# Scientific Abstract Highlights

## Research and Investigator Initiated Trials Supported by Alcon Presented at The American Academy of Optometry Annual Meeting

October 7-22, 2020 | Virtual

Alcon
SEE BRILLIANTLY

# Introduction

## 2020 American Academy of Optometry

We are excited to showcase some of the scientific abstracts accepted for presentation during AAO 2020 at Home, presented by the American Academy of Optometry, in this abstract book. The presentations range from studies conducted by Alcon to studies on Alcon products independently conducted. We are particularly proud of our support for investigator-initiated clinical studies that further the Optometry community's knowledge of how Alcon products can best support patient care. Ultimately, this allows Alcon to ensure that what we do and what we say is backed by high quality clinical data.

In addition to this publication, you are welcome and encouraged to contact our medical affairs associates with any further clinical science related questions. Our goal is to ensure clinicians are well informed of both the science and technology behind Alcon's products, and thus, are in the best position to deliver the highest quality care to patients. We encourage you to visit our Alcon Medical Affairs website – AlconScience.com – in order to learn more about how medical science matters to us. In addition to scientific and medical publications on products and therapeutic areas relating to Alcon devices, you can find more information on educational grants, wetlabs, equipment placement, and our areas of interest for investigator-initiated trials.

Through all of these scientific and educational activities, we are proud to support your ability to provide exceptional patient care.

# Table of Contents



**This abstract book includes studies executed by Alcon or supported through independent research grants from Alcon. Studies which used Alcon products outside their FDA approved indications for use are not included in this abstract book.**

# iLux® Efficacy after One Week of Treatment

*David Geffen, OD, FAAO[1]; Thao N. Yeh, OD, PhD, MPH, FAAO[2]; Mohinder M. Merchea, OD, PhD, MBA, FAAO[2]*

## Purpose

Previous studies have shown iLux® to be effective in improving dry eye symptoms and gland function at 2 and 4 weeks after treatment. Since time-to-effect is important for many patients, especially pre-surgical patients, this study assessed efficacy 1 week after treatment with the iLux® device.

## Methods

Patients with meibomian gland dysfunction (MGD) symptoms for at least 3 months prior to the study were enrolled. iLux® treatment was provided in two zones in the lower eyelid of both eyes. Meibomian gland assessment score (MGS; 0-45), tear-breakup time (TBUT), Standard Patient Evaluation of Eye Dryness (SPEED), and Ocular Surface Disease Index (OSDI) were efficacy endpoints. Pain score and corneal staining were safety endpoints.

## Results

Thirty subjects (20 females; 52.9 ± 11.9 years old) were enrolled and completed the study. MGS improved significantly from 4.1±3.1 (baseline) to 15.8±7.1 (1 week) (+11.6±6.9 change; $p<0.0001$) and 3.7±3.1 to 16.7±7.6 (+13.0±7.3 change; $p<0.0001$) for right and left eyes, respectively. TBUT changed from 4.9±4.1 to 8.4±3.6 seconds (+3.5±2.7 change; $p<0.0001$) and from 5.2±4.2 to 8.9±3.9 seconds (+3.7±3.5 change; $p<0.0001$) for right and left eyes, respectively. SPEED decreased from 16.1±5.3 to 7.2±6.1 (-8.6±7.0 change; $p<0.0001$), and OSDI decreased from 45.2±21.3 to 19.0±16.8 (-26.3±24.3 change; $p<0.0003$). All subscores for SPEED (frequency and severity of burning, dryness, eye fatigue, and soreness) and OSDI were also statistically significantly improved at 1 week compared to baseline ($p<0.0004$). Pain scores were higher than baseline immediately post-treatment (equivalent to tolerable) but returned to baseline by 1 week. Corneal staining also improved from baseline (1.43±1.98) to 1-week (0.77±1.65) ($p<0.0023$).

## Conclusions

The iLux® safely and effectively improved meibomian gland function and dry eye symptoms in MGD patients by one week post-treatment. The short time-to-effect can optimize ocular surface health within a short period and minimize delay to surgery.

## Affiliations

[1]Gordon Schanzlin New Vision, San Diego, CA, US
[2]Alcon Vision, LLC Fort Worth, TX, US

# Dry Eye Symptom Relief with a Phospholipid / Propylene Glycol / Hydroxypropyl Guar Nanoemulsion Ocular Lubricant

*Thao N. Yeh, OD, PhD, MPH, FAAO[1]; Mohinder M. Merchea, OD, PhD, MBA, FAAO[1]*

## Purpose

SYSTANE® COMPLETE is a nanoemulsion ocular lubricant containing phospholipids, propylene glycol (PG), and hydroxypropyl guar (HPG). This study assessed the frequency of clinically significant symptom relief.

## Methods

Post-hoc analysis of a multi-center, open-label, single-arm, interventional study. Adult patients who had a clinical diagnosis of aqueous-deficient (ADE), evaporative (EDE), and mixed (MDE) dry eye received one drop of PG / HPG twice daily and were asked to rate sensation (0-10 scale) upon instillation on Day 1, dry eye symptoms (0-10 scale) upon instillation and over 8 hours on Day 1, and ocular surface discomfort (visual analogue scale, VAS; 0-100 scale) after 14 days of treatment. Clinically significant change was defined as a 7% change in score.

## Results

134 patients received the study treatment. The median age of the study cohort was 59 (range: 18–87) years, and majority of patients were female (75.4%). Dry eye sub-types were similarly represented (ADE=41; EDE=44; MDE=49). Upon instillation, 52% of patients reported no blur, while approximately 3-out-of-4 patients reported no burning, stinging, or foreign body sensation (75%, 72%, and 80%, respectively). 75% of patients experienced clinically significant improvement in dry eye symptoms compared to baseline immediately upon instillation, and the trend was consistent throughout the day (78% after 4 hours; 76% after 8 hours). Among moderate and severe dry eye patients, 83% and 95% of patients, respectively, experienced clinically significant improvement in symptoms upon instillation and 73% and 100%, respectively, after 8 hours. Finally, after 14 days of treatment, 60% of all patients reported clinically significant reduction in ocular surface discomfort score compared to baseline.

## Conclusions

SYSTANE® COMPLETE provides clinically significant dryness symptom relief beginning at installation to 8 hours after initial dosing, with nearly all severe dry eye patients and at least 73% of moderate dry eye patients reporting clinically-significant improvement. After 14 days, the majority of patients continued to experience clinically reduced ocular surface discomfort compared to baseline.

## Affiliations

[1]Alcon Vision LLC, Fort Worth, TX, US

# Six-Month Therapeutic Profiles of Lipid and Non-Lipid-Based Artificial Tear Supplements in Managing Dry Eye Disease

*Jennifer P. Craig, PhD, MSc, BSc (Hons), FCOptom, FAAO, FBCLA, FACLS[1,2]; Alex Muntz, MSc Optom, PhD[3]; Michael T.M. Wang, MBChB[1], Doerte Luensmann, PhD, Dipl. Ing. (AO), FAAO[4]; Jacqueline Tan, BOptom (Hons), PhD, FBCLA[5]; Sonia Trave Huarte, BSc[2]; Ally L. Xue, BOptom[3]; Lyndon Jones, PhD, DSc, FCOptom, FAAO, FCAHS[4]; Mark D.P. Willcox, BSc (Hons), PhD, FAAO[5]; James S. Wolffsohn, BSc (MCOptom), PhD, MBA[1,2]*

## Purpose
To evaluate the six-month therapeutic efficacy of a lipid and a non-lipid based artificial tear supplement drop for the management of dry eye disease (DED).

## Methods
Participants fulfilling the TFOS DEWS II criteria for DED were enrolled in a prospective, multicentre, double-masked, parallel group, randomised controlled trial, and were instructed to administer a lipid-based (Systane® Complete) or a non-lipid-based (Systane® Ultra) drop four times daily for six months. Symptoms and tear film and ocular surface characteristics were assessed each month, and compliance determined by returned bottle weight.

