



**School of  
Optometry and Vision  
Science**

**Faculty of Science**

University of Waterloo    519-888-4567, ext. 33085  
200 University Avenue West    Fax 519-746-5977  
Waterloo, Ontario, Canada    N2L 3G1  
optometry@uwaterloo.ca  
www.optometry.uwaterloo.ca

# **Protease and cytokine composition in post lens tear reservoir of scleral lenses for Keratoconic eyes**

## **Information and Consent Letter**

# **INFORMATION RELATED TO YOUR PARTICIPATION**

**Please note that your participation in this study does not replace the need  
for regular eye examinations.**

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Attending regular eye examinations as recommended by your eye care professional (at least every two years) is essential to ensure that your eyes are healthy. Eye conditions such as glaucoma, diabetes, cataracts and macular disease can only be detected during a full eye examination. Only the front portion of the eye – and, more specifically, only conditions associated with contact lens wear – are assessed during the initial screening visit and all subsequent visits needed for participation in this study. Visits as part of this study do not replace any scheduled visits due with your eye care practitioner. After completion of this study you should resume your eye care with your usual eye care practitioner.

## 1. What is this study about?

The purpose of the study is to evaluate changes in chemicals in the tear film while wearing large gas permeable lenses that is scleral lenses and to determine how these lenses impact the health of the front part of the eye. The contact lenses used in this study are licensed by Health Canada and marketed in Canada. This study is part of Dr. Debby Yeung's, one of the investigator's, Master thesis project.

## Who may participate in this study?

This study will involve up to twenty participants at this clinic location. To be eligible for this study, you must be at least 18 years old with a condition called keratoconus. Keratoconus causes a progressive distortion of the cornea and require specialty contact lenses to correct the vision. Your vision and ocular health eligibility will be determined at a screening visit.

You may be eligible for inclusion in the study if you:

- Have had an eye examination in the last two years.
- Are at least 18 years of age and have full legal capacity to volunteer.
- Have read and understood the information consent letter.
- Are willing and able to follow instructions and maintain the appointment schedule.
- Have been diagnosed with keratoconus

You may be excluded from the study if you:

- Are using any topical medication (including medications applied directly to the eye, or eye drops) that in the opinion of the investigator may affect the study measures.
- Have any ocular pathology or anomaly that would affect the wearing of contact lenses.
- Have a history of ocular surgeries, including refractive surgery.
- Are presently participating in any other type of eye related clinical or research study.
- Have any known allergies or sensitivities to the diagnostic pharmaceuticals or study products used in this study, such as fluorescein.

## 2. What products will be used in this study?

The lenses used in this study are rigid gas permeable lenses, namely ZenLens™ manufactured by Alden Optical Laboratory. The lens designs are currently approved by Health Canada and are marketed in Canada.

You will be fitted with two designs of ZenLens™ lenses and you will wear each pair of lenses during the day for about two weeks. The order in which you will be asked to wear the study lenses will be determined randomly (by chance) – similar to the chance of throwing heads or tails with the toss of a coin.

Regardless of the study schedule, you should cease use of the study products and contact Dr. Debby Yeung or Dr. Luigina Sorbara by phone at (416) 624-7167 or (519) 888-4567 (extension 33085), respectively, if you feel any discomfort or pain.

## 3. What is the time commitment for this study?

This study has a total of six visits, over 5 study days: a screening visit, and a lens fitting visit, two lens delivery visits, and two follow-up visits. The total time commitment for all study visits is approximately

6 hours. However, the total study visit time commitment may be different for you, as the needed visit time will depend on how easily you can adapt to the lenses.

**Study visit 1** (1 hour  $\pm$  0.5 hours) – Screening and baseline measurement visit. Your eligibility for this study will be determined and baseline measurements, including a baseline tear sample collection, will be obtained **after you remove your contact lenses**.

