INFORMATION AND CONSENT FORM

TITLE: Clinical Performance of Qualis Silicone Hydrogel Soft Contact Lens over 3 Months of Daily Wear

PROTOCOL NO.:
AVDR 2019-05
WIRB® Protocol #20200417

SPONSOR: Unicon Optical Co., Ltd.

INVESTIGATOR:
Azinda Morrow, OD
Clinical Vision Research Center
SUNY College of Optometry
33 West 42nd Street
New York, NY 10036
United States

STUDY-RELATED PHONE NUMBER(S):
(212) 938-4052 (Monday - Thursday 9:00am-7:00pm, Friday 9:00am-5:00pm)
(650) 438-2522 (After hours)

- **This is a consent form for research participation.** This document contains important information about this study and what to expect if you decide to participate, including the purpose, procedures, risks and possible benefits, to allow you to make an informed decision. This process is known as informed consent. Please consider the information carefully. You will be given a copy of this form to review at your leisure, or to ask advice from others. The study doctor or study staff will answer any questions you may have about this form or about the study. Please read the document carefully, and do not hesitate to ask any questions to clarify any concerns you may have. After reading the consent form, if you would like to participate, you will be asked to sign this form, and will be given a copy to take home and keep for your records.

- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time, without having to give a reason. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with the Clinical Vision Research Center or SUNY College of Optometry. If you are a student or employee at the SUNY College of Optometry, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

KEY INFORMATION ABOUT THIS STUDY

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

You are being asked to participate in a research study in order to compare two types of soft contact lenses designed for people with nearsightedness. Researchers want to evaluate the safety and performance of a novel soft contact lens called Qualis Silicone Hydrogel. This is also referred to as the "study contact lens", meaning it is an investigational device and it is not currently approved by the United States Food and Drug Administration (FDA). The performance of the study contact lens will be compared to a currently marketed soft contact lens called Acuvue Vita. The lenses will be worn by participants for at least 5 days per week and at least 6 hours per day. Removal of the contact lenses will occur nightly before bed. The same lenses will be reused for up to one month with daily cleaning and disinfection, to be specified in the study. A new supply of contact lenses and cleaning care solution will be provided at interim follow up visits. All participants will be randomly assigned into either the study contact lens or the Acuvue Vita. One of two solutions for daily cleaning, disinfection, and storage will also be randomly assigned. The care products to be randomly assigned in the study are Clear Care Contact Lens Solution and Biotrue Multi-Purpose Contact Lens Solution. PuriLens Plus Preservative Free Saline will also be supplied, if needed. You will have a 67% chance of being assigned to the study contact lens and a 33% chance of being assigned the control contact lens and an equal chance of being assigned to either care products.

Why is this study being done?

This study is being conducted in order to collect safety and efficacy data on the safety and performance of the Qualis Silicone Hydrogel Soft Contact Lens for daily wear. The data collected will be compared to Acuvue Vita Monthly Wear Contact Lens.

How many people will take part in this study?

Up to 75 participants will enroll in this study, distributed over 3 locations across the United States.

What will happen if I take part in this study?

This study includes six scheduled visits and is expected to last about 3 months per subject. The study staff will tell you when to come in for your study visits. The table below shows the approximate amount of time each visit will take.

Visit	Description	≈ Duration
1	(Screening/Enrollment/Baseline/Lens Dispense) Day 0 Explanation of the study, informed consent, contact lens and medical history, comfort/vision/handling/symptoms questionnaire, standard clinical vision and eye health examination, dispense lens and educate on proper use, evaluate lens fit, schedule follow up visit	2 hours
2, 3, 4, 5	(Follow-up) Day 7, Day 14, Day 30, and Day 60 Changes to medical history, comfort/vision/handling/symptoms questionnaire, standard clinical vision and eye health examination, contact lens fit evaluation, dispense additional lens and care products (if applicable), schedule follow up visit	1.5 hours
6	(Follow-up/Study Completion) Day 91 Changes to medical history, comfort/vision/handling/symptoms questionnaire, standard clinical vision and eye health examination, contact lens fit evaluation, study completion forms	1.75 hours

STUDY PROCEDURES

If you agree to participate in this study and you sign this form, the study doctor or study staff will perform the procedures listed below when you come in for study visit. If you would like more information about any procedure listed below, ask the study doctor or study staff.

Some of the study procedures that are to be performed might be done as part of your regular medical care even if you do not take part in this research study. However, these study visits do not take the place of your regular eye exams.

Visit 1 (Screening, Enrollment, Baseline Data Collection, Lens Dispense)

You will arrive to Visit 1 with spectacles. If you decide to be in the study, you will have the following tests done to find out if you qualify to be in this study:

- Health and medication questions: the study staff will ask you about your background (including your age and race/ethnicity), your health, your medical history, and the medications and supplements you take. You should tell the study staff if you take any over-the-counter or prescription medications (including supplements, such as vitamins or herbs)
- Contact lens history: the study staff will ask you about the name and type of contact lens you have worn
- Study questionnaires: you will be asked to complete a questionnaire about your vision with the contact lens you have been wearing

- Eye exam: the study staff will test your vision in various light conditions and will perform an examination of the front part of your eyes with a slit lamp (a beam of light and microscope) and other equipment. A dye normally used in eye examinations will also be used to examine the front of your eye. This procedure may be performed at other visits. These are standard procedures in daily practice.

You should ask the study staff to describe these procedures and the equipment used during the eye exam.