## Results
Baseline measurements for participants (total n=99; 64% females; mean±SD age: 44±16 years) did not differ between treatment groups (all $p>0.05$). Both groups showed significant symptomatic improvements after one month, and by six months averaged a reduction of 11, 3- and 17-points in OSDI, DEQ-5 and SANDE scores, respectively (all $p<0.05$). Upper lid wiper epitheliopathy decreased after two months (all $p\leq0.01$), while NIBUT, corneal and conjunctival staining improved after four months (all $p<0.05$). All temporal-therapeutic trends were similar between groups, except for tear lipid layer grades, which improved after three months only in the lipid group, and with significantly greater improvement in cases with baseline lipid grade ≤3 ($p=0.02$). By six months, one in five participants no longer had DED according to TFOS DEWS II global consensus diagnostic criteria.

## Conclusions
Lipid and non-lipid based artificial tear solutions offered rapid symptomatic relief within a month of regular, daily use. More profound, structural improvements in tear film and ocular surface integrity arise only after several months of use. Both preparations demonstrated long-term efficacy and a good tolerability profile, but the preferential use of lipid-based preparations for the management of patients exhibiting evaporative DED is recommended.

## Affiliations
[1]Department of Ophthalmology, New Zealand National Eye Centre, The University of Auckland, Auckland, NZ
[2]Ophthalmic Research Group, Life and Health Sciences, Aston University, Birmingham, UK
[3]The University of Auckland, Auckland, NZ
[4]University of Waterloo, Waterloo, ON, CA
[5]School of Optometry and Vision Science, University of New South Wales, Sydney, AU

# Seasonal Changes in Incidence and Prevalence of Allergic Conjunctivitis in the AAO IRIS® Registry

*Jerry D'Aversa, OD[1]; Marguerite McDonald, MD, FACS[1]; Manan Kocher, PhD[2]; Thao N. Yeh, OD, PhD, MPH, FAAO[3]; Mohinder M. Merchea, OD, PhD, MBA, FAAO[3]*

## Purpose

The American Academy of Ophthalmology (AAO) Intelligent Research in Sight (IRIS®) offers real-world data to study the epidemiology of ocular diseases among patients in the United States. This study aimed to generate real-world evidence on seasonal changes in incidence and prevalence of allergic conjunctivitis.

## Methods

Patients with medical records between Dec 2016 and Dec 2019 in the AAO IRIS® database were included in the study. Patients were considered positive for allergic conjunctivitis if they had at least one of the following diagnoses of conjunctivitis: acute follicular, acute atopic, chronic giant papillary, vernal, other mucopurulent, and unspecified blepharoconjunctivitis. Incidence and prevalence were determined for each season (winter, spring, summer, and fall) in the study period.

## Results

Of the 44,147,777 patients in the database, 2,226,185 were positive for allergic conjunctivitis. Overall, cases peaked during the spring (Incidence: 4.1-4.6%; Prevalence: 3.45-3.55%) and troughed during the winter (Incidence: 2.7-3.1%; Prevalence: 2.81-2.98%); 58.7% of patients were Caucasian, 8.0% were Black/African American, 4.3% were Asian, and 27.7% either did not or refused to identify their race. Despite the low prevalence of Asian patients in the database, the Asian population consistently presented with highest incidence (Spring: 6.9-8.8%; Winter: 4.4-5.8%) and prevalence (Spring: 7.9%-10.2%; Winter: 6.3-8.3%) rates over nearly all seasons, while Caucasian and Native American/Alaskan Natives presented with lowest incidence and prevalence. With respect to geographical region, 38% of patients were in the South, 28% in the North, 18% in the Midwest, and 16% in the West. The North consistently presented with highest incidence (Spring: 3.9-4.0%; Winter: 3.5-4.1%), while the Midwest had the lowest incidence and prevalence among the regions.

## Conclusions

The real-world evidence suggests that incidence and prevalence of allergic conjunctivitis is highest in the spring and lowest in the winter, which is consistent with seasonal environmental changes. Incidence and prevalence are consistently highest among the Asian population, which represented only 4.3% of the study population, and lowest among the Caucasian population, which represented 58.7% of the study population. Frequency is also greatest in the North and least in the Midwest. The relationship between race and geographical region is unclear and would require further analysis.

## Affiliations

[1]OCLI Vision, New York, NY, US
[2]Verana Health, San Francisco, CA, US
[3]Alcon Vision, LLC Fort Worth, TX, US

# Clinical Performance Evaluation of the Delefilcon A Toric Daily Disposable Silicone Hydrogel Contact Lens

*Katherine Bickle, OD, MS, FAAO[1]; Britt Gustafson, OD[2]; Bradley Giedd, OD, MS, FAAO[3]*

## Purpose

The new delefilcon A toric daily disposable silicone hydrogel contact lenses utilizing the precision 8|4 toric lens design, have a core lens material containing 33% water that transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. This study evaluated lens settling time, oscillation with blink, absolute axis orientation, and lens fit of delefilcon A toric contact lenses.

## Methods

Forty-seven subjects were fitted with delefilcon A toric lenses in this prospective, multi-center, bilateral, non-dispense study. Subjects were required to have a cylindrical correction ranging from -0.75 to -2.50 DC at an axis within ±10° of 50°, 90°, 140°, or 180°. Lenses were worn for approximately 1 hour. Lens settling time (in seconds), lens oscillation with blink on a 4-point scale (none, < 3°, 3° to 5°, > 5°), and axis orientation at 1 and 3 minutes were assessed. Lens movement (overall fit) was assessed using a 5-point scale (Unacceptably tight, Acceptably tight, Optimal fit / movement, Acceptably loose, Unacceptably loose). Lens centration was assessed using a 3-point scale (Optimal centration, Acceptable decentration, Unacceptable decentration).

## Results

The mean (standard deviation (SD)) lens settling time for delefilcon A toric lens was 36.7 (54.6) seconds. All lenses oscillated ≤5˚ with blink. The mean (SD) absolute axis orientation after 1 minute was 3.2 (5.3) degrees and after 3 minutes was 2.1 (3.2) degrees. Lens movement and centration was acceptable to optimal for all delefilcon A toric lenses (movement = 90.4% optimal; centration = 96.8% optimal).

## Conclusions

Delefilcon A toric lenses showed quick lens settling, minimal oscillation with blink, and good axis orientation after only 1 minute of wear. Lens movement and centration were acceptable to optimal for all lenses. Overall, delefilcon A toric lenses achieved excellent lens stability, lens alignment and lens fit.

## Affiliations

[1]ProCare Vision Center, Granville, OH, US
[2]The Eye Doctors, Inc., Eden Prairie, MN, US
[3]Maitland Vision, Maitland, FL, US

# Clinical Comparison of Verofilcon A and Etafilcon A Daily Disposable Contact Lenses

*Jason Miller, OD, MBA, FAAO[1]; Bradley Giedd, OD, MS, FAAO[2]; Lakshman Subbaraman, PhD, BSOptom, MSc, FAAO[3]*

## Purpose

To compare the subjective performance of verofilcon A daily disposable silicone hydrogel contact lenses, which have a core with 51% water content and a surface with >80% water content, with those of etafilcon A hydrogel contact lenses, which have a water content of 58%.

## Methods

In this prospective, multicenter, clinical study, successful wearers of spherical soft contact lenses for distance correction were randomized to wear verofilcon A or etafilcon A lenses for 8 (-1/+2) days. After a washout period, subjects were dispensed the alternative lenses. Exploratory endpoints included subjective overall lens preference (5-point scale [strongly prefer lens 1; somewhat prefer lens 1; no preference; strongly prefer lens 2; somewhat prefer lens 2]) and subjective ratings (10 point scale) of end-of-day (EOD) vision, overall handling, insertion comfort, EOD comfort, lens handling at insertion, overall comfort, overall quality of vision, vision throughout the day, and lens handling at removal. Sample size calculation was based on a prior clinical study, which evaluated the performance of verofilcon A and three other marketed soft contact lenses, including etafilcon A lenses.

## Results

Ninety-two subjects were enrolled, with 46 each initially randomized to verofilcon A and etafilcon A lenses and subsequently crossed over to the other lens type. Of the study subjects, 68 (73.9%) preferred or strongly preferred verofilcon A lenses, whereas 21 (22.9%) preferred or strongly preferred etafilcon A lenses ($p < 0.0001$). Mean ± SD ratings of EOD vision (8.6±1.5 vs. 7.7±1.9), overall handling (8.7±1.5 vs. 6.9±2.3), insertion comfort (9.2±1.0 vs. 7.7±1.9) and EOD comfort (8.0±1.9 vs. 7.0±2.2) were all significantly ($p \leq 0.0001$ each) higher for verofilcon A than for etafilcon A lenses. Mean ± SD ratings of lens handling at insertion (9.0±1.4 vs. 6.9±2.5), overall comfort (8.6±1.5 vs. 7.4±1.8), overall quality of vision (8.9±1.2 vs. 8.2±1.8), vision throughout the day (8.9±1.3 vs. 8.1±1.8), and lens handling at removal (8.3±2.1 vs. 7.7±2.2) were statistically significantly higher for verofilcon A than for etafilcon A lenses.

