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

STUDY ID

CLN705-M102

PROTOCOL

NCT05702541

Feasibility Clinical [redacted] Protocol for CLN705-M102

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

[redacted] Protocol Number and Version:	CLN705-M102, Version 4.0
[redacted]	
Sponsor Name and Address:	Alcon Research, LLC and its affiliates ("Alcon") 6201 South Freeway Fort Worth, Texas 76134-2099
Test Product(s):	LID223194 MF SiHy Contact lenses

Sponsor Contact Details

[redacted]

Investigator Agreement:

- I have read the Feasibility Clinical [redacted] Protocol described herein and the Feasibility Clinical Master 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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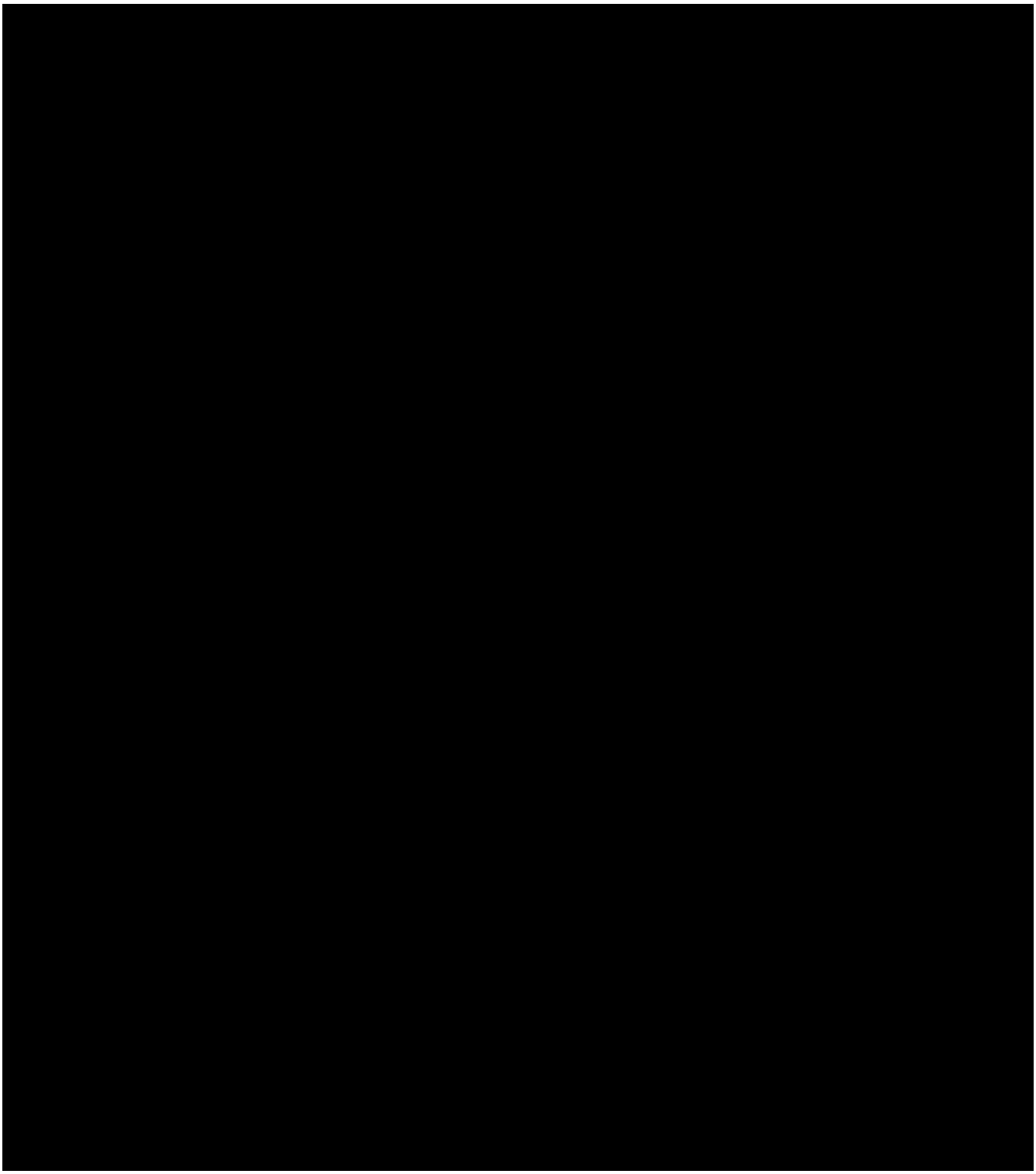
Abbreviations and Acronyms

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
[redacted]	[redacted]
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]
[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

Abbreviation	Definition
VA	Visual acuity

1 FEASIBILITY CLINICAL [redacted] PROTOCOL



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1.2 Study Overview

[redacted]Protocol Study Details		
Study Rationale and Objective	In this clinical trial, clinical performance of LID#223194 Multifocal contact lens and a commercially available Air Optix plus HydraGlyde Multifocal contact lens will be assessed.	
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 (LID223194): 2 days (+ 3 days) Comparator Product (AirOptix HydraGlyde MF [AOHG MF]): 2 days (+3 days) Exposure of study lenses in 2 different periods over 3 visits	
Number of Subjects	Planned to enroll: ~35	Target to complete: 25 - 30
Study Population	• Habitual soft Multifocal contact lens wearers aged ≥ 40 years with normal eyes (not needing ocular medication, other than correction for refractive error). Subjects should have at least 3 months wearing experience, wear these lenses at least 5 days per week and at least 8 hours per day. • To qualify, subjects must require cylindrical correction ≤ 0.75D, be able wear study contact lens with sphere power ranging between +3.00D and -7.00D and requiring a near ADD of LO, MED or HI [redacted]	
Lens Assignment	Subjects will be randomized in a 1:1 manner to receive one of 2 lens sequences: • Sequence 1: LID223194/AOHG MF • Sequence 2: AOHG MF/LID223194	

