Clinical Evaluation of a Monthly Replacement Daily Wear Silicone Hydrogel Multifocal Toric Contact Lens

STUDY ID

CLR624-M103

PROTOCOL and STATISTICAL ANALYSIS PLAN

NCT05886907

Alcon

Feasibility Clinical [redacted] Protocol for CLR624-M103

Title: Assessing the Clinical Performance of Two Frequent Replacement Silicone Hydrogel Multifocal Toric Contact Lenses

[redacted] Protocol Number and Version:	CLR624-M103, Version 1.0
[redacted]	
Sponsor Name and Address:	Alcon Research, LLC and its affiliates ("Alcon") 6201 South Freeway Fort Worth, Texas 76134-2099
Test Product(s):	MFT SiHy Contact Lenses; LID223188

[redacted]

Investigator Agreement:

- I have read the Feasibility Clinical [redacted] Protocol described herein and the Feasibility Clinical [redacted] Protocol governing it, recognize its confidentiality, and agree to conduct the described trial in compliance with Good Clinical Practice (GCP), the ethical principles contained within the Declaration of Helsinki, this protocol, all applicable regulatory authority regulations, and conditions of approval imposed by the reviewing IRB or regulatory authority.
- I will supervise all testing of the device involving human subjects and ensure that the requirements relating to obtaining informed consent and IRB review and approval are met in accordance with applicable local and governmental regulations.
- I have read and understand the appropriate use of the investigational product(s) as described in the protocol, current Investigator's Brochure, product information, or other sources provided by the sponsor.
- I understand the potential risks and side effects of the investigational product(s).
- I agree to maintain adequate and accurate records in accordance with government regulations and to make those records available for inspection.
- I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements of the sponsor and government agencies.
- I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed of their obligations in meeting the above commitments.

Have you ever been disqualified as an investigator by any Regulatory Authority? ☐ No ☐ Yes
Have you ever been involved in a study or other research that was terminated? ☐ No ☐ Yes If yes, please explain here:

Principal investigator:

Signature Date

Name and professional position:

Address:

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Abbreviations and Acronyms

Abbreviation	Definition
ADE	Adverse device effect
AE	Adverse event
BCVA	Best corrected visual acuity
°C	Degrees Celsius
CDMA	Clinical Development & Medical Affairs
CSS	Clinical Site Specialist
CT&OL	Clinical Trial & Operations Lead
D	Diopter(s)
eCRF	Electronic case report form
ESP	Eye Surface Profiler
GA	Georgia
GCP	Good Clinical Practice
ICF	Informed consent form
ID	Identification
IP	Investigational product
IRB	Institutional review board
JCR	Johns Creek Research
LID	Lens identification number
logMAR	Logarithm of the minimum angle of resolution
[redacted]	[redacted]
MFT	Multifocal toric contact lens
[redacted]	[redacted]
MR	Manifest refraction
[redacted]	[redacted]
OD	Right eye
OS	Left eye
OU	Both eyes
PI	Principal investigator
R&D	Research & Development
SADE	Serious adverse device effect
SiHy	Silicone hydrogel
US or USA	United States
VA	Visual acuity

1 FEASIBILITY CLINICAL [redacted] PROTOCOL

1.1 Revision History

Version	Brief Description and Rationale
1	Initial Version of this document

1.2 Study Overview

[redacted] Protocol Study Details		
Study Rationale and Objective	The purpose of this clinical trial is to assess on-eye performance and overall fit of the [redacted] Multifocal Toric contact lens to aid in confirmation of the study lens design.	
Investigator(s) Site	Johns Creek Research Clinic 11460 Johns Creek Parkway Johns Creek, GA, 30097 USA	
External Organizations	Not Applicable	
Planned Duration of Exposure	~4 days total (test and comparator) Test Product: LID223188 for 2 (+3) days Comparator Product: Ultra MFT for 2 (+3) days	
Number of Subjects	Planned to enroll: ~30	Target to complete: 20
Study Population	Volunteer subjects aged 40 or over who are habitual multifocal soft contact lens wearers, have at least 3 months of recent contact lens wearing experience. [redacted]	
Lens Assignment	Subjects will not be randomized in this study	
Study Design	☒ Prospective ☐ Randomized ☒ Pre-determined order • Even subject #: Lens Pair 1 – LID223188, Lens Pair 2 – Ultra MFT	☒ Single-masked (trial subject) ☐ Open-label