## Conclusions

These results demonstrate that verofilcon A lenses performed better than etafilcon A lenses with respect to overall preference, and other subjective endpoints evaluated in this study.

## Affiliations

[1]EyeCare Professionals of Powell, Powell, OH, US
[2]Maitland Vision Center, Maitland, FL, US
[3]Alcon Research, LLC, Johns Creek, GA, US

# Use of Likert Questionnaires to Compare Subjective Performance of Two Daily Disposable Soft Contact Lenses

*Jason Miller, OD, MBA, FAAO[1]; Bradley Giedd, OD, MS, FAAO[2]; Lakshman Subbaraman, PhD, BSOptom, MSc, FAAO[3]*

## Purpose

To determine the utility of 5-point Likert questionnaire and to compare the subjective performance of verofilcon A daily disposable silicone hydrogel contact lenses, with etafilcon A hydrogel contact lenses using Likert questionnaires.

## Methods

In a prospective, multicenter, cross-over, clinical study, successful spherical soft contact lens wearers were randomized to wear verofilcon A or etafilcon A lenses for 8 (-1/+2) days (n=92 completed). After a washout period, subjects were dispensed the alternative lenses. Likert questionnaires (5-point scale) were completed at end-of-day during the 1-week follow-up visits conducted after the first and second treatment periods. The following statements related to the subjects' experiences with the lenses were included in the Likert questionnaire: "My lenses felt fresh all day"; "My vision was clear all day"; "My lenses felt comfortable all day"; "The lens holds its shape when I remove it from the pack"; "It was easy to put my lenses in"; "It was easy to take my lenses out"; "No matter what I was doing today, my lenses let me see clearly"; and "My lenses stayed moist all day". Subjects selected one of the following options for each statement based on their experience on that particular day: strongly agree; agree; neither disagree nor agree; disagree; strongly disagree. In addition, subjects responded to the statement "My lenses made it feel like there was nothing in my eyes" using one of the following options: none of the time; rarely; often; very often; nearly all of the time. Due to pilot nature of these endpoints, no inferential statistics were conducted.

## Results

At the 1-week follow-up, the combined percentage of subjects who strongly agreed or agreed with each of the statements related to lens freshness (72.8 vs 56.6%), all day vision clarity (80.4 vs 70.7%), all day lens comfort (72.8 vs 51.1%), lens shape when handling (92.4 vs 38.1%), ease of inserting lenses (93.5 vs 48.9%), ease of removing lenses (82.6 vs 75%), vision clarity during daily activities (85.9 vs 67.4%), and lens moistness (72.9 vs 61.9%) was higher for the verofilcon A lenses than for the etafilcon A lenses. In addition, the combined percentage of subjects who reported that their lenses made it feel like there was nothing in their eyes either very often or nearly all of the time was higher (63.1 vs 46.7%) for the verofilcon A lenses than for etafilcon A lenses.

## Conclusions

Compared to etafilcon A, the Likert questionnaire revealed higher percentage of subjects wearing verofilcon A who strongly agreed or agreed with questions about lens freshness, comfort, vision and handling.

## Affiliations

[1]EyeCare Professionals of Powell, Powell, OH, US
[2]Maitland Vision Center, Maitland, FL, US
[3]Alcon Research, LLC, Johns Creek, GA, US

# Antimicrobial Activity Comparison of Eight Multipurpose Solutions

*Cindy McAnally, BS[1]; Rhonda Walters, BS[1]; Elise Miller, BS[1]; Manal Gabriel, DDS, PhD[1]; Monica Crary, PhD[1]; Paul Shannon, PhD, MBA[1]*

## Purpose

This study compares the antimicrobial activity of eight multipurpose solutions (MPS). The intrinsic antimicrobial efficacy in a test tube (ISO 14729 Stand-alone) as well as the efficacy during real world usage with contact lenses and cases (ISO 18259) were utilized to evaluate the antimicrobial efficacy profiles of the MPS solutions against bacteria, fungi, and two strains of Acanthamoeba spp.

## Methods

Commercially available MPS: OPTI-FREE® PureMoist® (1), OPTI-FREE® Replenish® (2), OPTI-FREE® Express® (3), Kombi Clean&Moist Acumed (4), All Clean Soft Avisor (5), Kombiologung Super Visiomax (6), Renu Multiplus (7) and Lite (8) were evaluated for their antimicrobial efficacy following ISO 14729 and ISO 18259. For ISO 14729, test tubes containing the various MPS were inoculated with 105-106 CFU/mL of bacteria (Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 9027, Serratia marcescens ATCC 13880) and fungi (Candida albicans ATCC 10231, Fusarium keratoplasticum ATCC 36031). A modified version of ISO 14729 was used to evaluated the efficacy against Acanthamoeba trophozoites where MPS were inoculated with 105 of Acanthamoeba trophozoites (ATCC 50370). For ISO 18259, four contact lens types paired with MPS in their manufacturer's lens cases were challenged with Fusarium as an indicator organism. All test samples were evaluated for viability loss at the recommended disinfection time (DT). For Acanthamoeba testing, inoculum controls and surviving organisms were calculated using 50% endpoint and log reductions (LR) determined. Statistical analysis was performed using a Student two-tailed t-test (p-value <0.05). ISO 14729 requires bacteria to be reduced by 3-logs and fungi by 1-log at DT and ISO 18259 has no criteria. There are no standards for testing MPS with Acanthamoeba.

## Results

Solutions 1-6 all met or exceed the primary criteria for ISO 14729. For ISO 18529, OPTI-FREE® products were more effective at eliminating F. keratoplasticum from all solution-lens-case combinations (avg 4.3-log) compared to all other MPS with LR ranging from 1.1-1.8. Solutions 4, 5 and 7 showed a loss of antimicrobial efficacy against Fusarium when comparing ISO 14729 (without lenses / cases) and ISO 18259 (with lenses and cases). Solutions 1-3 had superior efficacy against Acanthamoeba trophozoites with an average of 4.5 log reduction compared to all other MPS from 0.5-3.0 log ($p<0.005$).

## Conclusions

While most MPS products show equivalent intrinsic antimicrobial efficacy, only OPTI-FREE® products demonstrate a higher degree of efficacy in more rigorous testing involving contact lenses and cases against the fungal pathogen Fusarium, and against the active / infective form of Acanthamoeba.

## Affiliations

[1]Alcon Vision LLC, Fort Worth, TX, US

# Clinical Performance of Verofilcon A Toric Daily Disposable Silicone Hydrogel Contact Lenses

*Wilson Movic, OD, FAAO[1]; Bradley Giedd, OD, MS, FAAO[2]; Lakshman Subbaraman, PhD, BSOptom, MSc, FAAO[3]*

## Purpose

The purpose of this pilot study was to assess contact lens alignment and fit characteristics of a new daily disposable (DD), toric silicone hydrogel contact lens made from verofilcon A material.

## Methods

This was a multicenter study in which 32 subjects bilaterally wore the new toric verofilcon A contact lenses. The study contact lenses were evaluated for lens alignment & fit characteristics. In this pilot study, lens alignment was determined in terms of the percentage of lenses with axis orientation within ±5°, ±10°, and ±20° of the intended 90° axis, and lens oscillation with blink on a 4-point scale (none, < 3°, 3° to 5°, > 5°). The lens fit characteristics were recorded in terms of lens position and movement. The lenses were fit on subject's eyes and were evaluated 20 minutes after insertion and after 7 hours of wear. In addition, lens settling time (in seconds) was determined.

## Results

The proportion of lenses orienting within 5°, 10°, or 20° of intended axis 20 minutes after insertion was 96.9%, 98.4%, and 100%, respectively. At 7 hours, the proportion of lenses orienting within 5°, 10°, or 20° of intended axis was 93.8%, 98.4%, and 100%, respectively. Lens oscillation with blink was less than 3° in 100% of the lenses 20 minutes after insertion and approximately 97% of lenses at 7 hours. All lenses (100%) had optimal or acceptable movement and optimal or acceptable position at 20 minutes after insertion and after 7 hours of wear. The mean (SD) lens settling time was 51.2 (41.5) seconds.

