Clinical Outcomes Following Refit from INFUSE One-Day Multifocal to DAILIES TOTAL1 Multifocal in Satisfied Presbyopic Wearers

Sponsor:	Gordon Schanzlin New Vision Institute 4130 La Jolla Village Drive Suite 300 La Jolla CA, 92037
Monitor:	Sponsor
Investigators:	David I. Geffen, OD, FAAO (Principal Investigator) Sarah C. Kasai, OD (Sub-Investigator) Lori Bende, OD (Sub-Investigator)
Clinical laboratory:	Gordon Schanzlin New Vision Institute 4130 La Jolla Village Drive Suite 300 La Jolla CA, 92037
Study Product:	ALCON DAILIES TOTAL 1 MULTIFOCAL CONTACT LENSES
Protocol Number:	GSNVI-INFUSETODT1 V1.0 28APRIL2026

Table of Contents

PI Introduction/Bio

David Geffen, OD, FAAO specializes in contact lenses, family eye care, low vision, and refractive surgery consultations. Dr. Geffen graduated from the University of California-Los Angeles with a Bachelor of Science in Biology, and later earned his Doctor of Optometry from the University of California-Berkeley School of Optometry. Before joining at Gordon Schanzlin New Vision Institute in 1994, Dr. Geffen had been in private practice in La Jolla for more than 10 years.

Dr. Geffen has gained a national reputation for his clinical research on contact lens products, and has lent his expertise to studies for companies such as Allergan, Johnson & Johnson, Bausch & Lomb, Ciba, Biocompatibles, and other contact lens manufacturers.

Dr. Geffen has published numerous articles on refractive surgery and contact lenses. He is also a prolific speaker on specialty lens designs, as well as refractive surgery and contact lens compliance issues. Dr. Geffen is a former director of Low Vision Services, Mericos Eye Institute at Scripps Hospital.

In addition to full eye examinations for contact lenses and glasses, Dr. Geffen offers services such as refractive surgery co-management and low vision evaluations.

Relevant publication track record

- Evaluation of Perfluorohexyloctane Eyedrops in Habitual Contact Lens Wearers (Clinical Ophthalmology 2024)
- Revolutionizing Comfort: Unveiling the Potential of Perfluorohexyloctane Eyedrops for Contact Lens Wearers (AAOpt Presentation 2024)

Recent participation in Alcon IITs

- The Effectiveness of Systane PRO in providing relief from multiple symptoms of dry eye disease (2025)

Newsweek featured Dr. Geffen as one of America's Best Eye Doctors in 2022.

He has served as a contributing editor to Contact Lens Spectrum and Optometry.

Executive Summary

NEED

There is a paucity of data on the wear experience of DAILIES TOTAL1 Multifocal contact lenses in a population that has previously worn INFUSE One-Day Multifocal.

STUDY OBJECTIVE

The purpose of this study is to determine the comfort and vision of DAILIES TOTAL1 Multifocal contact lenses in a population of satisfied INFUSE One-Day Multifocal contact lens wearers

STUDY HYPOTHESIS

A high proportion (≥70%) of satisfied INFUSE One-Day Multifocal wearers will report asymptomatic dry eye status (CLDEQ-8 <12) after 2 weeks of wear with DAILIES TOTAL1 Multifocal (DT1MF).

SUPPORTS CLINICAL MESSAGE

DAILIES TOTAL1 Multifocal provides excellent comfort, vision and satisfaction in satisfied INFUSE One-Day Multifocal wearers. A majority of patients would like to continue wearing the lens. X out 10 would recommend to a friend/family.

STUDY DESIGN

Cohort	30 presbyopic, current satisfied INFUSE One-Day Multifocal contact lens wearers	**Endpoints**	**Primary:** The proportion of participants with CLDEQ-8 <12 after 2-weeks of wearing DAILIES TOTAL1 Multifocal (w finalized prescription) **Secondary**: 1. VAS in comfort, overall vision and satisfaction 2. CLDEQ-8 score after two weeks of DT1MF wearing 3. Other Likert statement related to experience with study lenses 4. SANDE and satisfaction ratings after two weeks 5. Functional scores using WPAI-SHP after two weeks 6. Distance, intermediate and near binocular VA at baseline (with Infuse MF) and after two weeks (with DT1MF) **Exploratory**: 1. Digital device average usage time with CLs