**Study visit 2** (1 hour  $\pm$  0.5 hours) – Lens fitting. Two sets of lenses will be designed and ordered for you based on the baseline measurements. You will be instructed on how to insert, remove, care for and handle the lenses properly.

**Study visit 3** (1 hour  $\pm$  0.5 hours) – You will try one of the two pair of lenses. The lens fit will be evaluated and measurements will be obtained with the lenses. If the lens fit is appropriate, you will be sent home with the lenses to wear.

**Study visit 4** (1 hour  $\pm$  0.5 hours) – After wearing the lenses during the day only for approximately two weeks, the lens fit will be evaluated again. A sample of your tears will be collected.

*This visit will be followed by a washout period of at least 72 hours.*

**Study visit 5** (1 hour  $\pm$  0.5 hours) – You will try the second pair of lenses. The lens fit will be evaluated and measurements will be obtained with the lenses. If the lens fit is appropriate, you will be sent home with the lenses to wear.

**Study visit 6** (1 hour  $\pm$  0.5 hours) – After wearing the lenses during the day only for approximately two weeks, the lens fit will be evaluated again. A sample of your tears will be collected.

#### **4. What is expected of me as a participant?**

The following procedures will be performed at your study visits.

##### **Visit 1 - Screening/Baseline**

You may attend this visit wearing your own contact lenses.

**Health and medication questions:** You will be asked about your background (including your age), your health, your medical history, and the medications and supplements you may take.

**Slit-lamp examination (slit lamp):** You will be asked to sit at an instrument that uses a bright light beam and microscope to examine both your eyes and the contact lenses. The investigator may instill a drop of fluorescein in your eyes; fluorescein is a yellow dye that will reveal any abrasions on the front of your eye (cornea). This dye will dissipate within 10 minutes, though the investigator will rinse your eyes with sterile saline if you intend to reinsert your contact lenses. Digital images, photographs/ videos of your eyes may be taken. Any digital images, photographs/ videos will be labeled with an identification number and will not show any identifying features.

**Anterior Segment Measurement (Visante optical coherence tomographer):** You will be asked to sit at an instrument that uses a bright red light beam and a microscope to obtain measurements of the front part of the eye (corneal sagittal height) without touching your eye. You will be asked to look at a light inside the instrument while the investigator performs the measurements. Digital images, photographs/videos of your eyes may be taken. Any digital images, photographs/ videos will be labelled with an identification number and will not show any identifying features.

**Automated refraction:** You will be asked to focus on a target while seated at an instrument that measures your approximate spectacle prescription.

**Corneal Topography:** You will be asked to hold your eyes open while looking into a device with illuminated rings. The illuminated rings are reflected off the tear film and the investigator looks for when

disturbances in those rings occur. The instrument measures the curvature of your cornea (the front of the eye).

**Vision test:** You will be asked to read and/or observe standardized letter charts from a standard distance.

**Non-Invasive Tear Film Break-Up Time and Redness measurement (Keratograph):** You will be asked to hold your eyes open while looking into a device with illuminated rings. The illuminated rings are reflected off the tear film and the investigator looks for when disturbances in those rings occur. This procedure will be performed with your own contact lenses and without contact lenses. The redness of the white part of your eye will also be imaged with this instrument.

**Tear Sample Collection:** The researcher will collect a small amount of your tears with a micro-capillary tube. No instrument will contact the surface of your eye.

### **Visit 2 – Lens Fitting**

**This visit typically takes place immediately after Visit 1.** You will be asked to attend this visit wearing your spectacles and the following procedures will be performed:

**Lens insertion:** You will be fitted with the study lenses. The investigator will choose a large-diameter gas permeable contact lenses for you based on measurements obtained at the screening visit.

**Lens examination (slit lamp):** You will be asked to sit at an instrument that uses a light and microscope to examine both your eye and your contact lens. A yellow dye (fluorescein) may be used for better visualization of the lens fit and surface characteristics. Digital images, photographs/videos of your eye/lens may be taken. Any digital images, photographs/ videos will be labeled with an identification number and will not show any identifying features.