## Conclusions

This pilot study of the new toric verofilcon A lenses shows optimal alignment and fit. The unique material features, advanced surface technology, optimal lens alignment, and fitting characteristics of this new verofilcon A toric lens will be a good option for lens wearers who require a toric lens.

## Affiliations

[1]VisionPoint Eye Center, Bloomington, IL, US
[2]Maitland Vision Center, Maitland, FL, US
[3]Alcon Research, LLC, Johns Creek, GA, US

# Driving Performance with Multifocal Contact Lenses and Progressive Addition Lens Spectacles

*Jennifer S. Fogt, OD, MS, FSLS, FAAO[1]; Kimberly R. Weisenberger, OD, MS[1]; Thomas Kerwin, PhD[2]; Cameron Wrabel[2]; Casey Schomer[2]; Abigail G. Menner, OD, FAAO, FSLS[1]; Nicklaus F. Fogt, OD, PhD, FAAO[1]*

## Purpose

The purpose of this study was to assess driving performance while wearing multifocal contact lenses and progressive addition spectacles.

## Methods

Nineteen presbyopic participants who were wearing progressive addition lens spectacles (PALS) with a minimum add power of +1.25 were recruited for the study. Subjects were fit with multifocal contact lenses (Dailies Total1® Multifocal, Alcon, Ft. Worth, TX), and returned for at least one follow up to assess and modify the fit as needed in order to achieve satisfactory vision at all distances. Participants wore lenses for at least two weeks before driving performance was assessed. The Driving Simulation Laboratory at The Ohio State University was used to evaluate driving performance in a controlled environment. Participants were randomized so that half of the subjects completed the driving task with the PALS first and the remainder wore the multifocal contact lenses (MFCL) first. After one driving session, subjects changed to the opposite vision correction before completing the second round of driving. The simulation environment consisted of a full-sized sedan on a motion platform, surrounded by a 260 degree projection screen. Participants were asked to follow a lead car and to identify various signs while driving. Mean velocity of the vehicle, standard deviation of the velocity, and standard deviation of lateral (lane) position on the road were recorded and analyzed.

## Results

Mean (± standard deviation) velocity for driving was 20.3±1.5 m/s (45.4± 3.4mph) with PALS wear and 20.3± 1.5 m/s (46.1±3.4 mph) with MFCL wear. Mean standard deviation of velocity was 1.1±0.5m/s (2.6±1.0 mph) with PALS and 1.2±0.8 m/s (2.6±1.7 mph) with MFCL. Mean standard deviation of lateral position was 0.13±0.03 m with PALs and 0.13±0.03 m with MFCL. None of these differences were statistically significant.

## Conclusions

In this study, there were no differences in common driving metrics while wearing PALS and MFCL.

## Affiliations

[1]The Ohio State University College of Optometry, Columbus, OH, US
[2]The Ohio State University, Columbus, OH, US

# The Subjective Response to Verofilcon A Daily Disposable Contact Lenses During Extensive Digital Device Use

*Marc Schulze, PhD, Dipl. Ing. (AO), FAAO[1]; Alison Ng, PhD, BSc (Hons), FAAO[1]; Doerte Luensmann PhD, Dipl. Ing. (AO), FAAO[1]; Sarah Guthrie, PhD[1]; Jill Woods, MSc, MCOptom, FAAO[1], Lyndon Jones, PhD, DSc, FCOptom, FAAO[1]*

## Purpose

To evaluate the subjective response of habitual lens wearers during extensive digital device use when switched to Precision1® (verofilcon A) daily disposable (DD) contact lenses (CLs).

## Methods

Volunteers between 18-40 years of age who used digital devices for at least 6 hours / day while wearing their habitual CLs were recruited for the study. Eligible participants were dispensed with verofilcon A DD CLs for a period of 2 weeks, during which they were required to wear the study CLs for at least 5 days/week and at least 10 hours/day. Participants returned after 14±2 days for their final visit, where they reported their CL wear time and time spent using digital devices, and rated their typical experience on a 0 to 100 scale, with 100 being best. Comfort, dryness and clarity of vision with verofilcon A were rated directly after insertion, after 6 hours of digital device use, and just before removal, as well as by rating their overall performance. Participants also completed a 4-point (strongly agree, slightly agree, slightly disagree, strongly disagree) Likert scale-based questionnaire. Subjective ratings were not normally distributed, therefore non-parametric analysis was conducted and data are reported as median (range). The Likert scale responses were analyzed using binomial testing.

## Results

Twenty participants completed the study (18F:2M), mean age of 25.1 ± 6.0 years (range 19-40). They reported their typical day to include median CL wear time of 13.8 hours (10.5-17), comfortable CL wear time of 12.1 hours (8-16.5) and digital device use of 9 hours (6-12). After 2 weeks of verofilcon A DD CL wear, subjective ratings after 6 hours of digital device use were high, with ratings for a typical day of 93 (68-100) for comfort, 93 (52-100) for dryness and 96 (70-100) for clarity of vision. After 2 weeks of wear, the majority of participants agreed that the study lenses provided good comfort (16/20 subjects; $p=0.01$) and good vision (18/20; $p<0.01$) all day long. Similarly, the majority of participants were satisfied with the comfort (16/20; $p=0.01$), vision (18/20; $p<0.01$) and overall performance (16/20; $p=0.01$) they experienced with the study lenses while using digital devices for ≥6 hours. Additionally, most reported they did not experience any eye strain while using verofilcon A lenses (n=16/20; $p=0.01$). No significant lens-related ocular findings were observed after 2 weeks of wear.

## Conclusions

After 2 weeks of wear, participants rated the performance of verofilcon A DD CLs very highly, with median overall performance ratings for comfort, dryness and vision all ≥93 on the 0 to 100 scale (with 100 being best). Verofilcon A DD CLs may be a viable alternative for those struggling with their habitual lens performance when spending long hours using digital devices.

## Affiliations

[1]University of Waterloo, Waterloo, ON, CA

# Clinical Outcomes after Topography-Guided Refractive Surgery in Eyes with Myopia and Astigmatism – Comparing Results with New Planning Software to Those Obtained Using the Manifest Refraction

*Phillip B. Brunson, OD, FAAO[1]; Paul M. Mann II, MD[1]; Paul M. Mann, MD, FACS[1]; Rick Potvin, OD, MASc, FAAO[2]*

## Purpose
To compare clinical outcomes from topography-guided laser refractive surgery based on new planning software to outcomes based on the manifest refraction.

## Methods
Clinical outcomes at a single site compared eligible eyes that received on-label topography-guided LASIK treatment of myopia or myopic astigmatism with correction based on either the manifest refraction or results from the Phorcides Analytical Engine (PAE) with a target postoperative follow up time of 90 days. Measures analyzed included the uncorrected (UCVA) and best-corrected (BCVA) visual acuity, the magnitude of refractive cylinder after surgery, the refractive error and changes from preoperative BCVA.

## Results
115 eyes treated with PAE planning and 133 eyes treated based off manifest refractions were included. Significantly more eyes in the PAE group had a BCVA of 20/15 or better ($p = 0.05$) and a UCVA of 20/15 or better ($p = 0.05$). Significantly more eyes in the Manifest group had a UCVA of 20/25 or worse (13/133 vs. 1/115 in the PAE group, $p = 0.002$).

## Conclusions
Topography-guided LASIK treatments utilizing PAE planning resulted in improved visual acuity and less residual cylinder.

## Affiliations
[1]Mann Eye Institute and Laser Centers, Houston, TX, US
[2]SiV Consulting, LLC, Akron, NY, US

# Visual and Refractive Outcomes of a New Non-Diffractive Extended Vision Intraocular Lens

*Scott Han, OD, FAAO[1]; Cathleen McCabe, MD[1]; Aldo A. Martinez, PhD, FAAO[2]*

## Purpose

To evaluate the visual and refractive outcomes of a new non-diffractive, extended-depth-of-focus, presbyopia-correcting intraocular lens (IOL), AcrySof® IQ Vivity™ (model DFT015), versus an aspheric monofocal IOL (SN60WF).