Alcon Product	DAILIES TOTAL1 Multifocal	**Design**	*Prospective, open-label, single arm study*
Comparator	N/A	**Time of follow-up**	21 days

STATISTICAL ANALYSIS
Descriptive statistical analysis (please see slide 11 on detailed statistical plan/analysis)
SAMPLE SIZE
30 subjects (33 subjects to account for drop out)
STUDY DURATION (Contract execution to CSR)
9 months

Strategic Imperative
SI-x: How does DAILIES TOTAL1 Multifocal perform in satisfied Infuse One-Day Multifocal (Ultra One-Day Multifocal) wearers?
RTI 26-CL032
Target abstract presentation date:
AOA/AAOpt 2027
Target manuscript submission date:
Contact Lens and Anterior Eye (CLAE)/Clinical Optometry 2027
Grant Request
IIT Budget: $126,105.00 USD
Funding Source: *Regional*
Funding Timeline: *Q2 2026 to Q1 2027*

Study Background & Unmet Medical Need

Background:

Despite advancements in contact lens (CL) technology, presbyopic patients often experience discomfort and dissatisfaction, leading to high dropout rates. This study aims to determine the success rate of refitting current, satisfied wearers of Bausch + Lomb Infuse Multifocal (kalifilcon A) contact lenses into DAILIES TOTAL1 Multifocal (delefilcon A) contact lenses. The goal is to understand how satisfied multifocal CL wearers respond to being refitted into an alternative daily disposable CL brand with different material properties and designs. This information will be valuable for clinicians when considering transitions due to patient preference, cost, material discontinuation, or the availability of newer technologies.

Unmet Medical Need:

There is a paucity of data on the wear experience of DAILIES TOTAL1 Multifocal contact lenses in a population that has previously worn INFUSE One-Day Multifocal. While existing multifocal lenses provide adequate refractive correction, they often fail to maintain the complex biochemical homeostasis of the aging tear film, leading to significant "end-of-day" discomfort and fluctuating vision as the lens surface dehydrates. There remains a critical clinical need for a lens material that doesn't simply offer physical lubrication but actively mimics the eye's natural environment—either through a high-oxygen water gradient surface to minimize mechanical friction or the infusion of osmoprotectants and electrolytes to prevent hyperosmotic stress. This study addresses the gap in providing a sustainable, all-day wearing experience that preserves both physiological health and the precise optical clarity required for multifocal success.

Study Design & Methodology

Study Design

Prospective, open-label, single-arm refit study. Participants serve as their own control for exploratory endpoints using paired baseline and follow-up measures. No washout period is required to preserve real-world ecological validity.

Study duration per participant: approximately 3 weeks

Methodology:

Procedures

Visit 1 — Baseline/ Dispense

- Informed consent
- Eligibility verification (including confirm satisfaction with current InfuseMF)

Subjects will be asked the following question: "**Are you satisfied with your current (Infuse MF) contact lenses?**" Subjects must answer 'yes' to continue in study.

- CLDEQ-8 baseline assessment
- SANDE (Symptom Assessment in Dry Eye)
- WPAI-SHP (Work Productivity and Activity Impairment Questionnaire)
- Power and ADD of habitual Infuse lenses
- Visual Acuity (VA) High-contrast LogMAR visual acuity measured at distance (20ft), intermediate (60cm), and near (40cm) with Infuse MF
- Daily average time of digital device usage while wearing habitual contact lenses (including tablet, phone, computer, TV and etc)
- Manifest Refraction
    - Refit into DAILIES TOTAL1 Multifocal
- Visual Acuity (VA) High-contrast LogMAR visual acuity measured at distance (20ft), intermediate (60cm), and near (40cm) with DT1 MF
- DT1mf Lens dispense

Visit 2 – Week 1 Follow-up visit (1 week after V1)

- Patient will follow up at 1 week in case power adjustment is needed, as determined by the PI

Visit 3— Week 3 Follow-up/Exit (2 weeks after V2)

- CLDEQ-8
- SANDE
- WPAI-SHP

- Satisfaction survey; intent to continue wearing, recommend Likert questions
  - Daily average time of digital device usage while wearing study contact lenses (including tablet, phone, computer, TV and etc)
  - Visual Acuity (VA) High-contrast LogMAR visual acuity is measured at distance (20ft), intermediate (60cm), and near (40cm) with DT1 MF.
- Safety evaluation

To outline the important study considerations for the DT1 Multifocal refit trial among habitual Infuse MF wearers, the methodology must account for the high expectations of a "satisfied" baseline population. The following summary details the key procedural considerations required to derive valid endpoints.