**Non-Invasive Tear Film Break-Up Time and Redness measurement (Keratograph):** You will be asked to hold your eyes open while looking into a device with illuminated rings. The illuminated rings are reflected off the tear film and the investigator looks for when disturbances in those rings occur. This procedure will be performed while wearing the study lenses. The redness of the white part of your eye will also be imaged with this instrument.

**Automated refraction:** You will be asked to focus on a target while seated at an instrument that measures your approximate spectacle prescription while wearing the study lens.

**Vision test:** You will be asked to read a computer letter chart from a standard distance while wearing the study lenses.

**The time between Visits 2 and 3 is usually 1-2 weeks, depending on the shipping time for the lenses.**

### **Visit 3 – Lens Delivery of First Study Lens**

**Lens insertion:** You will try on the first set of study lenses. The type which you will be wearing will be assigned randomly (by chance, similar to the chance of throwing heads or tails with the toss of a coin), which means that neither you nor the study investigator will choose which set of lenses you wear first.

**Lens examination (slit lamp):** You will be asked to sit at an instrument that uses a light and microscope to examine both your eye and your contact lens. A yellow dye (fluorescein) may be used for better visualization of the lens fit and surface characteristics. Digital images, photographs/videos of your eye/lens may be taken. Any digital images, photographs/ videos will be labeled with an identification number and will not show any identifying features.

**Vision test:** You will be asked to read a computer letter chart from a standard distance while wearing the study lenses.

**Non-Invasive Tear Film Break-Up Time and Redness measurement (Keratograph):** You will be asked to hold your eyes open while looking into a device with illuminated rings. The illuminated rings are reflected off the tear film and the investigator looks for when disturbances in those rings occur. This procedure will be performed while wearing the study lenses. The redness of the white part of your eye will also be imaged with this instrument.

**Tear Sample Collection:** The researcher will collect a small amount of your tears with a micro-capillary tube. No instrument will contact the surface of your eye.

**Ocular Symptom Questionnaire:** You will be asked to rate your ocular symptoms with the study lens, including comfort, dryness and vision.

#### **Visit 4 – Follow-up of First Study Lens**

This visit will take place approximately two weeks after Visit 3, after having worn the lenses during the day only for two weeks, **for a maximum of 6-8 hours of daily wear**. The following procedures will be conducted:

**Lens examination (slit lamp):** You will be asked to sit at an instrument that uses a light and microscope to examine both your eye and your contact lens. A yellow dye (fluorescein) may be used for better visualization of the lens fit and surface characteristics. Digital images, photographs and/or video recordings of your eyes may be taken. Any digital images, photographs/ videos will be labeled with an identification number and will not show any identifying features.

**Slit-lamp examination (slit lamp):** You will be asked to sit at an instrument that uses a bright light beam and microscope to examine both your eyes and the contact lenses. The investigator may instill a drop of fluorescein in your eyes; fluorescein is a yellow dye that will reveal any abrasions on the front of your eye (cornea). This dye will dissipate within 10 minutes, though the investigator will rinse your eyes with sterile saline if you intend to reinsert your contact lenses. Digital images, photographs/ videos of your eyes may be taken. Any digital images, photographs/ videos will be labeled with an identification number and will not show any identifying features.

**Non-Invasive Tear Film Break-Up Time and Redness measurement (Keratograph):** You will be asked to hold your eyes open while looking into a device with illuminated rings. The illuminated rings are reflected off the tear film and the investigator looks for when disturbances in those rings occur. This procedure will be performed while wearing the study lenses. The redness of the white part of your eye will also be imaged with this instrument.

**Ocular Symptom Questionnaire:** You will be asked to rate your ocular symptoms with the study lens, including comfort, dryness and vision.

You will be asked to remove the study lens.

**Tear Sample Collection:** The researcher will collect a small amount of your tears with a micro-capillary tube. No instrument will contact the surface of your eye.