## Methods

Patients from one site of a prospective, multicenter, randomized US study were bilaterally implanted with DFT015 (n=9) or SN60WF (n=9). Manifest refraction spherical equivalent (MRSE) prediction error, binocular uncorrected and distance-corrected visual acuity (VA) at distance (4 m), intermediate (66 cm), and near (40 cm), and quality of vision, were measured at 6 months. Autorefraction was not used in the study to refract patients; instead, subjective manifest refraction was conducted and incorporated fogging steps to push plus. VA testing was performed using an electronic VA test system (M&S Technologies). Quality of vision was assessed subjectively with the Questionnaire for Visual Disturbance, a validated assessment of patient-reported visual symptoms.

## Results

At 6 months postoperatively, 100% and 88.9% of first eyes implanted with DFT015 and SN60WF achieved an absolute MRSE prediction error of ≤0.5 D, respectively. Mean binocular uncorrected and distance-corrected VA for DFT015 (mean logMAR ± standard deviation) were 0.00 ± 0.08 and -0.04 ± 0.05 at distance, 0.04 ± 0.08 and 0.07 ± 0.10 at intermediate, and 0.23 ± 0.11 and 0.32 ± 0.13 at near, respectively. DFT015 provided a >1-line improvement in intermediate and near VA, and comparable distance VA (20/20 or better), versus SN60WF. For both groups, the majority of patients were not at all bothered by starbursts, halos, and glare; and frequency rates were similar between groups.

## Conclusions

DFT015 improved near and intermediate VA compared with an aspheric monofocal IOL, while maintaining good distance VA and low rates of visual disturbances.

## Affiliations

[1]Laser Eye Surgeon Florida, Sarasota, FL, US
[2]Alcon Vision LLC, Fort Worth, TX, US

# Randomized Prospective Assessment of Efficacy and Safety of a new Trifocal IOL

*Jackie Armani, OD, FAAO[1]; Jessie Lemp-Hull, MS, DrPH[1]; Aldo A. Martinez, PhD, FAAO[1]*

## Purpose

To evaluate the effectiveness of AcrySof® IQ PanOptix® Trifocal Intraocular Lens (IOL) Model TFNT00 when compared to the AcrySof® Monofocal IOL Model SN60AT to support a PMA submission for the AcrySof® IQ PanOptix® Trifocal IOL.

## Methods

Prospective, non-randomized, vision assessor-masked, multicenter (twelve sites in the USA), parallel-group study. Monocular VA at 40cm, 66cm and distance (4m) were measured for up to 6-months post-operatively. Safety was assessed through secondary surgical interventions (SSIs) cumulative & persistent adverse event (AE) rates, and serious AEs (SAE) were compared to ISO 11979-7:2014 safety and SPE grid rates for posterior chamber IOLs.

## Results

A total of 243 subjects implanted in at least 1 eye and 241 (127 in the TFNT00 group and 114 in the SN60AT group) completed the study. Mean age was 67.3 years and 67.5% females. TFNT00 was superior to SN60AT for DCVA at 40cm [LSMeans difference of ~4 lines (0.42 logMAR)] and DCVA at 66cm [LSMeans difference of ~2 lines (0.26 logMAR)]. TFNT00 was also non-inferior for CDVA at 4 m [95% UCL of the difference of LSMeans (0.02 logMAR)]. Starbursts, halos, and glare were rated as the most bothersome symptoms in the TFNT00 group; however, <5% of subjects rated these symptoms as “bothered very much”. The rate of SSIs for TFNT00 was below the SPE threshold as set forth by ISO 11979-7.

## Conclusions

The TFNT00 IOL provided better vision at 40cm and 66cm and similar vision at 4m compared with SN60AT. TFNT00 IOL is safe and effective when used as intended and according to the instructions for use and it is expected to offer the benefit of increased freedom from the need for eyeglasses or contact lenses, at a range of near to distance vision.

## Affiliations

[1]Alcon Vision, LLC Fort Worth, TX, US

# Extended Depth-of-Focus Intraocular Lenses: Comparative Evaluation of a New Non-Diffractive Extended Depth-of-Focus and Monofocal Intraocular Lens

*Jessica Mark, OD[1]; Thomas Hunter Newsom, MD[1]; Aldo A. Martinez, PhD, FAAO[2]*

## Purpose

Extended depth-of-focus (EDOF) intraocular lenses (IOLs) are intended to address vision quality issues associated with multifocal IOLs while maintaining continuous vision from intermediate to distance. Current EDOF technologies can fall short in providing monofocal-like distance vision quality and contrast sensitivity. It is expected that non-diffractive technologies, which do not split the light, could be better suited to provide monofocal-like distance visual quality and visual disturbance profiles, as well as improved visual acuity (VA) at intermediate distance. AcrySof® IQ Vivity™ (model DFT015) is a new EDOF presbyopia-correcting IOL with a non-diffractive design. This study aimed to evaluate the visual outcomes of DFT015 versus an aspheric monofocal IOL (model SN60WF).

## Methods

Patients bilaterally implanted with DFT015 (n=11) or SN60WF (n=11) from a single site of a prospective, multicenter, randomized US study were assessed at 6 months for manifest refraction spherical equivalent (MRSE); binocular defocus curve; binocular uncorrected VA at distance (4 m), intermediate (66 cm), and near (40 cm); and quality of vision. VA testing was performed using an electronic VA test system (M&S Technologies). Quality of vision was assessed subjectively with the Questionnaire for Visual Disturbance, a validated assessment of patient-reported visual symptoms.

## Results

At 6 months, the majority of first eyes in the DFT015 (90.9%) and SN60WF (81.8%) groups had an absolute MRSE of 0.25 D or less, and no eyes presented with an MRSE of >0.5 D. The DFT015 binocular defocus curve showed VA of 20/32 or better from distance to -2.0 D (50 cm). Binocular uncorrected VAs at distance, intermediate, and near were 20/20, 20/20, and 20/32 or better with DFT015 and 20/20, 20/32, and 20/50 or better with SN60WF, respectively. Thus, DFT015 provided a 1–2-line improvement in mean binocular intermediate and near VA versus SN60WF, with comparable distance VA in the two groups. For both groups, the majority of patients (≥63.6%) were not at all bothered by starbursts, halos, and glare; moreover, no patients were bothered very much by these visual disturbances. In both groups, similarly low rates of severe glare, halos, and starbursts were reported.

## Conclusions

DFT015 improved near and intermediate vision without affecting distance vision, compared with an aspheric monofocal IOL, and maintained low rates of visual disturbances.

*In the Vivity FDA clinical trial, 1%-2% of Vivity patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances. In the same clinical trial, 1%-2% of the monofocal patients reported very bothersome starbursts, blurred vision, or dark area visual disturbances.

**This is site-specific data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

## Affiliations

[1]Newsom Eye & Laser Center, Tampa, FL, US
[2]Alcon Vision LLC, Fort Worth, TX, US

# Objective and Subjective Assessment of Vision Quality of a New Trifocal IOL

*Michael Petrik, OD, MSc, FAAO[1]; Jessie Lemp-Hull, MS, DrPH[1]; Aldo A. Martinez, PhD, FAAO[1]*

## Purpose

To evaluate the contrast sensitivity (CS), low contrast VA & subjective photic phenomena after bilateral implantation with the AcrySof® IQ PanOptix® Trifocal Intraocular Lens (IOL) Model TFNT00 (T) compared to bilateral implantation of the AcrySof® Monofocal IOL Model SN60AT (S).

## Methods

Prospective, non-randomized, vision assessor-masked, multicenter (twelve sites in the USA), parallel-group study. Binocular distance CS was performed in 129 (T) and 114 (S) subjects using a backlit sine wave grating chart system (CSV1000, VectorVision) at 6 months post-op under 4 conditions: photopic (~85 cd/m2) with & without glare; mesopic (approximately 3 cd/m2) with & without glare. Binocular low contrast VA was evaluated using a 10% low contrast VA chart under photopic conditionsat 4 m, 66 cm, and 40 cm and under mesopic conditions at 4 m. A validated Patient Reported Outcomes questionnaire was used to assess visual disturbances.