[redacted]**Protocol Study Details**		
	• Odd subject #: Lens Pair 1 – Ultra MFT, Lens Pair 2 – LID223188	
	☐ Single group ☐ Parallel group ☒ Crossover ☐ Other	☐ Contralateral ☒ Bilateral ☐ Monocular lens wear
	Visit Schedule: 1. Visit 1: Screening/Baseline/Dispense Lens Pair 1 2. Visit 2 (2 (+3) days after Visit 1): Follow-up Lens Pair 1 (to occur at least 4-6 hours after lens insertion)/Dispense Lens Pair 2 3. Visit 3 (2 (+3) days after Visit 2): Follow-up Lens Pair 2 (to occur at least 4-6 hours after lens insertion)/Exit [redacted]	
Decision Criteria	No prospective decision criteria have been defined for this study.	
Assessments	1. **VA with study lenses (logMAR; distance @ 4m: OU,** [redacted]	

[redacted]**Protocol Study Details**	
[redacted]	
Safety Assessments	1. AEs 2. Biomicroscopy 3. Device deficiencies
Inclusion Criteria	1. Subject must be at least 40 years of age and require an ADD. 2. Subject must be able to understand and must sign an informed consent form (ICF) that has been approved by an Institutional Review Board (IRB). 3. Currently wears multifocal soft contact lenses in both eyes during the past 3 months. 4. Manifest cylinder power between -0.75 D and -1.00 D 5. BCVA logMAR 0.1 (Snellen 20/25) or better in each eye. 6. Subject must be willing to stop wearing habitual lens for the study duration and able to fit with available contact lens powers (see Section 1.3). 7. Subject must possess spectacles that provide a corrected visual acuity of 20/40 or better OU.
Exclusion Criteria	1. Any anterior segment infection, inflammation, or abnormality or disease (including systemic) that contraindicates contact lens wear, as determined by the investigator. 2. Any use of systemic or ocular medications for which contact lens wear could be contraindicated, as determined by the investigator. 3. History of refractive surgery or plan to have refractive surgery during the study or irregular cornea in either eye. 4. Ocular or intraocular surgery (excluding placement of punctal plugs) within the previous 12 months or planned during the study. 5. Biomicroscopy findings at screening that are moderate (Grade 3) or higher and/or corneal vascularization that is mild (Grade 2) or higher, and/or any infiltrate.

[redacted]Protocol Study Details	
	6. Current or history of pathologically dry eye in either eye that, in the opinion of the investigator, would preclude contact lens wear. 7. Current or history of herpetic keratitis in either eye. 8. Eye injury in either eye within 12 weeks immediately prior to enrollment for this trial. 9. Current or history of intolerance, hypersensitivity, or allergy to any component of the study products. 10. The investigator, his/her staff, family members of the investigator, family members of the investigator's staff, or individuals living in the households of the aforementioned persons may not participate in the study. 11. Participation of the subject in a clinical trial within the previous 3 days or currently enrolled in any clinical trial. 12. Monovision contact lens wearer.
Enrollment Stopping Criteria	Enrollment stopping criteria will not be defined for this study.

[redacted]

Analysis Plan	
[redacted]	
	The following product or lens naming conventions will be used: • [redacted] • Ultra MFT
Subject Characteristics and Study Conduct Summaries	The following will be presented: • Conduct • Demographics • Ct.gov AE table
Assessment Analysis Strategy	Several effectiveness assessments are being conducted in this study. Results from selected assessment will be summarized using descriptive statistics according to its measurement scale. Listings will be provided as necessary. The Safety Analysis Set will serve as the analysis data set for all effectiveness analyses.
Planned Effectiveness Analyses	The following assessments will be summarized with descriptive statistics, and listings will be generated when applicable:

[redacted]Protocol Study Details

Title	Assessment	Analysis
VA with study lenses	Visual Acuity • 4m (OU, [redacted]	Listing, table for continuous variables (Dispense, Follow-up)

[redacted]

[redacted]Protocol Study Details	
	[redacted]
Interim Analysis	At the discretion of the CDMA Project Lead, interim evaluations may be undertaken to provide early insight into product safety and/or effectiveness.
Sample Size and Power Calculations	No formal sample size calculation is provided given the descriptive and feasibility nature of the study.

1.3 Study Product and Associated Materials

	Test Product 1 [redacted]/LID223188	**Comparator Product 1** Ultra MFT
Primary component/ material	Lehfilcon A	Samfilcon A
Manufacturer	Alcon Laboratories, Inc.	Bausch + Lomb
Power Range	Any combination of the following, as available: • Sphere: Plano to -4.00D in 1D steps • Cyl: -0.75D • Axis: 170, 180, 010, 090 • Add: Lo, Med, Hi	Any combination of the following, as available: • Sphere: Plano to -4.25D in 0.25D steps • Cyl: -0.75D • Axis: 170, 180, 010, 090 • Add: Lo, Hi
Supply	The sponsor will provide this test product.	The site will procure this comparator product.
Packaging and Labeling	Primary label on blister foil pack includes: • material name or identifier • base curve • diameter • packing solution • power • lot number • expiration date • content statement • investigational device statement • sponsor information • country of origin Secondary color-coded label on packages	Commercial primary label on blister foil pack.

