Clinical Evaluation of a Manufacturing Process for a Frequent Replacement Silicone Hydrogel Multifocal Contact Lens

STUDY ID

CLN705-M103

PROTOCOL

NCT05765227

Feasibility Clinical [redacted] Protocol for CLN705-M103

Title: Clinical evaluation of a manufacturing process for a frequent replacement silicone hydrogel multifocal contact lens

[redacted] Protocol Number and Version:	CLN705-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):	Lehfilcon A Multifocal SiHy contact lens [redacted] Air Optix plus Hydraglyde MF contact lens (AOHG MF) [redacted]

Sponsor Contact Details

[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
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

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 evaluate the clinical performance of a manufacturing process on a frequent replacement multifocal contact lens	
Investigator(s) Site	Johns Creek Research Clinic 11460 Johns Creek Parkway Johns Creek, GA, 30097 USA	
External Organizations	Not Applicable	
Planned Duration of Exposure	Subjects will be exposed to up to 2 study lenses per eye, each will be worn for 2 days (+3 days): • Study Lens 1 [redacted]	
Number of Subjects	Planned to enroll: Up to 150 subjects [redacted]	Target to complete: Up to 150 subjects
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	

[redacted]**Protocol Study Details**		
	between +3.00D and -7.00D and requiring a near ADD of LO, MED or HI [redacted]	
Lens Assignment	No formal randomization will be implemented (a predetermined order will be provided by Sponsor, if applicable).	
Study Design	☒ Prospective ☐ Randomized	☒ Single-masked (trial subject) ☐ Open-label
	☐ Single group ☐ Parallel group ☐ Crossover ☒ Other: either single group or crossover depending on number of study lenses evaluated	☐ Contralateral ☒ Bilateral ☐ Monocular lens wear
	Visit Schedule: • If only 1 study lens to be tested in a trial: 1. Visit 1 - Screening/Baseline/Dispense Lens 1 2. Visit 2 (2 (+3) days after Visit 1) Follow-up Lens 1 (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; OU) @ 4m** [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. 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. [redacted]

[redacted] Protocol Study Details	
	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, as available 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. 11. Participation of the subject in a clinical trial within the previous 2 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]	[redacted]
Analysis Plan	
Statistical Analysis	[redacted]

<table>
<tr><th colspan="2">[redacted]Protocol Study Details</th></tr>
<tr><td></td><td>The following product or lens naming conventions will be used:
[redacted]
[redacted]
[redacted]
• AOHG MF
[redacted]</td></tr>
<tr><td>Subject Characteristics and Study Conduct Summaries</td><td>The following will be presented:
• Conduct</td></tr>
<tr><td>Assessment Analysis Strategy</td><td>[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.</td></tr>
<tr><td>Planned Effectiveness Analyses</td><td>[redacted]
<table>
<tr><th>Title</th><th>Assessment</th><th>Analysis</th></tr>
<tr><td>VA with study lenses</td><td>Visual Acuity
[redacted]
• 4m (OU)
[redacted]
[redacted]</td><td>Table for continuous variables (Dispense, Follow-up)</td></tr>
</table>
[redacted]</td></tr>
</table>

[redacted] Protocol Study Details	
	[redacted]
[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 1 [[redacted] MF contact lenses or LID]	Comparator Product 1 [AIR OPTIX plus HydraGlyde Multifocal]	[redacted]
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.	
Packaging and Labeling	Primary label on blister foil pack includes, at a minimum: • material name or identifier • base curve	Commercial primary and secondary labeling and packaging	

	Test Product 1 [[redacted] MF contact lenses or LID]	Comparator Product 1 [AIR OPTIX plus HydraGlyde Multifocal]	[redacted]
	• 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 [If product is marketed		

	Test Product 1 [[redacted]MF contact lenses or LID]	**Comparator Product 1 [AIR OPTIX plus HydraGlyde Multifocal]**	[redacted]
	include the following] Commercial primary label on blister foil pack includes: • material name • base curve • diameter • packing solution • power • lot number • expiration date • content statement • country of origin • manufacturer information		
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.	
Associated	• CLEAR CARE Cleaning and Disinfecting Solution will be used with study		

	Test Product 1 [[redacted] MF contact lenses or LID]	**Comparator Product 1 [AIR OPTIX plus HydraGlyde Multifocal]**	[redacted]
Materials	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	[redacted]	Exit	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)				
1	**Informed Consent**	X					
2	**Demographics**	X					
3	**Medical History**	X	X			X	X
4	**Concomitant Medications**	X	X			X	X
5	**Inclusion/ Exclusion**	X					
6	**Habitual lens** *(brand, power)*	X					
7	**VA w/ habitual correction** *(OD, OS, Snellen distance)*	X	(X)		X	(X)	X
8	**Manifest refraction (***most plus sphero-cylindrical***)** ***(data for repeat subjects – ILB in EDC)***	X			(X)	(X)	
9	**BCVA** *(OD, OS, logMAR; distance and near with manifest refraction)*	X			(X)	(X)	
10	**Biomicroscopy**	X	X			X	
[redacted]							

	Procedure/ Assessment	Visit 1	Visit 2	[redacted]	Exit	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)				
[redacted]							
13	**Dispense study lenses**	X				(X)	X
[redacted]							
17	**VA w/ study lenses,** ***(logMAR)*** • Distance (4m; OU) [redacted]	X	X			(X)	
[redacted]							

	Procedure/ Assessment	Visit 1	Visit 2	[redacted]	Exit	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)	[redacted]			
[redacted]							
27	Collect worn lenses		X			(X)	
28	AEs	X	X		X	X	
29	Device deficiencies	X	X		X	X	

	Procedure/ Assessment	Visit 1	Visit 2	[redacted]	Exit	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)	[redacted]			
30	**Exit Form**	(X)	(X)	[redacted]	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.

If worn IP is to be returned, provide all of the following specifications:

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