## Results

No clinically relevant differences were observed between groups at any spatial frequency in photopic or mesopic CS with or without glare. Mesopic CS at 3, 6 and 12 CPD was lower than the photopic conditions in both groups. Low contrast VA reduced the percentage of subjects achieving 0.3 logMAR or better compared to high contrast VA for both groups; however differences in both photopic and mesopic distance low contrast VA between groups were not clinically significant (within 1 line). A greater than 1 line improvement in low contrast intermediate VA and a greater than 3 line improvement in low contrast near VA was observed for the T group over the S group. Starbursts & halos were perceived in the group T (57% & 65%); however, the majority of subjects reported these symptoms as “not bothered at all” or only “bothered somewhat” (88% & 89%, respectively).

## Conclusions

Mean CS values for TNFT00 were within the normal range for the population. There was no clinically significant difference in CS between the groups, comparing all spatial frequencies, regardless of lighting condition or the presence of glare source. <5% subjects with the TNFT00 IOL reported starbursts & halos as “bothered very much” at Month 6.

## Affiliations

[1]Alcon Vision LLC, Fort Worth, TX, US

# Range of Vision and Spectacle Independence with a New Trifocal IOL

*Sandra Bozich, OD, FAAO[1]; Jessie Lemp-Hull, MS, DrPH[1]; Aldo A. Martinez, PhD, FAAO[1]*

## Purpose

To evaluate the depth of focus (DoF) performance and spectacle independence after bilateral implantation with the AcrySof® IQ PanOptix® Trifocal Intraocular Lens (IOL) Model TFNT00 (T) when compared to the AcrySof® Monofocal IOL Model SN60AT (S).

## Methods

Prospective, non-randomized, vision assessor-masked, multicenter (twelve sites in the USA), parallel-group study to support a PMA submission for the TFNT00 IOL. To evaluate the DoF depth of focus, binocular defocus curves were generated between +1.50 D and -2.50 D in 0.50 D steps (0.25 D steps from +0.50 to -0.50 D). All testing was performed on an electronic visual acuity test system (CTS, M&S Technologies). The assessment of need for eyeglass/contact lenses wear was performed with the PRO instrument (IOLSAT).

## Results

A total 243 subjects with a mean age of 67.3 years were implanted in at least 1 eye and 241 (127 in the T group and 114 in the S group) completed the study. The T IOL provided superior mean performance of 0.1 logMAR or better DoF from -2.5D to 0.00D (40 cm to infinity). The T IOL was superior in the % of subjects (80.5%) who responded “never to the need of wearing eyeglasses to see” VS the S IOL group (8.2%). There were 91.8% of subjects in the T group and 11.8% of subjects in the S group reported rarely to never needing glasses to see up close and 99.2% of subjects in the T group VS 67.3% of subjects in the S group reporting rarely to never needing glasses to see at arms’ length.

## Conclusions

The AcrySof® IQ PanOptix® Trifocal provided a superior range of vision from distance to 40cm (~16 inches) and decreased overall need for eyeglasses, compared to the monofocal SN60AT IOL.

## Affiliations

[1]Alcon Vision LLC, Fort Worth, TX, US

# Novel Design and Clinical Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens

*Justin Schweitzer, OD, FAAO[1]; John Berdahl, MD[1]; Vance Thompson, MD[1]; Aldo A. Martinez, PhD, FAAO[2]*

## Purpose

AcrySof® IQ Vivity™ (model DFT015) is a new non-diffractive, extended depth-of-focus (EDOF), presbyopia-correcting intraocular lens (IOL). It utilizes an innovative wavefront-shaping technology (X-WAVE™), which provides an EDOF while utilizing all the light entering the eye and simultaneously avoiding the halos and artifacts associated with diffractive lenses. This wavefront-shaping technology comprises two smooth-surface transition elements, which work synergistically to stretch and shift the wavefront and thus deliver a naturally occurring extended focal range. This study aimed to evaluate the clinical outcomes of DFT015 versus an aspheric monofocal IOL (model SN60WF).

## Methods

Patients from one site of a prospective, multicenter, randomized US study were bilaterally implanted with DFT015 (n=10) or SN60WF (n=9). Manifest refraction spherical equivalent (MRSE), binocular defocus curve, binocular best-corrected distance visual acuity (BCDVA), and distance-corrected intermediate visual acuity (DCIVA) and near visual acuity (DCNVA) were measured at 6 months. Fogging steps to push plus were applied as part of the manifest refraction protocol. All visual acuity (VA) testing was performed using an electronic VA test system (M&S Technologies). Spectacle need and quality of vision were assessed subjectively with the validated patient-reported outcome questionnaires Intraocular Lens Satisfaction (IOLSAT) and Questionnaire for Visual Disturbance (QUVID), respectively.

## Results

At 6 months, the majority of first eyes in the DFT015 (90.0%) and SN60WF (88.9%) groups had an absolute MRSE of 0.50 D or less. The DFT015 binocular defocus curve showed VA of 0.1 logMAR or better from distance to beyond -1.5 D. DFT015 provided >1-line improvement in mean binocular DCNVA and DCIVA versus SN60WF (~20/32 and better than 20/25 with DFT015 vs ~20/50 and ~20/32 with SN60WF, respectively), with a similar BCDVA in the two groups (better than 20/20). For both groups, the majority of patients (80% with DFT015 and ≥67% with SN60WF) were not at all bothered by starbursts, halos, and glare; moreover, no patients were bothered very much by these visual disturbances. In both groups, similarly low rates of severe glare, halos, and starbursts were reported. A higher proportion of patients reported never/rarely needing spectacles for seeing at arm's length and up close with DFT015 versus SN60WF (90% and 60% with DFT015 vs 67% and 0% with SN60WF, respectively).

## Conclusions

Compared with an aspheric monofocal IOL, the new EDOF IOL DFT015 improved near and intermediate VA while maintaining good distance VA, low rates of visual disturbances, and reduced spectacle need.

*In the Vivity FDA clinical trial, 1%-2% of Vivity patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances. In the same clinical trial, 1%-2% of the monofocal patients reported very bothersome starbursts, blurred vision, or dark area visual disturbances.

**This is site-specific data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

## Affiliations

[1]Vance Thompson Vision, Sioux Falls, SD, US
[2]Alcon Research, LLC, Fort Worth, TX, US

# The Impact of Image Registration for Ablation Orientation on Clinical Outcomes After Wavefront-Optimized Refractive Surgery in Eyes with Myopia and Astigmatism

*Phillip B. Brunson, OD, FAAO[1]; Paul M. Mann II, MD[1]; Paul M. Mann, MD, FACS[1]; Rick Potvin, OD, MASc, FAAO[2]*

## Purpose

Compare clinical outcomes from laser refractive surgery performed with the same laser with and without incorporating iris registration technology to compensate for ocular cyclotorsion.

## Methods

Clinical outcomes at a single site after wavefront-optimized (WFO) LASIK using the Wavelight excimer laser with and without the Vario imaging system for iris registration (IR) were evaluated. Eligible subjects were those that received on-label WFO treatment of myopia with astigmatism > 1.5 D. Measures of interest included the amount of residual refractive cylinder, refractive error, and the best-corrected (BCVA) and uncorrected (UCVA) visual acuities, with a target follow up of 90 days.

## Results

112 eligible eyes that were treated with IR, and 126 similar eyes treated without IR (NO IR), were included. Total eyes with residual cylinder > 0.50 D was higher in the NO IR group vs IR group (6% vs. 1%, respectively, p = 0.04). Significantly more eyes in the IR group had UCVA (p = 0.01) and BCVA of 20/15 or better (p = 0.003). 96% IR group eyes and 91% NO IR group eyes had UCVA of 20/20 or better.

## Conclusions

IR with the VARIO imaging device reduced overall variability in outcomes.

## Affiliations

[1]Mann Eye Institute and Laser Centers, Houston, TX, US
[2]SiV Consulting, LLC, Akron, NY, US

# Visual Outcomes, Quality of Vision, and Patient-Reported Outcomes: Trifocal Intraocular Lens vs. Extended Depth of Focus Intraocular Lens

*Ashley Owyang, OD[1]; Dan B. Tran, MD[1]; Rick Potvin, OD, MASc, FAAO[2]; Jin Hwang[1]*

## Purpose

To evaluate patients' visual acuity, spectacle independence, quality of vision, and contrast sensitivity, comparing results from bilateral implantation of AcrySof® IQ PanOptix® trifocal intraocular lens and bilateral implantation of Tecnis Symfony® extended depth of focus intraocular lens.