	Test Product 1 [redacted]/LID223188	**Comparator Product 1** Ultra MFT
	includes: • clinical protocol number • material name or identifier • power • an investigational use only statement • tracking or handling unit number	
Storage	Lenses should be stored at room temperature.	Refer to manufacturer's instructions.
Other	Replacement lenses are allowed only if there is a device deficiency (e.g., torn lens) or if the lens falls on the ground and investigator wants to insert a new lens.	
Associated Materials	• CLEAR CARE Cleaning and Disinfecting Solution will be used with study lenses for the duration of study. • LacriPure rinsing/reinsertion PRN will be used as needed with study lenses. • Lubrication/re-wetting drops will not be permitted during study lens wear.	

Table 1-1 Schedule of Study Procedures and Assessments

	Procedure / Assessment	Visit 1	Visit 2		Visit 3	Unscheduled Visit / Early Exit Visit	Source Only*
		Screening / Baseline / Dispense Pair 1	Follow-up Pair 1 (2 [+3] days after Visit 1)	Dispense Pair 2	Follow up Pair 2 (2 [+3] days after Visit 3) / Exit		
1	**Informed Consent**	X					
2	**Demographics**	X					
3	**Medical History**	X	X	X	X	X	X
4	**Concomitant Medications**	X	X	X	X	X	X
5	**Inclusion/ Exclusion**	X					
6	**Habitual lens** *(brand, power)*	X					
7	**VA w/ habitual correction** *(logMAR; distance OD, OS, OU and near OU only)*	X	(X)	(X)	X Distance only	X	X
8	**Manifest refraction**	X	(X)	(X)	(X)	(X)	
9	**BCVA** *(logMAR; distance OD, OS, OU and near OU only, with manifest refraction)*	X	(X)	(X)	(X)	(X)	
10	**Biomicroscopy**	X	X	(X)	X	X	
[redacted]							

	Procedure / Assessment	Visit 1	Visit 2		Visit 3	Unscheduled Visit / Early Exit Visit	Source Only*
		Screening / Baseline / Dispense Pair 1	Follow-up Pair 1 (2 [+3] days after Visit 1)	Dispense Pair 2	Follow up Pair 2 (2 [+3] days after Visit 3) / Exit		
		Lens Pair 2)					
[redacted]	[redacted]	[redacted]					
14	**Dispense study lenses**	X		X		(X)	
15	**Slit lamp photo/video of study lenses**	(X)	(X)	(X)	(X)	(X)	(X)
16	**VA with study lenses** *(logMAR; distance @ 4m: OU,* [redacted]	X	X	X	X	(X)	

[redacted]

	Procedure / Assessment	Visit 1	Visit 2		Visit 3	Unscheduled Visit / Early Exit Visit	Source Only*
		Screening / Baseline / Dispense Pair 1	Follow-up Pair 1 (2 [+3] days after Visit 1)	Dispense Pair 2	Follow up Pair 2 (2 [+3] days after Visit 3) / Exit		
[redacted]							

	Procedure / Assessment	Visit 1	Visit 2		Visit 3	Unscheduled Visit / Early Exit Visit	Source Only*
		Screening / Baseline / Dispense Pair 1	Follow-up Pair 1 (2 [+3] days after Visit 1)	Dispense Pair 2	Follow up Pair 2 (2 [+3] days after Visit 3) / Exit		
[redacted]							
26	**Collect worn lenses**	(X)	X	(X)	X	(X)	
27	**AEs**	X	X	X	X	X	
28	**Device deficiencies**	X	X	X	X	X	
29	**Exit Form**	(X)	(X)	(X)	X	(X)	

(X) assessment performed as necessary, e.g., decrease of VA by 2 lines or more with investigational product (IP)

[redacted]

1.4 Study-Specific Lens Returns

1.4.1 Worn IP

Worn IP will be returned to the sponsor. Use the following instructions for collection, storage, and shipping, unless otherwise instructed by the sponsor.

- Removal from eye: Clean hands
- Storage container: Unused screw-top lens case
- Label information:
  - Protocol number
  - Site number
  - Subject ID
  - Eye
  - Lens type/ identification
  - Date collected
- Storage solution: PURILENS Plus Preservative Free Saline (PURILENS Plus Saline)
- Storage temperature: Refrigerated 4-10°C
- Timing of return: Study Completion
- An inventory/list of lenses being returned

[redacted]

1.4.2 Lens Return (ADE/Device Deficiency)

The directions for the collection, storage, and return of lenses associated with an AE or device deficiency are listed in the [redacted] Protocol.