Study Considerations:

1. Longitudinal Baseline Control

Consideration: Baseline assessments (Visit 1) must be performed while the subject is wearing their habitual Infuse Multifocal lenses to capture a "satisfied" state of ocular comfort and visual acuity before the intervention.

2. Standardized Fitting Approach

To minimize investigator bias and ensure "First-Lens Fit Success," the study must strictly follow the manufacturer's fitting guidelines for DAILIES TOTAL1 (DT1) Multifocal.

Consideration: Refitting involves matching the effective power and add levels of the habitual lens to the corresponding DT1 parameters. A mandatory approximately 15-minute equilibration period is required before performing over-refraction to allow the new study lenses to stabilize on the eye.

3. Multi-Domain Subjective Assessment

The methodology employs three distinct validated instruments to capture different aspects of the patient experience:

CLDEQ-8 (Contact Lens Dry Eye Questionnaire-8): Focuses on lens-specific discomfort and end-of-day dryness. It evaluates the frequency and intensity of dryness and discomfort, as well as the frequency of "closing your eyes" due to lens awareness. A decrease of ≥3 points from the Infuse baseline to the DT1 follow-up is considered a clinically meaningful improvement in comfort.

SANDE (Symptom Assessment in Dry Eye): Captures the global frequency and severity of symptoms using a 100 Visual Analog Scale (VAS). The SANDE score provides a sensitive measure of "global" symptom shifts that may not be captured by lens-specific tools.

WPAI-SHP (Work Productivity and Activity Impairment-Specific Health Problem): Evaluates the functional impact of lens wear on work productivity and daily activities. The WPAI-SHP quantifies the impact of "contact lens discomfort" on work productivity. It specifically measures "Presenteeism" (reduced productivity while working) and "Activity Impairment". This assesses if the material properties of DT1 MF lead to a functional "real-world" benefit, such as increased comfort during sustained computer use.

Likert scales on satisfaction, intent to purchase and willingness to recommend to friend and family will also be collected

4. Subjective Surface Monitoring

A critical safety consideration is the assessment of the corneal epithelium during the material transition from Kalifilcon A to Delefilcon A.

Consideration: Corneal Fluorescein Staining (CFS) is performed at baseline (inclusion/exclusion) and Day 21 (safety evaluation). Sodium fluorescein is instilled to evaluate the integrity of the corneal epithelium. Staining is graded using the NEI/Industry scale, which divides the cornea into five zones (Superior, Inferior, Temporal, Nasal, and Central), each graded from 0 to 3.

5. Wash-in / Adaptation Period

The study allows for a 14-day wearing period of the finalized prescription before the final endpoint derivation.

Consideration: This duration is essential to move past the "novelty effect" of a new lens and to allow the ocular surface to adapt to the new study lens, ensuring the data reflects long-term wearability.

Study Endpoints

The goal of this clinical trial is to evaluate the clinical and functional outcomes associated with transitioning satisfied Bausch + Lomb Infuse Multifocal (kalifilcon A) wearers to DAILIES TOTAL1 (DT1) Multifocal (delefilcon A) lenses.

Primary Endpoint:

- The proportion of participants with CLDEQ-8 <12 after 2-weeks of wearing DAILIES TOTAL1 Multifocal (w finalized prescription)

Secondary Endpoints:

- VAS in comfort, overall vision and satisfaction
- CLDEQ-8 score after two weeks of DT1MF wearing
- Other Likert statement related to experience with study lenses
- SANDE and satisfaction ratings after two weeks
- Functional scores using WPAI-SHP after two weeks
- Distance, intermediate and near binocular VA after two weeks (with DT1MF)