If you decide that you want to be in the study, and the study staff says you can continue in the study they will:

- Fit and provide contact lenses and contact lens solution and train you on the proper use and care for the lenses.
- Evaluate the fit of the study contact lenses.
- Schedule follow up visits.

Which contact lenses you wear will be assigned randomly (by chance), which means that neither you nor the study doctor will get to choose which contacts you wear. If you are fit with the study contact lenses to wear between study visits, you should wear the study contact lenses as the study staff has instructed you to wear them. You are the only one who should wear the study contact lenses. You should make sure that other people do not wear them.

Visits 2, 3, 4, 5, and 6 (Follow-up Visits)

At the follow-up visits, the following tests will take place:

- You will have several different eye evaluations including a vision test and an examination of the front part of your eyes
- You will have several contact lens evaluations
- You will be asked about your experience with the study contact lenses (how you like them, if you have had any problems with them) and complete a questionnaire.

Following the 6th and final scheduled visit, you will be asked to return your study contact lenses to the study staff. You should talk to the study doctor about your options for correcting your eyesight after the study is over. You should bring your spectacles to all study visits.

Additional Study Procedures

If you have any problems using the study contact lenses or problems with your eyes during the study, you should stop using the study contact lenses and tell the study staff immediately. You may need to come in for an unscheduled visit to check on any problems you are having.

During some of the study visits, the following tests may take place:

- You may have an examination of the back part of your eye
- You may have eye examinations to check up on the health of your eyes. Your eyes may be checked for changes and a culture (sample) may be taken for tests

Remote Study Procedures

With consideration for the global pandemic (COVID-19), the follow-up study visit procedures listed below may be conducted remotely (via telephone or video conference) to reduce physical exposure time between you and study personnel:

- Questionnaires (vision/comfort/handling/wear time/symptoms)
- Changes in medication and health history
- Scheduling

If you are willing to participate in remote reporting it must occur on the same day of the scheduled in-person visit and must be prior to the visit with the exception of scheduling, which may occur at any time between visits. Any eligible procedure not conducted remotely prior to the visit will be conducted during the in-person visit.

PARTICIPANT RESPONSIBILITIES:

As a participant, your responsibilities include:

- Follow the instructions you are given
- Keep your study visit appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment
- Tell the study doctor or study staff about any side effects of wearing the study contact lenses, any of the study procedures, any doctor visits you have had outside the study, or any changes in your health
- Tell the study doctor or study staff if you believe you might be pregnant
- Keep the study contact lenses in a safe place and for your use only
- Tell the study doctor or study staff if you want to stop being in the study at any time

Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The SUNY College of Optometry and the Clinical Vision Research Center.

POSSIBLE RISKS OR DISCOMFORTS RELATED TO THE STUDY:

What risks, side effects or discomforts can I expect from being in the study?

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF YOU EXPERIENCE:

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness**
- **Or Other Eye Problems,**

IF ANY OF THESE SYMPTOMS OCCUR, YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE CLINICAL VISION RESEARCH CENTER / PRINCIPAL INVESTIGATOR.

- Lenses for daily wear (i.e. you are instructed to remove and clean/disinfect your lenses at the end of each day), should not be worn while sleeping. Clinical studies have shown that the risk of serious eye problems is increased when lenses are worn overnight.
- Studies have shown that contact lens wearers who smoke have a higher rate of eye problems than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye.[1]
- Proper use and care of your contact lenses and lens care products are essential for the safe use of these products.
- The overall risk of serious eye problems may be reduced by carefully following directions for lens care.

[1]New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

The following problems may also occur when wearing contact lenses:

- Burning, stinging, and/or itching of the eyes
- Less comfort after daily wear than when the lens was first placed on the eye
- A feeling like there is something in the eye (foreign body, scratched area)
- Reduced vision or temporary loss of vision due to peripheral infiltrates (white blood cells), peripheral corneal ulcers (inflammation of the cornea), and/or corneal erosion (defects in the corneal surface)
- Local or generalized edema (swelling)
- Corneal neovascularization (small blood vessels growing into the cornea)
- Corneal staining (defect in the corneal surface)
- Redness
- Tarsal abnormalities (bumps on the inside upper eye lid)

- Iritis (internal inflammation of the eye)
- Conjunctivitis (infection or inflammation of the white part of the eye or under the eyelids)
- Excessive watering, unusual eye secretions, or redness of the eye
- Poor visual acuity
- Blurred vision
- Rainbows or halos around objects
- Sensitivity to light
- Dry eyes may also occur if lenses are worn continuously or for too long a time

If you experience any eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems, you should immediately remove the study contact lenses and contact the study doctor. All eye care should be performed by a study investigator for the duration of the study.

Some of these possible risks or discomforts may result in you not being able to wear contact lenses, either for a short time or ever again. You must own wearable and functional eyeglasses to correct your vision if you become unable to wear contact lenses.

The pupils of your eyes may need to be dilated. The risk is the same as in a standard dilated examination. A dilating drug standardly used by eye care practitioners will be used if dilation is required. Some people may have an allergic reaction to the dilating drug. Prior to use of this drug you will be asked if you have glaucoma or any other eye condition, as well as a history of allergy to this type of drop.