A period of at least 72 hours will be applied between **Visits 4 and 5**, during which you will be asked to wear your spectacles.

### **Visit 5 - Lens Delivery of Second Study Lens**

This visit will take place at least 24 hours after Visit 4. You will be asked to attend this visit wearing your spectacles.

The same procedures as listed under Visit 3 will be performed. You will be fitted with your second study lens.

### **Visit 6 – Follow-up of Second Study Lens**

This visit will take place approximately two weeks after Visit 5, after having worn the lenses during the day only for one week.

The same procedures as listed under Visit 6 will be performed. At the completion of this visit, you will exit the study.

## **5. Are any risks associated with this study?**

Study lenses can be worn on a daily wear or extended wear basis. In this study the lenses will be worn on a daily wear basis, from 6-8 hours daily. The contact lenses used are approved by Health Canada and are commercially available.

When contact lenses are worn there is a small risk of an adverse event compared to not wearing contact lenses.

Complications that may occur during the wearing of contact lenses include discomfort, dryness, aching or itching eyes, excessive tearing, discharge, hyperemia and variable or blurred vision. More serious risks may include photophobia, iritis, corneal edema or eye infection.

Although contact lens-related infections are very infrequent, the possibility does exist. The occurrence rate of incurring a bacterial infection for patients that wear rigid gas permeable lenses is approximately two/10,000 per year.

A dye (fluorescein) normally used for eye examinations, is being used in this study. Although rare, it is possible that you may have an allergic reaction to the dye. If you have a known allergy to fluorescein, please advise the investigator.

If you experience any pain or discomfort during lens wear, any of the symptoms described above, or there is any health concern or a case of emergency, please contact Dr. Debby Yeung or Dr. Luigina Sorbara at (416) 624-7167 or (519) 888-4567 extension 33085, respectively. **If either of the researchers cannot be reached, please go to the emergency department at St. Mary's Hospital.**

## **6. What are the benefits of participation?**

This study may provide an alternative mode of correction for some people who experience distortion in their vision caused by keratoconus. Also, this study may benefit optometric practitioners by expanding their knowledge about evaluating the comfort and fit of large diameter rigid gas permeable lenses. This knowledge will help them to choose the appropriate lenses giving the best fit and visual acuity, along with comfort.

## **7. Is there remuneration for participation?**

In appreciation for your involvement in the study, you will receive \$20 for each visit, up to \$120 upon to the completion of the study. The amount received is taxable. It is your responsibility to report this amount for income tax purposes. **Parking at the clinic's lot will be reimbursed.**



## 8. Can I withdraw from the study?

You are free to decide whether or not to participate in this study. Your decision will not influence the eye care available to you either at the School of Optometry or with your own optometrist. You have the right to withdraw from the study at any time without penalty, by advising the study investigator. You may be removed from the study if you do not comply with the study protocol or the investigator believes it to be in your best interest. **Your participation may be discontinued and/or the study could be terminated the University of Waterloo's Office of Research Ethics at any time.** In the event that you are discontinued from the study, you will receive remuneration for any study visits completed.

## 9. Confidentiality and security of data

All information you provide as a participant, any data we collect as result of your participation, including your private health information, plus records of your participation in this study will be held confidential except as disclosure is required by local, state, federal laws, provincial law, and any other regulations, or as described in this informed consent document. You will be assigned an identification number, which will appear on all study records in place of your name. **Any data collected in this investigation may be submitted for publication or used in meetings/ presentations.** Neither your name nor information disclosing your identity will be released or published.

For the purpose of monitoring the research, your study records may be inspected at the School of Optometry and Vision Science, Contact Lens Clinic by the Office of Research Ethics at the University of Waterloo, and by regulatory authorities in Canada, namely Health Canada; however, no records containing identifiable/personal information will be permitted to leave the custody of the School of Optometry and Vision Science, Contact Lens Clinic. These reviews are done to check on the quality of the study, to check the information collected in this study, to check how the study is conducted, to monitor participants' safety, or for other uses allowed by law.