## Methods

This was a prospective, non-interventional, masked, two-arm comparative study of outcomes following successful, uncomplicated bilateral cataract surgery. Subjects were assessed during a single visit, 3 to 24 months after surgery. Visual acuity measures included the uncorrected and best distance-corrected binocular near, intermediate, and distance visual acuity (measured at 40cm, 60cm, and 4-6m respectively), with the distance-corrected near visual acuity of most interest. Other measures included a spectacle independence questionnaire, a quality of vision questionnaire and best-corrected binocular distance contrast sensitivity (mesopic and photopic). Nineteen EDOF and 13 trifocal subjects have been evaluated to date, matched for age and sex.

## Results

The spherical equivalent refraction ($p = 0.28$) and refractive cylinder ($p = 0.92$) were not significantly different between groups. The EDOF group had a mean distance corrected VA (DCVA) better than the trifocal group ($p < 0.01$) but both were better than 20/20. The trifocal DCVA was one line better and near VA was 2 lines better than the EDOF group ($p < 0.01$ for both). The reported need for spectacles at near was higher in the EDOF group ($p = 0.02$). Contrast sensitivity was similar between IOLs in photopic ($p = 0.11$) and mesopic ($p = 0.05$) conditions.

## Conclusions

Similar refractive results were observed between the IOL groups. They had similar contrast sensitivity, suggesting comparable visual quality. The major difference was the better distance VA with the EDOF lens and the better near and intermediate VA with the trifocal lens, with the trifocal group reporting a much lower need for spectacles at near.

## Affiliations

[1]Coastal Vision Medical Group, Orange, CA, US
[2]SiV Consulting, LLC, Akron, NY, US

# Important Product Information

## PRECISION1® and DAILIES TOTAL1®

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

## iLux®

**Indication:** The iLUX® Device is indicated for the application of localized heat and pressure therapy in adult patients with chronic disease of the eyelids, including Meibomian Gland Dysfunction (MGD), also known as evaporative dry eye.

**Contraindications:** Do NOT use the iLUX® Device in patients with the following conditions: Patients whose pupils have been pharmaceutically dilated; patients who have undergone ocular surgery within prior 12 months; patients with ocular injury or trauma, chemical burns, or limbal stem cell deficiency (within prior 3 months); patients with active ocular herpes zoster or simplex of eye or eyelid or a history of these within prior 3 months; patients with cicatricial lid margin disease; patients with active ocular infection, active ocular inflammation or history of chronic, recurrent ocular inflammation within prior 3 months; patients with an ocular surface abnormality that may compromise corneal integrity; patients with lid surface abnormalities that affect lid function in either eye; patients with aphakia; or patients with permanent makeup or tattoos on their eyelids.

**Warnings / Precautions:** Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

The Disposable may not fit all eyes, such as eyes with small palpebral fornices. Use of the iLUX® device is NOT recommended in patients with the following conditions: moderate to severe allergic, vernal or giant papillary conjunctivitis; severe eyelid inflammation; systemic disease conditions that cause dry eye; in patients who are taking medications known to cause dryness; or patients with punctal plugs.

**Potential Adverse Reactions:** Potential adverse effects may include eyelid/eye pain requiring discontinuation of the treatment procedure, eyelid irritation or inflammation, temporary reddening of the skin, ocular surface irritation or inflammation (e.g., corneal abrasion, conjunctive edema or conjunctival injection (hyperemia)), and ocular symptoms (e.g., burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance, sensitivity to light).

**Attention:** Please refer to the User Manual for a complete list of contraindications, instructions for use, warnings and precautions for the iLUX® Device.

## AcrySof® Family of Single-Piece IOLs

### (AcrySof® UV, AcrySof® IQ, AcrySof® IQ Toric, AcrySof® IQ ReSTOR®, AcrySof® IQ ReSTOR® Toric, AcrySof® IQ PanOptix® and AcrySof® IQ PanOptix® Toric IOLs)

**Caution:** Federal law restricts these devices to sale by or on the order of a physician.

**Indication:** The family of AcrySof® single-piece intraocular lenses (IOLs) includes AcrySof® UV-absorbing IOLs ("AcrySof® UV"), AcrySof® IQ, AcrySof® IQ Toric, AcrySof® IQ ReSTOR®, AcrySof® IQ ReSTOR® Toric, AcrySof® IQ PanOptix® and AcrySof® IQ PanOptix® Toric IOLs. Each of these IOLs is indicated for visual correction of aphakia in adult patients following cataract surgery. In addition, the AcrySof Toric IOLs are indicated to correct pre-existing corneal astigmatism at the time of cataract surgery. The AcrySof® IQ ReSTOR IOLs are for cataract patients with or without presbyopia, who desire increased spectacle independence with a multifocal vision. The AcrySof® IQ PanOptix® lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity with a reduced need for eyeglasses, compared to a monofocal IOL. All of these IOLs are intended for placement in the capsular bag.

**Warnings / Precautions:**
**General cautions for all AcrySof® and AcrySof® UV IOLs:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting any IOL in a patient with any of the conditions described in the Directions for Use that accompany each IOL. Caution should be used prior to lens encapsulation to avoid lens decentration or dislocation. Physicians should target emmetropia, and ensure that IOL centration is achieved.

**Additional Cautions associated with AcrySof® IQ ReSTOR® and AcrySof® IQ PanOptix® IOLs:** Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. These may include some perceptions of halos or starbursts, as well as other visual symptoms. Therefore, patients implanted with multifocal IOLs should exercise caution when driving at night or in poor visibility conditions. A reduction in contrast sensitivity may occur in low light conditions. Spectacle independence rates vary with all multifocal IOLs; as such, some patients may need glasses when reading small print or looking at small objects. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). Posterior capsule opacification (PCO), may significantly affect the vision of patients with multifocal IOLs sooner in its progression than patients with monofocal IOLs.

**Additional Cautions associated with AcrySof® IQ Toric, AcrySof® UV Toric ReSTOR® Toric, and AcrySof® IQ PanOptix® Toric IOLs:** Optical theory suggests that, high astigmatic patients (i.e. > 2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. Prior to surgery, physicians should provide prospective patients with a copy of the appropriate Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ Toric, AcrySof® IQ ReSTOR®, AcrySof® IQ ReSTOR® Toric, and AcrySof® IQ PanOptix® Trifocal IOLs.

**Attention:** Refer to the Directions for Use labeling for the specific IOL for a complete list of indications, warnings and precautions.

## AcrySof® IQ Vivity™ Family of Extended Vision IOLs

**Caution:** Federal (USA) law restricts this device to the sale by or on the order of a physician.

**Indication:** The AcrySof® IQ Vivity™ Extended Vision IOLs include AcrySof® IQ Vivity™ and AcrySof® IQ Vivity™ Toric and are indicated for primary implantation for the visual correction of aphakia in adult patients with <1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof® IQ Vivity™ IOL is intended for capsular bag placement only. In addition, the AcrySof® IQ Vivity™ Toric IOL is indicated for the reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism.

**Warnings / Precautions:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. This lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. Most patients implanted with the Vivity™ IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the Vivity IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic. It is possible to experience very bothersome visual disturbances, significant enough that the patient could request explant of the IOL. In the Vivity™ clinical study, 1% to 2% of Vivity™ patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ Vivity™ IOLs.

**Attention:** Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.

## WaveLight® Excimer Laser Systems

This information pertains to all WaveLight® Excimer Laser Systems, including the WaveLight® ALLEGRETTO WAVE®, the ALLEGRETTO WAVE® Eye-Q and the WaveLight® EX500.

**Caution:** Federal (U.S.) law restricts the WaveLight® Excimer Laser Systems to sale by or on the order of a physician. Only practitioners who are experienced in the medical mangement and surgical treatment of the cornea, who have been trained in laser refractive surgery (including laser calibration and operation) should use a WaveLight® Excimer Laser System.