Unforeseeable Risks

It is possible that problems and side effects of the study contact lenses that nobody knows about could happen to you, which include your eyesight getting worse. If the study doctor learns any new information about the study contact lenses while you are in the study, and it is the kind of information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

Women of Child-bearing Potential

If you are a woman, you cannot be in this study if you are pregnant or breastfeeding. If you decide to be in the study:

- You must not be pregnant.
- You must not plan to become pregnant during the study.
- You must not be breastfeeding.

If you think that you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you will be removed from the study. The study doctor may request to have information about the pregnancy and the birth of the child. The study doctor may share this information with the sponsor and the IRB.

POTENTIAL BENEFITS

What benefits can I expect from being in the study?

Participation in this study will not benefit you directly. The study contact lenses might help correct your eyesight while you are wearing them, but you may not continue to wear the study contact lenses after you finish the study. Your eyesight might not be corrected by the study contact lenses or might get worse while you are in this study. Information from this study may help researchers come up with new treatments to help others in the future.

ALTERNATIVES

What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. You do not have to be in this study to get help for your eyesight. The study doctor will talk to you about other things you can do for eyesight. Some other things you can do are:

- Wear eyeglasses
- Use FDA-approved soft or hard contact lenses and solutions
- Get laser or other refractive surgery
- Have no vision correction

You can talk to your primary eye care provider about your options, including their risks and benefits before you take part in this study.

CONFIDENTIALITY OF STUDY INFORMATION

During the study, the study sponsor may share technical, economic, or business information about the study contact lenses with you. By agreeing to participate in this study, you agree not to share information about the study contact lenses with anyone outside the study without first obtaining written permission from the study sponsor. To ask questions about this, talk to the study doctor or study staff.

Will my study-related information be kept confidential?

Your records of being in this study will be kept private, except when ordered by law. The following people have access to your study records:

- The investigator, including study staff
- The sponsor company, or research institutions [including the Contract Research Organization (CRO), monitor(s) and auditor(s)]
- The United States Food and Drug Administration (FDA)
- Office for Human Research Protections or other federal, state, or international regulatory agencies
- Western Institutional Review Board and SUNY Institutional Review Board
- The Institutional Review Board (IRB)

If the results of this study are made public, information that identifies you will not be used.

If we find information that significantly impacts your health during any of the study procedures, the study doctor will notify you. Individual research results will not be shared with you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

FINANCIAL CONSIDERATIONS

Unicon Optical Co., Ltd. is the sponsor financially covering the costs related to this study, as well as paying the study doctor / study site to perform this study.

Costs

There is no cost to participate. You will be responsible for transportation and parking in order to attend study visits at The SUNY College of Optometry / Clinical Vision Research Center.

The study is not meant to replace your regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

You may have to pay the costs of diagnosing and treating a condition or injury that you or others think may be related to the study. This could happen if:

- the sponsor and/or the study doctor do not think the condition or injury is related to the study
- you have not followed the directions the study doctor or study staff gave you about the study

See the section below entitled “Research-related Injury”

Will I be paid for taking part in this study?

You will be compensated for your time (away from your normal activity). The compensation schedule for completed study visits is as follows: Visit 1: $75; Visit 2: $75; Visit 3: $75; Visit 4: $75; Visit 5: $75 and Visit 6: $75. If you do not complete the study, you will be compensated for the visit(s) you do complete. A completed visit means all scheduled study procedures have been carried out.

RESEARCH - RELATED INJURY:

Every effort to prevent study-related injury will be taken by the study doctors and staff. If you are injured as a direct result of your participation in this study, while following the study doctor's instructions and study requirements, you may obtain care at the Clinical Vision Research Center. Medical care will be made available to you at no cost to treat physical injury directly resulting from study procedures. No other form of compensation is offered.

SPONSOR LIABILITY:

If you have not followed the study doctor's instructions about the study, the sponsor may not pay these expenses.

What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

WHOM TO CONTACT

You can ask questions about the study any time. If you have any issues, problems with your eyes during the study, experience a research-related injury, feel sick or have questions, concerns, or complaints you can call Dr. Morrow or the Clinical Vision Research Center at 212-938-4052 during the day (Monday-Thursday 9:00am-7:00pm, Friday 9:00am-5:00pm), or (650) 438-2522 (after hours).

Institutional Review Boards responsible for human subjects research (Western Institutional Review Board and SUNY College of Optometry Institutional Review Board) have reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Please visit the WIRB website www.wirb.com for more information about research studies and the role of a research subject.

PARTICIPANT'S STATEMENT

If you consent, please read and then sign below

- I have read (or someone has read to me) and understand this information
- It has been written in a language that I can read and understand
- This study has been explained to me
- All of my questions about the study, the study treatment, and possible risks and side effects have been answered to my satisfaction
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study
- I understand that I will be given a signed copy of this document to keep

Printed name of participant	**Signature of participant**
	Date

Investigator/Research Staff

I have explained the research to the participant before requesting the signature above. There are no blanks in this document. A copy of this form has been given to the participant.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in this research study, the study doctor and study staff will collect or create personal health information about you (for example, medical histories, photographs, results of any tests, and examinations or procedures you undergo while in the study) and record it on study forms. The study doctor will keep this personal health information in your study-related records (that we will refer to as “your study records”). In addition, the study doctor may obtain, and include in your study records, information regarding your past, present and/or future physical or mental health and/or condition. Your study doctor may ask you to sign a separate authorization to obtain some or all of your medical records from your doctor. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called “Protected Health Information” (or “PHI”).