[redacted]**Protocol Study Details**		
Study Design	☒ Prospective ☒ Randomized	☒ Single-masked (trial subject) ☐ Open-label
	☐ Single group ☐ Parallel group ☒ Crossover ☐ Other	☐ Contralateral ☒ Bilateral ☐ Monocular lens wear
	Visit Schedule: 1. Visit 1 - Screening/Baseline/Dispense Lens 1 2. Visit 2 (2 (+3) days after Visit 1) Follow-up (to occur at least 4-6 hours after lens insertion) Lens Pair 1/Dispense Lens 2 3. Visit 3 (2(+3) days after Visit 2) Follow-up (to occur at least 4-6 hours after lens insertion) /Exit	
	[redacted]	
Decision Criteria	Not applicable	
Assessments	1. **VA with study lenses (logMAR; OU) @ 4m**	
	[redacted]	
Safety Assessments	1. AEs 2. Biomicroscopy 3. Device deficiencies	

[redacted]Protocol Study Details	
Inclusion Criteria	1. Subject must be at least 40 years of age. 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. Subject must be willing to stop wearing their habitual contact lenses for the duration of study participation. 4. Currently wears multifocal soft contact lenses in both eyes for a minimum of 5 days per week and 8 hours per day during the past 3 months. 5. Manifest cylinder ≤ 0.75 D in each eye. 6. BCVA 0.1 logMAR or better in each eye. 7. Able to fit with available contact lenses : within a range of powers from +3.00D to -7.00 and requiring a near ADD of LO, MED or HI 8. 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. 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 [redacted] in the study.

[redacted]Protocol Study Details	
	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	
Statistical Analysis	[redacted] The following product or lens naming conventions will be used: • LID223194 • AOHG MF
Subject Characteristics and Study Conduct Summaries	The following will be presented: • Demographics Characteristics (listing)
Assessment Analysis Strategy	[redacted]. 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.

[redacted]

[redacted]Protocol Study Details

[redacted]

VA with study lenses	Visual Acuity • [redacted] • 4m (OU)	Table for continuous variables [redacted]

[redacted]

[redacted]Protocol Study Details	
[redacted]	
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 **LID223194** [redacted]	**Comparator Product** **AIR OPTIX plus HydraGlyde Multifocal**
Primary component/ material	Lehfilcon A	Lotrafilcon B
Manufacturer	Alcon Laboratories, Inc.	Alcon Laboratories, Inc.
Power Range	• LO Add with +1.00 to -5.00D (in 0.25D steps) spherical power as available • MED Add with +3.00D to -7.00D (in 0.25D steps) spherical power as available • HI Add with +3.00D to -7.00D (in 0.25D steps) spherical power as available	• LO Add with +1.00 to -5.00D (in 0.25D steps) spherical power as available • MED Add with +3.00D to -7.00D (in 0.25D steps) spherical power as available • HI Add with +3.00D to -7.00D (in 0.25D steps) spherical power as available
Supply	The sponsor will provide this test product.	The site will procure this comparator product

	Test Product **LID223194** [redacted]	**Comparator Product** **AIR OPTIX plus HydraGlyde Multifocal**
Packaging and Labeling	Primary label on blister foil pack includes, at a minimum: • 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 includes: • clinical protocol number • material name or identifier • power • an investigational use only statement • tracking or handling unit number	Commercial primary label on blister foil pack
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.	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.

	Test Product **LID223194** [redacted]	**Comparator Product** **AIR OPTIX plus HydraGlyde Multifocal**
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.	• 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 Lens 1	Follow up Lens 1 (2 (+ 3) Days) after Visit 1 (minimum 4 - 6 hrs after insertion)	Dispense Lens 2	Follow up Lens 2 (2(+3) Days) after Visit 2 (minimum 4-6 hrs after insertion)/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					X
7	**VA w/ habitual correction** *(OD, OS, Snellen distance)*	X	(X)	(X)	(X)	(X)	X
8	**Manifest refraction (***most plus spherical equivalent***)**	X				(X)	
9	**BCVA** *(OD, OS, logMAR; distance and near with manifest refraction)*	X				(X)	
10	**Biomicroscopy**	X	X		X	X	
[redacted]							

13	**Randomize**	X					
14	**Dispense study lenses**	X		X		(X)	
[redacted]							
18	**VA w/ study lenses, *(logMAR)*** • Distance (4m; OU)	X	X	X	X	(X)	
[redacted]							

[redacted]

27	**AEs**	X	X	X	X	X	
28	**Device deficiencies**	X	X	X	X	X	
29	**Exit Form**	(X)	(X)	(X)	X	(X)	

[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]

Notify via email the CSS and Clinical Trial & Operations Lead when lenses are returned.

[redacted]