Exploratory Endpoint

- Digital device average usage time with CLs

Study Assessments

	Visit 1 Baseline	Visit 2 (~1 week after V1)	Visit 3 (~2 weeks after V2*
Informed Consent	X		
Eligibility Confirmation	X		
CLDEQ-8	X		X
SANDE	X		X
WPAI-SHP	X		X
DT1 MF Lens Fitting & Dispense	X	X (PI to optimize the power if needed)	
VAS, satisfaction Survey and other Likert statements			X
Safety Assessment		X	X

*After wearing the finalized prescription

Inclusion & Exclusion Criteria

Inclusion Criteria:

- Age ≥40 years at the time of enrollment.
- Current satisfied wearer of Bausch + Lomb Infuse One-Day Multifocal (kalifilcon A) contact lenses in both eyes, CLDEQ-8 < 12 at baseline.
- Minimum wearing time of at least 8 hours per day, at least 5 days per week, for a minimum of 30 days prior to Visit 1.
- Best-corrected distance visual acuity (BCDVA) of at least 20/25 (0.18 LogMAR) or better in each eye.
- Manifest refraction within the parameters of the study lenses (e.g., Sphere: +6.00D to -10.00D; Add: Low, Med, High).
- Willingness to adhere to the study protocol, including the use of DAILIES TOTAL1 (DT1) Multifocal lenses for 8 hours per day, at least 5 days per week, and completion of all questionnaires (e.g. CLDEQ-8, SANDE, WPAI-SHP, VAS and other Likert question items).
- Ability to provide written informed consent and follow investigator instructions

Exclusion Criteria:

- Presence of active ocular infection, inflammation, or clinically significant ocular surface disease (e.g., severe dry eye, pterygium, or keratoconus).
- Uncontrolled systemic disease or use of systemic medications known to significantly affect the tear film (e.g., antihistamines or isotretinoin), unless on a stable dose for ≥90 days.
- History of refractive surgery (LASIK, PRK, RK) or intraocular surgery (Cataract/IOL)
- Clinically significant ectropion, entropion, or trichiasis that may interfere with lens performance (4).
- Baseline Corneal Fluorescein Staining (CFS) score of >2 in any single zone of the NEI/Industry scale (6).
- Subjects currently wearing a monovision or modified-monovision contact lens fit.
- Subjects who are pregnant or lactating (due to hormonal fluctuations affecting the tear film).
- Participation in any other clinical trial within the past 30 days of enrollment.

Statistical Analysis

The Primary Endpoint will be summarized as the proportion of participants who have satisfied CLDEQ-8 scores (scores <12). Questionnaire scores will be presented with descriptive statistics.

Primary endpoint reported with exact (Clopper–Pearson) 95% confidence intervals.

Data will be captured and managed using REDCap electronic data tools.[7,8] Data Analysis Plan Statistical analysis will be performed using SPSS v28.0 or Stata.

The study will enroll 30 subjects (60 eyes) who are habitual, satisfied wearers of Bausch + Lomb Infuse Multifocal lenses.

Sample Size Justification

Target enrollment: 30 participants. This will be a prospective study to understand if satisfied Infuse Multifocal CL wearers can be successfully refit into Dailies Total1 Multifocal CLs. The Primary Endpoint will be simply analyzed as the proportion of subjects who have CLDEQ-8 scores <12 at the end of the study. We estimate that 30 completed subjects will be enough to gain a general understanding of CL success and patient reported outcomes based upon past research (Duong et al., 2021a; Duong et al., 2021b). A sample size of N=30 would satisfy the requirements of the Central Limit Theorem, ensuring the normality of the sampling distribution for parametric testing. Thus, 33 subjects can be recruited, so if a subject drops out before completing the study, they will be replaced.

The study is exploratory and not powered as a confirmatory superiority trial.

Study Timeline

Milestones	Estimated Timelines (# months)
Contracting	1 month
IRB Approval	1 month
First Patient, First Visit (FPFV) date or Data Collection start date	1 month after IRB
Last Patient, Last Visit (LPLV) date or Data Analysis start date	4 months after FPFV
Final Clinical Study Report (CSR)	2 months after LPLV

Share of Voice (SoV) Plan

	Target Congress	Target Presentation Date
Abstract in Congress	AOA/AAOpt	2027

	Target Journal	Target Submission Date
Manuscript	Contact Lens and Anterior Eye (CLAE) / Clinical Optometry	2027

Recruitment

Participants will be recruited using IRB-approved recruitment materials, including flyers and digital advertisements. Recruitment flyers will be posted in co-managing clinic locations and shared via electronic methods, including email distribution and social media platforms associated with the study site.