Under federal law (the “Privacy Rule”), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or “disclosed” (given to anyone) for research purposes without your permission. This permission is called an “Authorization”. Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study doctor and staff to use your PHI to conduct this study.

By signing this Authorization, you also are agreeing to allow the study doctor to disclose PHI as described below:

- The investigator, including study staff at the Clinical Vision Research Center
- The sponsor of this study and anyone working on behalf of the sponsor to conduct this study (referred to as "the sponsor"). The sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The study staff will assign a code number and/or letters to your records, which means you will not ordinarily be identified in the records sent to the sponsor. The sponsor may, to the extent allowed by law, look at your complete study records that identify you. In addition, the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct
- The Western and SUNY College of Optometry Institutional Review Boards (“IRB”) may have access to your PHI in relation to its responsibilities as an Institutional Review Board
- The study doctor or sponsor may disclose your PHI to the United States Food and Drug Administration (“FDA”) or similar regulatory agencies in the United States and/or foreign countries
- RealTime, the company that manages participant reimbursements, will have access to your basic demographic information (name, date of birth, and address)

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

After your encoded Protected Health Information is disclosed to the study sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The study sponsor and people who work with the study sponsor may use the results of this study for other research purposes in the future, including:

- Reviewing the safety or effectiveness of the study drug and other products or therapies
- Evaluating other products or therapies for patients
- Developing a better understanding of disease
- Improving the design of future clinical research studies

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

The results of the study may be published in a medical book or journal or presented at meetings for educational purposes. Neither your name nor any other personal health information that specifically identifies you will be used in those materials or presentations.

You have a right to see and make copies of your PHI, as per national or regional regulations.

You are agreeing, however, by signing this form, not to see or copy some or all of your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization, and use of your PHI will be used and reported for as long as the study is ongoing.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, stating that you are revoking your Authorization to Use or Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this study.

You will receive a copy of this Authorization after you have signed it.

Printed Name of Participant

Signature of Participant Date

Printed Name of Person Obtaining the Authorization

Signature of Person Obtaining the Authorization Date

IRB APPROVED
AS MODIFIED
Jun 14, 2020

INFORMATION AND CONSENT FORM

TITLE: Clinical Performance of Qualis Silicone Hydrogel Soft Contact Lens over 3 Months of Daily Wear

PROTOCOL NO.: AVDR 2019-05
WIRB® Protocol #20200417
2020W0036

SPONSOR: Unicon Optical Co., Ltd.

INVESTIGATOR: Jennifer Fogt, OD, MS FAAO FSLS
The Ohio State University College of Optometry
338 W 10th Ave
Columbus OH 43210
United States

STUDY-RELATED PHONE NUMBER(S): Jennifer Fogt, OD, MS FAAO FSLS
614-292-8858
614-292-0882 (After Office Hours)

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

You are being asked to participate in a research study in order to compare two types of soft contact lenses for people with nearsightedness. Researchers want to evaluate the safety and

performance of a novel soft contact lens called Qualis Silicone Hydrogel. This is also referred to as the "study contact lens", meaning it is an investigational device and it is not currently approved by the United States Food and Drug Administration (FDA). The performance of the study contact lens will be compared to a currently marketed soft contact lens called Acuvue Vita. The lenses will be worn by participants for at least 5 days per week and at least 6 hours per day. Removal of the contact lenses will occur nightly before bed. The same lenses will be reused for up to one month with daily cleaning and disinfection. A new supply of contact lenses and clearing care solution will be provided at interim follow up visits. All participants will be randomly assigned into either the study contact lens or Acuvue Vita. One of two solutions for daily cleaning, disinfection and storage will also be randomly assigned. The care products to be randomly assigned in the study are Clear Care Contact Lens Solution and Biotrue Multi-Purpose Contact Lens Solution. PuriLens Plus Preservative Free Saline will also be supplied. You will have a 67% chance of being assigned to the study contact lens and a 33% chance of being assigned the control contact lens and an equal chance of being assigned to either care products.

Why is this study being done?

This study is being conducted in order to collect scientifically valid data on the safety and performance of the Qualis Silicone Hydrogel Soft Contact Lens for daily wear. The data collected will be compared to Acuvue Vita Monthly Wear Contact Lens.

How many people will take part in this study?

Up to 75 participants will enroll in this study.

What will happen if I take part in this study?

This study includes six scheduled visits and is expected to last about 3 months per subject. The study staff will tell you when to come in for your study visits. The table below shows the approximate amount of time each visit will take.

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Study Procedures

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Some of the study procedures might be done as part of your regular medical care even if you do not take part in this research study. However, these study visits do not take the place of your regular eye exams.

Visit 1 (Screening, Enrollment, Baseline Data Collection, Lens Dispense)

You will arrive to Visit 1 with spectacles. If you decide to be in the study, you will have the following tests done to find out if you qualify to be in this study:

- Eye exam: the study staff will test your vision in various light conditions and give you an examination of the front part of your eyes with a slit lamp (a beam of light and microscope) and other equipment. A dye normally used in eye examinations will be used to examine the front of your eye. This procedure may be performed at other visits. These are standard procedures in daily practice. You should ask the study staff to describe these procedures and the equipment used during the eye exam.
- Health and medication questions: the study staff will ask you about your background (including your age and race/ethnicity), your health, your medical history, and the medications and supplements you take. You should tell the study staff if you take any over-the-counter or prescription medications (including supplements, such as vitamins or herbs)
- Contact lens history: the study staff will ask you about the name and type of contact lens you have worn
- Study questionnaires: you will be asked to complete a questionnaire about your vision with the contact lens you have been wearing

If the study staff says you can be in the study they will:

- Provide contact lenses and contact lens solution and train you on the proper use and care for the lenses.
- Evaluate the fit of the study contact lenses.
- Schedule follow up visits.