**Indication:** FDA has approved the WaveLight® Excimer Laser systems for use in laser-assisted in situ keratomileusis (LASIK) treatments for: the reduction or elimination of myopia of up to -12.00 D and up to 6.00 D of astigmatism at the spectacle plane; the reduction or elimination of hyperopia up to + 6.00 D with and without astigmatic refractive errors up to 5.00 D at the spectacle plane, with a maximum manifest refraction spherical equivalent of + 6.00 D; • the reduction or elimination of naturally

occurring mixed astigmatism of up to 6.00 D at the spectacle plane; and the wavefront-guided reduction or elimination of myopia of up to -7.00 D and up to 3.00 D of astigmatism at the spectacle plane. In addition, FDA has approved the WaveLight® ALLEGRETTO WAVE® Eye-Q Excimer Laser System, when used with the WaveLight® ALLEGRO Topolyzer® and topography-guided treatment planning software for topography-guided LASIK treatments for the reduction or elimination of up to -9.00 D of myopia, or for the reduction or elimination of myopia with astigmatism, with up to -8.00 D of myopia and up to 3.00 D of astigmatism. The WaveLight® Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism) with documentation of a stable manifest refraction defined as ≤ 0.50 D of preoperative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia.

**Contraindications:** The WaveLight® Excimer Laser Systems are contraindicated for use with patients who: are pregnant or nursing; have a diagnosed collagen vascular, autoimmune or immunodeficiency disease; have been diagnosed keratoconus or if there are any clinical pictures suggestive of keratoconus; are taking isotretinoin (Accutane*) and/or amiodarone hydrochloride (Cordarone*); have severe dry eye; have corneas too thin for LASIK; have recurrent corneal erosion; have advanced glaucoma; or have uncontrolled diabetes.

**Warnings:** The WaveLight® Excimer Laser Systems are not recommended for use with patients who have: systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status; a history of Herpes simplex or Herpes zoster keratitis; significant dry eye that is unresponsive to treatment; severe allergies; a history of glaucoma; an unreliable preoperative wavefront examination that precludes wavefront-guided treatment; or a poor quality preoperative topography map that precludes topography-guided LASIK treatment. The wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination. Every step of every wavefront measurement that may be used as the basis for a wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment. Topography-guided LASIK requires preoperative topography maps of sufficient quality to use for planning a topography-guided LASIK treatment. Poor quality topography maps may affect the accuracy of the topography-guided LASIK treatment and may result in poor vision after topography-guided LASIK.

**Precautions:** The safety and effectiveness of the WaveLight® Excimer Laser Systems have not been established for patients with: progressive myopia, hyperopia, astigmatism and / or mixed astigmatism, ocular disease, previous corneal or intraocular surgery, or trauma in the ablation zone; corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage; residual corneal thickness after ablation of less than 250 microns due to the increased risk for corneal ectasia; pupil size below 7.0 mm after mydriatics where applied for wavefront-guided ablation planning; history of glaucoma or ocular hypertension of > 23 mmHg; taking the medications sumatriptan succinate (Imitrex*); corneal, lens and/or vitreous opacities including, but not limited to cataract; iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eye tracking; or taking medications likely to affect wound healing including (but not limited to) antimetabolites. In addition, safety and effectiveness of the WaveLight® Excimer Laser Systems have not been established for: treatments with an optical zone < 6.0 mm or > 6.5 mm in diameter, or an ablation zone > 9.0 mm in diameter; or wavefront-guided treatment targets different from emmetropia (plano) in which the wavefront calculated defocus (spherical term) has been adjusted; In the WaveLight® Excimer Laser System clinical studies, there were few subjects with cylinder amounts > 4 D and ≤ 6 D N. ot all complications, adverse events, and levels of effectiveness may have been determined for this population. Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery.

**Adverse Events and Complications:**

**Myopia:** In the myopia clinical study, 0.2% (2/876) of the eyes had a lost, misplaced, or misaligned flap reported at the 1 month examination. The following complications were reported 6 months after LASIK: 0.9% (7/818) had ghosting or double images in the operative eye; 0.1% (1/818) of the eyes had a corneal epithelial defect. **Hyperopia:** In the hyperopia clinical study, 0.4% (1/276) of the eyes had a retinal detachment or retinal vascular accident reported at the 3 month examination. The following complications were reported 6 months after LASIK: 0.8% (2/262) of the eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface. **Mixed Astigmatism:** In the mixed astigmatism clinical study, two adverse events were reported. The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. UCVA was decreased due to this event. The second event involved the treatment of an incorrect axis of astigmatism. The axis was treated at 60 degrees instead of 160 degrees. The following complications were reported 6 months after LASIK: 1.8% (2/111) of the eyes had ghosting or double images in the operative eye. **Wavefront-Guided Myopia:** The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). No adverse events occurred during the postoperative period of the wavefront-guided LASIK procedures. In the Control Cohort, one subject undergoing traditional LASIK had the axis of astigmatism programmed as 115 degrees instead of the actual 155 degree axis. This led to cylinder in the left eye. The following complications were reported 6 months after wavefront-guided LASIK in the Study Cohort: 1.2% (2/166) of the eyes had a corneal epithelial defect; 1.2% (2/166) had foreign body sensation; and 0.6% (1/166) had pain. No complications were reported in the Control Cohort. **Topography-Guided Myopia:** There were six adverse events reported in the topography-guided myopia study. Four of the eyes experienced transient or temporary decreases in vision prior to the final 12 month follow-up visit, all of which were resolved by the final follow-up visit. One subject suffered from decreased vision in the treated eye, following blunt force trauma 4 days after surgery. One subject experienced retinal detachment, which was concluded to be unrelated to the surgical procedure.

**Clinical Data:**

**Myopia:** The myopia clinical study included 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%. Of the 782 eyes that were eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 6-month stability time point, 98.3% were corrected to 20/40 or better, and 87.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: visual fluctuations (28.6% vs. 12.8% at baseline). Long term risks of LASIK for myopia with and without astigmatism have not been studied beyond 12 months. **Hyperopia:** The hyperopia clinical study included 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%. Of the 212 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 69.4% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "much worse" at 6 months post-treatment: halos (6.4%); visual fluctuations (6.1%); light sensitivity (4.9%); night driving glare (4.2%); and glare from bright lights (3.0%). Long term risks of LASIK for hyperopia with and without astigmatism have not been studied beyond 12 months. **Mixed Astigmatism:** The mixed astigmatism clinical study included 162 eyes treated, of which 111 were eligible to be followed for 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%. Of the 142 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 97.3% achieved acuity of 20/40 or better, and 69.4% achieved acuity of 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: sensitivity to light (52.9% vs. 43.3% at baseline); visual fluctuations (43.0% vs. 32.1% at baseline); and halos (42.3% vs. 37.0% at baseline). Long term risks of LASIK for mixed astigmatism have not been studied beyond 6 months. **Wavefront-Guided Myopia:** The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). 166 of the Study Cohort and 166 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%. Of the 166 eyes in the Study Cohort that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better. Of the 166 eyes in the Control Cohort eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20. In the Study Cohort, subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: light sensitivity (47.8% vs. 37.2% at baseline) and visual fluctuations (20.0% vs. 13.8% at baseline). In the Control Cohort, the following visual symptoms were reported at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: halos (45.4% vs. 36.6% at baseline) and visual fluctuations (219% vs. 18.3% at baseline). Long term risks of wavefront-guided LASIK for myopia with and without astigmatism have not been studied beyond 6 months. **Topography-Guided Myopia:** The topography-guided myopia clinical study included 249 eyes treated, of which 230 eyes were followed for 12 months. Accountability at 3 months was 99.2%, at 6 months was 98.0%, and at 12 months was 92.4%. Of the 247 eyes that were eligible for the UCVA analysis at the 3-month stability time point, 99.2% were corrected to 20/40 or better, and 92.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "marked" or "severe" at an incidence greater than 5% at 1 month after surgery: dryness (7% vs. 4% at baseline) and light sensitivity (7% vs. 5% at baseline). Visual symptoms continued to improve with time, and none of the visual symptoms were rated as being "marked" or "severe" with an incidence of at least 5% at 3 months or later after surgery. Long term risks of topography-guided LASIK for myopia with and without astigmatism have not been studied beyond 12 months.

**Information for Patients:** Prior to undergoing LASIK surgery with a WaveLight® Excimer Laser System, prospective patients must receive a copy of the relevant Patient Information Booklet, and must be informed of the alternatives for correcting their vision, including (but not limited to) eyeglasses, contact lenses, photorefractive keratectomy, and other refractive surgeries.

**Attention:** Please refer to a current WaveLight® Excimer Laser System Procedure Manual for a complete listing of the indications, complications, warnings, precautions, and side effects.