In addition, the study team will identify potential participants through review of the clinic's existing patient database. This review will be limited to patients who have previously been fitted with Infuse Multifocal Contact Lenses and who may meet preliminary eligibility criteria. Only authorized study personnel will access this information for recruitment purposes.

Identified patients may be contacted by phone, email, or other HIPAA-compliant methods to inform them about the study and assess interest in participation. Initial contact will be limited to providing general study information, and no study procedures will be conducted prior to obtaining informed consent.

Interested individuals will be instructed to contact the study team using the information provided or may choose to respond directly to outreach. All recruitment materials and methods will be IRB-approved prior to use, and no coercive or misleading language will be included.

Consent and Screening

All participants will undergo an informed consent process prior to the initiation of any study-related procedures.

Potential participants will not be provided with the informed consent form (ICF) prior to Visit 1. The informed consent process will take place on-site at the study visit. At that time, participants will be given sufficient time to review the ICF, ask questions, and discuss participation with study staff prior to signing. Written informed consent will be obtained before any study-specific procedures are performed.

Screening procedures will occur after informed consent is obtained and will include review of medical and ocular history, as well as any necessary clinical assessments to confirm eligibility. Eligibility will be determined based on the Inclusion and Exclusion Criteria outlined in the protocol. Only participants who meet all eligibility criteria will be enrolled in the study.

Early Withdrawal of Subjects

Participants may be withdrawn from the study prior to completion for the following reasons:

- Voluntary withdrawal of consent at any time
- Occurrence of adverse events or safety concerns
- Failure to comply with study procedures or protocol requirements
- Investigator determination that continued participation is not in the participant's best interest

In the event of early withdrawal or study termination, participants may be asked to return any unused study materials, including contact lenses, if applicable. The reason for withdrawal will be documented when available.

Risks

In addition to other study-related risks, participants undergoing corneal fluorescein staining with sodium fluorescein may experience:

- Mild, brief stinging or irritation upon instillation
- Temporary blurred vision immediately following application
- Rarely, allergic reactions such as itching, redness, or swelling

These effects are typically transient and resolve without intervention.

Ethical Considerations

This study will be conducted in accordance with:

- The approved study protocol
- Principles of Good Clinical Practice (GCP)
- Applicable federal, state, and local regulatory requirements
- Institutional Review Board (IRB) requirements and determinations

The rights, safety, and well-being of study participants will be the primary consideration throughout the study.

Study Supplies

All contact lenses used in this study are FDA-approved medical devices and are not investigational. They will be used in accordance with their approved labeling.

Confidentiality

All participant information will be kept confidential to the extent permitted by law. Data will be de-identified where possible and stored securely with access limited to authorized study personnel.

Participant information will not be sold to third parties.

De-identified data may be used for future research purposes without additional consent, in compliance with applicable regulations and IRB approval.

Compensation

Participants will receive compensation for their time and participation in the study. Compensation will be provided as $125 per completed study visit, for a total of up to $375 for all three visits.

Compensation will be provided at the end of the participant's study involvement. If a participant withdraws early or does not complete all study visits, compensation will be prorated based on the number of visits completed and provided at the time of withdrawal or study termination. Compensation is not contingent upon completion of all study visits.

The method and timing of compensation will be described in the informed consent form.

Supply:

- One (1) DT1mf fitting set.
- Study lenses in quantities sufficient to support conduct of the Study. For planning purposes only, total lens usage is currently estimated at up to approximately 4,500 single lenses ("30 subjects * 2 eyes * 25 minimum).

1. Risks to Subject Privacy
    a. There is a risk of loss of confidentiality of subject information. The site will take adequate measures to minimize this risk by safeguarding all documents associated with subject and the study and by using a unique, anonymized, subject identifying number for each subject.

2. Potential Benefits of Participation
    a. Subjects enrolled in this study may experience an improvement in the clinical signs and symptoms of their dry eye disease.