Which contact lenses you wear may be assigned randomly (by chance), which means that neither you nor the study doctor would get to choose which contacts you wear. If you are fit with the study contact lenses during the study visits, you should wear the study contact lenses as the study staff has instructed you to wear them. If the study lenses are given to you to wear at home, the study staff will give you written instructions on how to take care of your lenses. You are the only one who should wear the study contact lenses. You should make sure that other people do not wear them.

If you have any problems using the study contact lenses or problems with your eyes during the study, you should stop using the study contact lenses and tell the study staff immediately. You may need to come in for an unscheduled visit to check on any problems you are having.

Visits 2, 3, 4, 5, and 6 (Follow-up Visits)

At the follow-up visits, the following tests will take place:

- You will have several different eye evaluations including a vision test an examination of the front part of your eyes
- You will have several contact lens evaluations
- You will be asked about your experience with the study contact lenses (how you like them, if you have had any problems with them) and complete a questionnaire.

Following the 6th and final scheduled visit, you will be asked to return your study contact lenses to the study staff. You should talk to the study doctor about your options for correcting your eyesight after the study is over. You should bring your spectacles to all study visits.

Remote Study Procedures

With consideration for the global pandemic (COVID-19), the follow-up study visit procedures listed below may be conducted remotely (via telephone or video conference) to reduce physical exposure time between you and study personnel:

- Questionnaires (vision/comfort/handling/wear time/symptoms)
- Changes in medication and health history
- Scheduling

If you are willing to participate in remote reporting it must occur on the same day of the scheduled in-person visit and must be prior to the visit with the exception of scheduling, which may occur at any time between visits. Any eligible procedure not conducted remotely prior to the visit will be conducted during the in-person visit.

Participant Responsibilities

As a participant, your responsibilities include:

- Follow the instructions you are given
- Keep your study visit appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment
- Tell the study doctor or study staff about side effects of wearing study contact lenses, doctor visits or any changes in your health
- Tell the study doctor or study staff if you believe you might be pregnant
- Keep the study contact lenses in a safe place and for your use only
- Tell the study doctor or study staff if you want to stop being in the study at any time

Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

What risks, side effects or discomforts can I expect from being in the study?

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF YOU EXPERIENCE:

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness**
- **Or Other Eye Problems,**

YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL.

- Lenses for daily wear (i.e. you are instructed to remove and clean/disinfect your lenses at the end of each day), should not be worn while sleeping. Clinical studies have shown that the risk of serious eye problems is increased when lenses are worn overnight.
- Studies have shown that contact lens wearers who smoke have a higher rate of eye problems than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye.[1]
- Proper use and care of your contact lenses and lens care products are essential for the safe use of these products.
- The overall risk of serious eye problems may be reduced by carefully following directions for lens care.

[1]New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

The following problems may also occur when wearing contact lenses:

- Burning, stinging, and/or itching of the eyes
- Less comfort after daily wear than when the lens was first placed on the eye
- A feeling like there is something in the eye (foreign body, scratched area)
- Reduced vision or temporary loss of vision due to peripheral infiltrates (white blood cells), peripheral corneal ulcers (inflammation of the cornea), and/or corneal erosion (defects in the corneal surface)
- Local or generalized edema (swelling)
- Corneal neovascularization (small blood vessels growing into the cornea)

- Corneal staining (defect in the corneal surface)
- Redness
- Tarsal abnormalities (bumps on the inside upper eye lid)
- Iritis (internal inflammation of the eye)
- Conjunctivitis (infection or inflammation of the white part of the eye or under the eyelids)
- Excessive watering, unusual eye secretions, or redness of the eye
- Poor visual acuity
- Blurred vision
- Rainbows or halos around objects
- Sensitivity to light
- Dry eyes may also occur if lenses are worn continuously or for too long a time

If you experience any eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems, you should immediately remove the study contact lenses and contact the study doctor. You should continue to see your regular eye care practitioner routinely as directed.

Some of these possible risks or discomforts may result in you not being able to wear contact lenses, either for a short time or ever again. You must own wearable and functional eyeglasses to correct your vision if you become unable to wear contact lenses.

The pupils of your eyes may need to be dilated. The risk is the same as in a standard dilated examination. A dilating drug standardly used by Eye Care Practitioners will be used if dilation is required. Some people may have an allergic reaction to the dilating drug. Prior to use of this drug you will be asked if you have glaucoma or any other eye condition, as well as a history of allergy to this type of drop.

A dye used to examine the front part of your eye may be used during a routine study eye examination.

Unforeseeable Risks

It is possible that problems and side effects of the study contact lenses that nobody knows about could happen to you, which include your eyesight getting worse. If the study doctor learns any new information about the study contact lenses while you are in the study, and it is the kind of information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

Women of Child-bearing Potential

If you are a woman, you cannot be in this study if you are pregnant or nursing a baby. If you decide to be in the study:

- You must not be pregnant.
- You must not plan to become pregnant during the study.
- You must not be nursing a baby.

If you think that you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you will be removed from the study. The study doctor may request to have information about the pregnancy and the birth of the child. The study doctor may share this information with the sponsor and the IRB.

