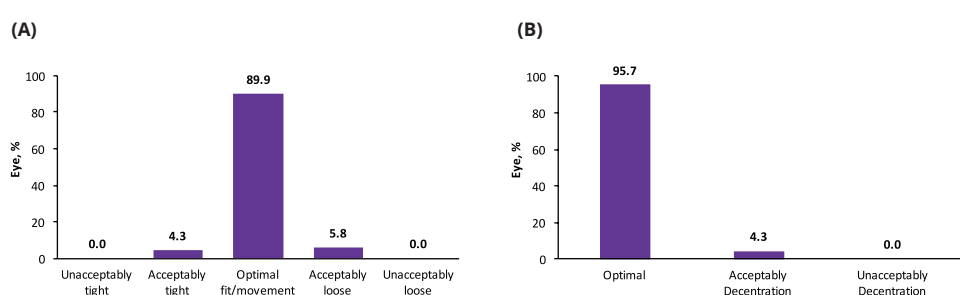
**Table 1.** Ocular characteristics at baseline (habitual contact lenses) and following 3 months of verofilcon A (PRECISION1™) contact lens wear (intent-to-treat population). Adapted from Cummings et al. 2019.

	Baseline (n=140 eyes)	3 months (n=138 eyes)
<b>Snellen visual acuity, n (%)</b>		
20/15	40 (28.6)	63 (45.7)
20/20	92 (65.7)	69 (50.0)
20/20	8 (5.7)	6 (4.3)
Visual acuity, logMAR	-0.03 ± 0.06	-0.05 ± 0.07

**Figure 1.** Subjective patient ratings of verofilcon A (PRECISION1™) contact lenses at 1, 2, and 3 months.



**Figure 2.** Lens fit/movement (A) and centration (B) of verofilcon A (PRECISION1™) contact lenses at 3 months.



\*Stacie Cummings is an employee of Alcon.

# Clinical Lens Fit Characteristics of a New Silicone Hydrogel Daily Disposable and Two Commercially Available Daily Disposable Contact Lenses

Gilbert Spear et al. Poster presented at the American Academy of Optometry (AAO) Annual Meeting, October 23-26, 2019; Orlando, Florida, Poster #58.\*

## OVERVIEW



### STUDY DESIGN

Two pilot studies were conducted to evaluate and compare the contact lens fit characteristics and overall performance of daily disposable contact lenses

**Study 1:** Multicenter double-masked, prospective, randomized, crossover study

**Study 2:** Prospective, double-masked, randomized, crossover study



### STUDY SITE(S)

**Study 1:** Three (3) sites in the USA

**Study 2:** Single site in the USA



### PATIENTS

**Study 1:** Twenty-two (22) patients (11 per test group)

**Study 2:** Twenty-two (22) patients (11 per test group)



### METHODOLOGY

Subjects were randomized to receive either verofilcon A (PRECISION1™) or the comparator lenses in a crossover sequence with; for respective studies, each lens type was worn bilaterally for 7-10 days



### CONTACT LENS TYPE(S)

**Study 1:** PRECISION1™ (verofilcon A) and 1-Day ACUVUE MOIST (etafilcon A)

**Study 2:** PRECISION1™ (verofilcon A) and clariti 1 day (somofilcon A)



### KEY ENDPOINT(S)

Outcomes included contact lens fit characteristics, including lens movement (5-point scale; -2 = unacceptably tight; +2 = unacceptably loose) and position (3-point scale; 0 = optimal; 2 = unacceptable decentration) at the end of wearing time

## ANALYSIS AND CONCLUSIONS

### Verofilcon A (PRECISION1™) silicone hydrogel contact lenses showed good lens fit characteristics.

A greater percentage of verofilcon A (PRECISION1™) lenses fit and centered optimally compared to etafilcon A and somofilcon A lenses.

## STUDY RESULTS

### PATIENT POPULATION

- In both studies, patient demographics were similar across comparator groups (Table 1)
- In **Study 1**, all patients completed the study; in **Study 2**, one subject randomized to wear somofilcon A followed by verofilcon A (PRECISION1™) lenses discontinued during the verofilcon A wear phase for reasons unrelated to the study

### LENS FIT/MOVEMENT AND CENTRATION

#### Study 1:

- At the end of the 8-day wearing period, lens fit/movement was optimal in 88.6% (39/44) of eyes wearing verofilcon A (PRECISION1™) lenses and 79.5% (35/44) of eyes wearing etafilcon A lenses (Figure 1)
- Lens centration at the end of the 8-day wearing period was optimal in 81.8% (36/44) of eyes wearing verofilcon A (PRECISION1™) and 70.5% (31/44) of eyes wearing etafilcon A

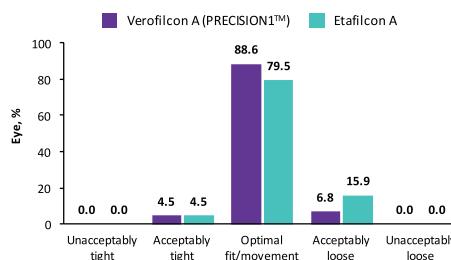
#### Study 2:

- At the end of the 8-day wearing period, lens fit/movement was optimal in 85.7% (36/42) of eyes wearing verofilcon A (PRECISION1™) lenses and in 79.5% (35/44) of eyes wearing somofilcon A lenses (Figure 2)
- Lens centration at the end of the 8-day wearing period was optimal in 90.5% (38/42) of eyes wearing verofilcon A (PRECISION1™) and 61.4% (27/44) of eyes wearing somofilcon A

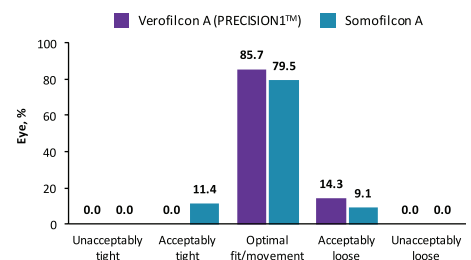
**Table 1.** Demographic characteristics of subjects in both studies. Adapted from Gilbert-Spear et al. 2019.

	verofilcon A followed by etafilcon A	etafilcon A followed by verofilcon A
<b>Study 1</b>	N=11	N=11
Age, mean ± SD	30.2 ± 10.5	31.5 ± 10.9
Age, range	18-45	18-56
Sex, female, n (%)	7 (63.6)	7 (63.6)
<b>Study 2</b>	N=11	N=11
Age, mean ± SD	32.5 ± 5.2	31.6 ± 7.6
Age, range	25-40	19-43
Sex, female, n (%)	7 (63.6)	7 (63.6)

**Figure 1.** Fit/movement of vericofilcon A and etafilcon A lenses after 8 days.



**Figure 2.** Fit/movement of vericofilcon A and somofilcon A lenses after 8 days.



\*Anne Brobst and Stacie Cummings are employees of Alcon.









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

**Rx** only