3. Data Handling and Record Keeping
    a. All personal and medical information collected from participants will be kept confidential and stored securely. Information will only be accessible to the study team members directly involved in the trial. Access to the study data will be restricted to authorized personnel only. The study team will have a designated file storage system where all data will be securely stored. Participants' identities will be kept anonymous and assigned a unique identification code. This code will be used to track their progress throughout the trial. Any data shared with external organizations or individuals will be de-identified to ensure that patient confidentiality is maintained.

4. Source Documentation
    a. The following documents are defined as source documents for this study:
        i. Informed Consent Documentation
        ii. Case Report Forms
        iii. Medical Records
        iv. Adverse Event Reports

5. Records Retention

a. All study records will be retained for a minimum of 7 years after the completion of the study or termination of the study, in accordance with applicable regulatory requirements. The PI and the sponsor are responsible for ensuring that all study records are retained in accordance with this protocol. All study records will be stored securely in a locked cabinet or a password-protected electronic system to prevent unauthorized access or loss. Study records will be made available to regulatory authorities upon request, and the Sponsor and PI will retain access to the study records for the duration of the retention period. At the end of the retention period, study records will be destroyed in a manner that maintains participant confidentiality and privacy.

6. Study Monitoring, Auditing, and Inspection
    a. The study monitoring team will be composed of the PI and designated study staff. The team will be responsible for monitoring the study progress, identifying, and resolving issues, and reporting to the Institutional Review Board (IRB) and other regulatory authorities. The study monitoring team will review the study data on an ongoing basis to ensure accuracy, completeness, and timeliness. This will include reviewing case report forms (CRFs) and adverse event reports. The study monitoring team will monitor and review all adverse events reported during the study to ensure that they are being appropriately documented, reported, and managed. The study monitoring team will review all protocol deviations and violations to ensure that they are appropriately reported and managed. The study monitoring team will monitor compliance with the protocol, Good Clinical Practice (GCP) guidelines, and applicable regulations. This will include reviewing the Investigator Site File (ISF) and ensuring that all required study documentation is maintained and up to date. The study monitoring team will conduct quality control activities to ensure that the study is being conducted to the highest standards. This will include reviewing the study monitoring plan, SOPs, and other study-related documents. Regular reports will be provided to the PI, IRB, and other regulatory authorities as required.

Study Budget

Clinical Study Budget for IIT #103124963 - Prospective Study	
How does DT1 MF perform in satisfied Infuse One-Day MF wearers?	
David I. Geffen, OD	
Number of Patients:	33
Currency:	USD

Study Costs	Cost
Essential documentation prep (protocol, informed consent, CRF binding)	$6,900.00
IRB/Ethics Committee	$4,500.00
Biostatistics/Data Analysis	$5,000.00
Close out	$500.00
Medical Writing (manuscript/final report, abstracts, presentation prep)	$16,100.00
Open Access Fee (based on journal fee)	$4,500.00
Patient reimbursement (33 patients x $375)	$12,375.00
TOTAL SITE BUDGET	**$126,105.00**

Per Patient Costs	Recruitment Visit	Follow-up visit 1	Follow-up visit 2	
		Cost	Cost	Total Cost
Study/Clinical Coordinator activity (informed consent, recruitment, retention, qualification verification)	$250.00	$75.00	$200.00	$525.00
Procedural Study Costs (VA, clinical evaluation, CL fit/assessment)	$475.00	$150.00	$375.00	$1,000.00
Procedural Study Costs (questionnaires, surveys)	$150.00	$0.00	$150.00	$300.00
IP Accountability	$50.00	$0.00	$50.00	$100.00
Total Per Patient Cost Incl. Reimbursement				$1,925.00
	Institutional Overhead	20%		$385.00
				$2,310.00

References

~~1. Geffen DI, Bende L. Satisfaction of Bausch + Lomb Infuse Multifocal Wearers Refit into DAILIES TOTAL1 Multifocal. Study Protocol. 2026.~~

2. Bausch + Lomb. Infuse Multifocal (kalifilcon A) Prescribing Information. 2024.

3. Alcon Laboratories. DAILIES TOTAL1 Multifocal (delefilcon A) Prescribing Information. 2024.

4. Abetz L, Rajagopalan K, Mertzanis P, et al. Development and validation of the WPAI-DED. Health Qual Life Outcomes. 2011;9:111.