What benefits can I expect from being in the study?

The study contact lenses might help correct your eyesight while you are wearing them, but there is no guarantee that this study will help you. Your eyesight might not be corrected by the study contact lenses or might get worse while you are in this study. Information from this study may help researchers come up with new treatments to help others in the future.

What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

You do not have to be in this study to get help for your eyesight. The study doctor will talk to you about other things you can do for eyesight. Some other things you can do are:

- Wear eyeglasses
- Use FDA-approved soft or hard contact lenses and solutions
- Receive the control contact lenses and solutions being used in this research even if you do not participate in this research study
- Get laser or other refractive surgery
- Have no vision correction

You can talk to your primary eye care provider about your options.

You should continue to go to your regular doctor even if you join this study.

Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

If the results of this study are made public, information that identifies you will not be used.

If we find information that significantly impacts your health during any of the study procedures, the study doctor will notify you. Individual research results will not be shared with you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

Authorization to Use and Disclose Information for Research Purposes

What information may be used and given to others?
The study doctor and study staff will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual.
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
- Records about the study device.

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor, or
  - owned by the sponsor.
  - Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.
  - If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported,
- The Ohio State University units involved in managing and approving the research study including the University Research Foundation and the Office of Responsible Research Practices, and
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

When will my permission end?
There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

May I withdraw or revoke (cancel) my permission?
Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

Financial Considerations

Unicon Optical Co., Ltd. is the sponsor financially covering the costs.

Costs

There is no cost to participate. You will be responsible for transportation and parking in order to attend study visits at The College of Optometry.

The study is not meant to replace your regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

Participating in this research study may lead to additional costs to you. In some cases, it is possible that your insurance company will not pay for these costs because you are taking part in a research study.

You may have to pay the costs of diagnosing and treating a condition or injury that you or others think may be related to the study. This could happen if:

- the sponsor and/or the study doctor do not think the condition or injury is related to the study
- you have not followed the directions the study doctor or study staff gave you about the study

See the section below entitled “Research-related Injury”

Will I be paid for taking part in this study?

You will receive the following payment(s) for participating in this study:

You will be compensated for your time (away from your normal activity) and travel related costs. You will receive up to $300 for completing all study visits. The compensation schedule is as follows: Visit 1: $50; Visit 2: $50; Visit 3: $50; Visit 4: $50; Visit 5: $50 and Visit 6: $50

What happens if I am injured because I took part in this study?

OHIO STATE UNIVERSITY LIABILITY:

If you are injured as a result of your participation in this study, you may obtain immediate care at The Ohio State University Wexner Medical Center. The cost of this treatment will be charged to you or your insurance company. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study. The Ohio State University has no funding set aside for the payment of health care expenses for this study.

SPONSOR LIABILITY:

If you have been injured by the study, contact the study doctor. They will treat you or refer you for treatment. If you get hurt or sick while you are in this study, and the study doctor and the study sponsor reasonably determine your illness or injury to be a direct result of the study, the

costs of medical treatment for this illness or injury not reimbursed or covered under your medical insurance will be paid by the study sponsor.

If you have not followed the study doctor's instructions about the study, the sponsor may not pay these expenses.

Your health plan might not cover the costs of study-related injuries. To ask questions about this, talk to the study doctor or study staff.

What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subject's research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

WHO TO CONTACT

You can ask questions about the study any time. If you feel sick or have questions, concerns, or complaints you can call the study doctor at 614-292-8858 during the day. You can also call 614-292-0882 at any time.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

IRB APPROVED
AS MODIFIED
Jun 14, 2020

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Please visit the WIRB website www.wirb.com for more information about research studies and the role of a research subject.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Signing the consent form

I have read the document (or it has been read to me). I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of participant	**Signature of participant**
	_____ **AM/PM**
	Date and time

Investigator/Research Staff

I have explained the research to the participant before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	_____ **AM/PM**
	Date and time

INFORMATION AND CONSENT FORM

TITLE: Clinical Performance of Qualis Silicone Hydrogel Soft Contact Lens over 3 Months of Daily Wear

PROTOCOL NO.: AVDR 2019-05
WIRB® Protocol #20200417

SPONSOR: Unicon Optical Co., Ltd.

INVESTIGATOR: Randall Sakamoto, OD, PhD, FAAO
1441 Kapiolani
Suite 2005
Honolulu, Hawaii 96814
United States

STUDY-RELATED PHONE NUMBER(S): 808-944-9911
808-330-9256 (24 hours)

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with Ala Moana Advance Eye Clinic.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

You are being asked to participate in a research study in order to compare two types of soft contact lenses for people with nearsightedness. Researchers want to evaluate the safety and performance of a novel soft contact lens called Qualis Silicone Hydrogel. This is also referred to as the "study contact lens", meaning it is an investigational device and it is not currently approved by the United States Food and Drug Administration (FDA). The performance of the study contact lens will be compared to a currently marketed soft contact lens called Acuvue Vita. The lenses will be worn by participants for at least 5 days per week and at least 6 hours per day. Removal of the contact lenses will occur nightly before bed. The same lenses will be reused for up to one month with daily cleaning and disinfection. A new supply of contact lenses and clearing care solution will be provided at interim follow up visits. All participants will be randomly assigned into either the study contact lens or Acuvue Vita. One of two solutions for daily cleaning, disinfection and storage will also be randomly assigned. The care products to be randomly assigned in the study are Clear Care Contact Lens Solution and Biotrue Multi-Purpose Contact Lens Solution. PuriLens Plus Preservative Free Saline will also be supplied. You will have a 67% chance of being assigned to the study contact lens and a 33% chance of being assigned the control contact lens and an equal chance of being assigned to either care products.

Why is this study being done?

This study is being conducted in order to collect scientifically valid data on the safety and performance of the Qualis Silicone Hydrogel Soft Contact Lens for daily wear. The data collected will be compared to Acuvue Vita Monthly Wear Contact Lens.

How many people will take part in this study?

Up to 75 participants will enroll in this study.

What will happen if I take part in this study?

This study includes six scheduled visits and is expected to last about 3 months per subject. The study staff will tell you when to come in for your study visits. The table below shows the approximate amount of time each visit will take.

Visit	Description	≈ Duration
1	(Screening/Enrollment/Baseline/Lens Dispense) Day 0 Explanation of the study, informed consent, contact lens and medical history, comfort/vision/handling/symptoms questionnaire, standard clinical vision and eye health examination, dispense lens and educate on proper use, evaluate lens fit, schedule follow up visit	2 hours
2, 3, 4, 5	(Follow-up) Day 7, Day 14, Day 30, and Day 60 Changes to medical history, comfort/vision/handling/symptoms questionnaire, standard clinical vision and eye health examination, contact lens fit evaluation, dispense additional lens and care products (if applicable), schedule follow up visit	1.5 hours
6	(Follow-up/Study Completion) Day 91 Changes to medical history, comfort/vision/handling/symptoms questionnaire, standard clinical vision and eye health examination, contact lens fit evaluation, study completion forms	1.75 hours

STUDY PROCEDURES

If you agree to participate in this study and you sign this form, the study doctor or study staff will do the procedures listed below when you come in for study visit. If you would like more information about any procedure listed below, ask the study doctor or study staff.

Some of the study procedures might be done as part of your regular medical care even if you do not take part in this research study. However, these study visits do not take the place of your regular eye exams.

Visit 1 (Screening, Enrollment, Baseline Data Collection, Lens Dispense)

You will arrive to Visit 1 with spectacles. If you decide to be in the study, you will have the following tests done to find out if you qualify to be in this study:

- Eye exam: the study staff will test your vision in various light conditions and give you an examination of the front part of your eyes with a slit lamp (a beam of light and microscope) and other equipment. A dye normally used in eye examinations will be used to examine the front of your eye. This procedure may be performed at other visits. These are standard procedures in daily practice. You should ask the study staff to describe these procedures and the equipment used during the eye exam.

- Health and medication questions: the study staff will ask you about your background (including your age and race/ethnicity), your health, your medical history, and the medications and supplements you take. You should tell the study staff if you take any over-the-counter or prescription medications (including supplements, such as vitamins or herbs)
- Contact lens history: the study staff will ask you about the name and type of contact lens you have worn
- Study questionnaires: you will be asked to complete a questionnaire about your vision with the contact lens you have been wearing

If the study staff says you can be in the study they will:

- Provide contact lenses and contact lens solution and train you on the proper use and care for the lenses.
- Evaluate the fit of the study contact lenses.
- Schedule follow up visits.

Which contact lenses you wear may be assigned randomly (by chance), which means that neither you nor the study doctor would get to choose which contacts you wear. If you are fit with the study contact lenses during the study visits, you should wear the study contact lenses as the study staff has instructed you to wear them. If the study lenses are given to you to wear at home, the study staff will give you written instructions on how to take care of your lenses. You are the only one who should wear the study contact lenses. You should make sure that other people do not wear them.

If you have any problems using the study contact lenses or problems with your eyes during the study, you should stop using the study contact lenses and tell the study staff immediately. You may need to come in for an unscheduled visit to check on any problems you are having.

Visits 2, 3, 4, 5, and 6 (Follow-up Visits)

At the follow-up visits, the following tests will take place:

- You will have several different eye evaluations including a vision test an examination of the front part of your eyes
- You will have several contact lens evaluations
- You will be asked about your experience with the study contact lenses (how you like them, if you have had any problems with them) and complete a questionnaire.

Following the 6th and final scheduled visit, you will be asked to return your study contact lenses to the study staff. You should talk to the study doctor about your options for correcting your eyesight after the study is over. You should bring your spectacles to all study visits.

Remote Study Procedures

With consideration for the global pandemic (COVID-19), the follow-up study visit procedures listed below may be conducted remotely (via telephone or video conference) to reduce physical exposure time between you and study personnel:

- Questionnaires (vision/comfort/handling/wear time/symptoms)
- Changes in medication and health history
- Scheduling

If you are willing to participate in remote reporting it must occur on the same day of the scheduled in-person visit and must be prior to the visit with the exception of scheduling, which may occur at any time between visits. Any eligible procedure not conducted remotely prior to the visit will be conducted during the in-person visit.

Participant Responsibilities

As a participant, your responsibilities include:

- Follow the instructions you are given
- Keep your study visit appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment
- Tell the study doctor or study staff about side effects of wearing study contact lenses, doctor visits or any changes in your health
- Tell the study doctor or study staff if you believe you might be pregnant
- Keep the study contact lenses in a safe place and for your use only
- Tell the study doctor or study staff if you want to stop being in the study at any time

Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with Ala Moana Advance Eye Clinic.