5. Chalmers RL, Begley CG, Moody K, Hickson-Curran SB. Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) and opinion of contact lens performance. Optom Vis Sci. 2012;89(10):1435-42.

6. Schaumberg DA, Gulati A, Magnuson AM, et al. Development and validation of a short questionnaire to assess the impact of dry eye on everyday life. Arch Ophthalmol. 2007;125(1):94-100.

7 Duong K, McGwin G, Jr., Franklin QX, Cox J, Pucker AD. Treating Uncomfortable Contact Lens Wear With Orthokeratology. Eye Contact Lens 2021;47:74-80.

8. Duong K, Pucker AD, McGwin G, Jr., Franklin QX, Cox J. Established soft contact lens wearers' awareness of and initial experiences with orthokeratology. Ophthalmic Physiol Opt 2021;41:673-682.

Appendix

Please remind subjects that ratings are to be given based on their most recent pair of study lenses given

VAS

Comfort (0 poor to 100 excellent)

Overall vision (0 poor quality to 100 excellent quality)

Satisfaction (0 poor to 100 excellent)

Likert questionnaires

Item	Responses (right to left)
How satisfied are you with the comfort these lenses provided?	Very satisfied Satisfied Neither satisfied nor dissatisfied Dissatisfied Very dissatisfied
How satisfied are you with your overall vision while wearing these lenses?	Very satisfied Satisfied Neither satisfied nor dissatisfied Dissatisfied Very dissatisfied
These lenses make it convenient for me to perform my daily activities.	Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree
I'm likely to continue wearing these contact lens after the study ends	Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree
I would recommend the study contact lenses to a family member or friend	Strongly Agree Agree Neither Agree nor Disagree Disagree Strongly Disagree

CLDEQ-8

Patient/Subject #:_____

Date:__/___/____Time:_____

CONTACT LENS QUESTIONNAIRE-8 (CLDEQ-8)

1. Questions about **EYE DISCOMFORT**:

   a. During a typical day in the past 2 weeks, **how** often did your eyes feel discomfort while wearing your contact lenses?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your eyes felt discomfort with your contact lenses, **how intense was this feeling of discomfort…**

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	1	2	3	4	5

2. Questions about **EYE DRYNESS:**

   a. During a typical day in the past 2 weeks, **how** often did your eyes feel dry?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your eyes felt dry, **how intense was this feeling of dryness…**

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	1	2	3	4	5

3. Questions about **CHANGEABLE, BLURRY VISION:**

   a. During a typical day in the past 2 weeks, **how** often did your vision change between clear and blurry or foggy while wearing your contact lenses?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your vision was blurry, **how noticeable was the changeable, blurry, or foggy vision …**

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	1	2	3	4	5

4. Question about **CLOSING YOUR EYES:** During a typical day in the past 2 weeks, **how** often did your eyes **bother you so much that you wanted to close them?**

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

5. Question about **REMOVING YOUR LENSES:** How often during the past 2 weeks, did your eyes *bother you so much* while wearing your contact lenses that you felt as if you needed to stop whatever you were doing and **take out your contact lenses?**

   1 Never
   2 Less than once a week
   3 Weekly
   4 Several times a week
   5 Daily
   6 Several times a day

SANDE Questionnaire

PLEASE COMPLETE THE FOLLOWING QUESTIONS REGARDING THE FREQUENCY AND SEVERITY OF YOUR DRY EYE SYMPTOMS.

1. Frequency of symptoms:
Please place an 'X' on the line to indicate how often, on average, your eyes feel dry and/or irritated:

Rarely _____ **All the time**

2. Severity of symptoms:
Please place an 'X' on the line to indicate how severe, on average, you feel your symptoms of dryness and/or irritation:

Very Mild _____ **Very Severe**

WPAI-SHP

Work Productivity and Activity Impairment Questionnaire: Specific Health Problem V2.0 (WPAI:SHP)

The following questions ask about the effect of your contact lens discomfort on your ability to work and perform regular activities. *Please fill in the blanks or circle a number, as indicated.*

1. Are you currently employed (working for pay)? _____NO ___ YES
   If NO, check "NO" and skip to question 6.

The next questions are about the **past seven days**, not including today.