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- Problems with contact lenses or lens care products could result in serious injury to the eye.[1]
- Proper use and care of your contact lenses and lens care products are essential for the safe use of these products.
- The overall risk of serious eye problems may be reduced by carefully following directions for lens care.

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- Burning, stinging, and/or itching of the eyes
- Less comfort after daily wear than when the lens was first placed on the eye
- A feeling like there is something in the eye (foreign body, scratched area)
- Reduced vision or temporary loss of vision due to peripheral infiltrates (white blood cells), peripheral corneal ulcers (inflammation of the cornea), and/or corneal erosion (defects in the corneal surface)
- Local or generalized edema (swelling)
- Corneal neovascularization (small blood vessels growing into the cornea)
- Corneal staining (defect in the corneal surface)
- Redness
- Tarsal abnormalities (bumps on the inside upper eye lid)
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- Conjunctivitis (infection or inflammation of the white part of the eye or under the eyelids)
- Excessive watering, unusual eye secretions, or redness of the eye
- Poor visual acuity
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- Sensitivity to light
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If you experience any eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems, you should immediately remove the study contact lenses and contact the study doctor. You should continue to see your regular eye care practitioner routinely as directed.

Some of these possible risks or discomforts may result in you not being able to wear contact lenses, either for a short time or ever again. You must own wearable and functional eyeglasses to correct your vision if you become unable to wear contact lenses.

The pupils of your eyes may need to be dilated. The risk is the same as in a standard dilated examination. A dilating drug standardly used by Eye Care Practitioners will be used if dilation is required. Some people may have an allergic reaction to the dilating drug. Prior to use of this drug you will be asked if you have glaucoma or any other eye condition, as well as a history of allergy to this type of drop.

A dye used to examine the front part of your eye may be used during a routine study eye examination.

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It is possible that problems and side effects of the study contact lenses that nobody knows about could happen to you, which include your eyesight getting worse. If the study doctor learns any new information about the study contact lenses while you are in the study, and it is the kind of information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

Women of Child-bearing Potential

If you are a woman, you cannot be in this study if you are pregnant or nursing a baby. If you decide to be in the study:

- You must not be pregnant.
- You must not plan to become pregnant during the study.
- You must not be nursing a baby.

If you think that you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you will be removed from the study. The study doctor may request to have information about the pregnancy and the birth of the child. The study doctor may share this information with the sponsor and the IRB.

What benefits can I expect from being in the study?

The study contact lenses might help correct your eyesight while you are wearing them, but there is no guarantee that this study will help you. Your eyesight might not be corrected by the study contact lenses or might get worse while you are in this study. Information from this study may help researchers come up with new treatments to help others in the future.

What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

You do not have to be in this study to get help for your eyesight. The study doctor will talk to you about other things you can do for eyesight. Some other things you can do are:

- Wear eyeglasses
- Use FDA-approved soft or hard contact lenses and solutions
- Receive the control contact lenses and solutions being used in this research even if you do not participate in this research study
- Get laser or other refractive surgery
- Have no vision correction

You can talk to your primary eye care provider about your options.

You should continue to go to your regular doctor even if you join this study.

Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;

- U.S. Food and Drug Administration;
- The Institutional Review Board (IRB)
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized staff not involved in the study may be aware that you are participating in a research study and have access to your information.

If the results of this study are made public, information that identifies you will not be used.

If we find information that significantly impacts your health during any of the study procedures, the study doctor will notify you. Individual research results will not be shared with you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

FINANCIAL CONSIDERATIONS

Unicon Optical Co., Ltd. is the sponsor financially covering the costs.

Costs

There is no cost to participate. You will be responsible for transportation and parking in order to attend study visits.

The study is not meant to replace your regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

You may have to pay the costs of diagnosing and treating a condition or injury that you

or others think may be related to the study. This could happen if:

- the sponsor and/or the study doctor do not think the condition or injury is related to the study
- you have not followed the directions the study doctor or study staff gave you about the study

See the section below entitled “Research-related Injury”

Will I be paid for taking part in this study?

You will be compensated for your time (away from your normal activity) and travel related costs. You will receive up to $300 for completing all study visits. The compensation schedule is as follows: Visit 1: $50; Visit 2: $50; Visit 3: $50; Visit 4: $50; Visit 5: $50 and Visit 6: $50

What happens if I am injured because I took part in this study?

SPONSOR LIABILITY:

If you have been injured by the study, contact the study doctor. They will treat you or refer you for treatment. If you get hurt or sick while you are in this study, and the study doctor and the study sponsor reasonably determine your illness or injury to be a direct result of the study, the costs of medical treatment for this illness or injury not reimbursed or covered under your medical insurance will be paid by the study sponsor.

If you have not followed the study doctor’s instructions about the study, the sponsor may not pay these expenses.

Your health plan might not cover the costs of study-related injuries. To ask questions about this, talk to the study doctor or study staff.

What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

WHO TO CONTACT

You can ask questions about the study any time. If you feel sick or have questions, concerns, or complaints you can call the study doctor at the numbers listed on the first page of this consent form.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

The IRB is a group of people who perform independent review of research.

The IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact the IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Please visit the IRB website www.wirb.com for more information about research studies and the role of a research subject.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	Signature of participant
	_____AM/PM Date and time

Investigator/Research Staff

I have explained the research to the participant before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant.

Printed name of person obtaining consent	Signature of person obtaining consent
	_____AM/PM Date and time