2. During the past seven days, how many hours did you miss from work because of problems associated with contact lens discomfort? *Include hours you missed on sick days, times you went in late, left early, etc., because of your contact lens discomfort. Do not include time you missed to participate in this study.*

   _____ HOURS

3. During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?

   _____HOURS

4. During the past seven days, how many hours did you actually work?

   _____HOURS *(If "0", skip to question 6.)*

5. During the past seven days, how much did your contact lens discomfort affect your productivity while you were working?

Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If your contact lens discomfort affected your work only a little, choose a low number. Choose a high number if your contact lens discomfort affected your work a great deal.

Consider only how much your contact lens discomfort affected productivity while you were working.

CONTACT LENS DISCOMFORT had no effect on my work	0	1	2	3	4	5	6	7	8	9	10	CONTACT LENS DISCOMFORT completely prevented me from working

CIRCLE A NUMBER

6. During the past seven days, how much did your contact lens discomfort affect your ability to do your regular daily activities, other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If contact lens discomfort affected your activities only a little, choose a low number. Choose a high number if contact lens discomfort affected your activities a great deal.

Consider only how much contact lens discomfort affected your ability to do your regular daily activities, other than work at a job.

CONTACT LENS DISCOMFORT had no effect on my daily activities	0	1	2	3	4	5	6	7	8	9	10	CONTACT LENS DISCOMFORT completely prevented me from doing my daily activities

CIRCLE A NUMBER

Reilly MC, Zbrozek AS, Dukes E: The validity and reproducibility of a work productivity and activity impairment measure. Pharmacoeconomics 1993; 4(5):353-365.

JOB AID - MS WORD IIT SYNOPSIS REVIEW

1. **SCOPE**

Activities in MS Word files for IIT Synopsis Review.

2. **OUT-OF-SCOPE**

Communications to PI or Sponsor Site.

3. **FIELD MEDICAL ASSOCIATE (FMA)**

a. When access the MS Word file for the first time:
   i. Use the **link** in **CG**.
   ii. Open the file in **MS Word App**.
   iii. Check that ***"AutoSave"*** is turned ***On*** in the left upper corner.
   iv. Make sure the ***"Track Changes"*** button is turned ***Off.***
   v. Copy and paste from the CyberGrants application in the **browser to MS Word** in the appropriate fields.
   vi. Complete MS Word document according to current MA parameters for Synopsis Deck.
   vii. Only share this MS Word link with the Alcon associates that are directly related to this specific IIT review and approval.

b. Before sending for review by Medical Director:
   i. Turn ***On "Track Changes> For Everyone"*** and ***"All Mark Up"*** in the ***Review*** tab.

c. When reaching out to investigator:
   i. **Do not share** this document link with **non-Alcon** associates, including the PI and Sponsor Site.

4. **REVIEWERS AND FMA**

Do	Use only the **link** in the CG email or CG website to access the MS Word file.
	Use **MS Word App** for review if MS Word does not allow all its capabilities in your browser version.
	Before reviewing, make sure: • ***"All Mark Up"*** **in the *Review* tab is turned *On.*** • ***"Track Changes > For Everyone"*** **in the *Review* tab is turned *On.*** • ***"AutoSave"*** **is turned *On* in the left upper corner.**
	Comments must be **few brief bullets**. If the comment cannot fit in few brief bullets, reach out to the FMA to set a **meeting** with the appropriate stakeholders.
Do Not	Use the ***"@name"*** function in the comments.
	Share this link if you are not the FMA.
	Download, Delete, Rename, Copy, Share, or Move this file under any circumstance.

Note: These MS Word Files are considered ***Confidentiality Classification - Restricted*** per V-QMS-0054411, *"Restricted Business Information is very sensitive information, that if disclosed to unauthorized individuals would cause significant or substantial harm to Alcon"*

5. **DOCUMENT RETENTION**

MS Word files for IIT Synopsis review must be retained for a time equal to Date in the file + 10 years, per V-QMS-0056266 QSP: Classification of Records for Retention>Retention Schedule>Group 2-Official Business Records>2.1. Non-Product Specific Records>Corporate Affairs>COR03 Charitable Giving.


GLOBAL
MEDICAL
AFFAIRS
science matters