Digital images, photographs and/or video recordings of your eyes taken for documenting and explaining the information collected in the study will not show any identifying facial features and will be labeled with an identification number rather than your name. These photographs and/or video recordings may be shown to other researchers within the Contact Lens Clinic, the School of Optometry, and others within their company to explain the data, and may be shown publicly (e.g. presentations or publications).

Records and data from this study will be retained for a minimum of 25 years. Paper copies of study data are safely held in a secure storage cabinet in a locked office at the School of Optometry and Vision Science at the University of Waterloo and will be only available to personnel involved in the data collection of this study. The electronic research data will be encrypted as per Guidelines laid out by UW Information and Systems Technology and stored on a password protected server held in a locked office at the School of Optometry and Vision Science. The image acquired, with all identifying information removed, will be kept on a secure password protected server stored in a locked office at the School of Optometry and Vision Science. Image data will be saved using a coded file name associated with each participant, and the list of the participants' names and corresponding numbers will be stored in a separate file at UW.

Access to electronic data, images, photographs, and video is limited to authorized study personnel.

Records will be confidentially disposed of in accordance with the guidelines laid out by the University of Waterloo. For more information regarding the University of Waterloo's policies on information security you can visit the following website: <https://uwaterloo.ca/secretariat-general-counsel/policies-procedures-guidelines/policy-8>.

## **10. Other important issues**

You will be informed of any new findings related to the study that could influence your decision about continuing to participate in the study. If you have any questions regarding the study procedures, please contact the study investigator(s).

## **11. Rights as participant**

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available at no cost to you and will be covered by the study coordinators.

## **12. Conflict of interest**

The study has no sponsor. However, the investigators may also have received funding from the manufacturers of other products used in this study. This funding is primarily directed towards supporting research and may also occasionally be used to fund professional development activities, for example attending conferences.

## **13. Research-related injury**

If you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigators and/or institutions from their legal and professional responsibilities. If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

If you have any urgent medical problem, injury or illness that is related to your participation in this study or have any questions, concerns or would like to speak to the study team for any reason please call:

Day Emergency Number:

- Dr. Debby Yeung at phone: (416) 624-7167
- Dr. Luigina Sorbara at phone (519) 888-4567 (extension 33085)

If either of the researchers cannot be reached, please go to the emergency department at St. Mary's Hospital.

## **14. Questions or concerns about participation in the study**

This project has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee. If you have any ethical concerns about your participation in this study, contact Dr. Maureen Nummelin, Chief Ethics Officer, Office of Research Ethics at 519-888-4567 ext. 36005 or by email at [maureen.nummelin@uwaterloo.ca](mailto:maureen.nummelin@uwaterloo.ca).



## Declaration of Informed Consent

I have read the above description prior to deciding to participate in this study. I have had an opportunity to ask questions and have received acceptable answers.

I am aware that this study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics committee and that if I have any ethical concerns or questions about my participation in this study, I may contact Dr Maureen Nummelin, Chief Ethics Officer, Office of Research Ethics at 519 – 888 - 4567 ext. 36005.

I am aware that any data collected during the course of the study will be secured in accordance with University of Waterloo policies.

I am aware that I may withdraw from the study at any time without affecting my relationship with the School of Optometry. I am aware that the investigator reserves the right to discontinue my participation from the study at any time, either in regards to the research or the health of my eyes.

I am aware that my participation in this study does not replace the need for regular eye examinations, and that attending regular eye examinations is essential to ensure that my eyes are healthy.

I am aware that my participation in this study is voluntary, but that following study procedures and attending scheduled session is important to the success of the research. I am aware that the study investigator(s) would appreciate notification if I am unable to attend a scheduled session, so that it can be rescheduled promptly.

I am aware that I need to report any adverse events, changes to my health or medication throughout the study to the study investigators.

I am aware that videos or photographs of my eyes may be taken for educational purposes which may be used in medical or scientific books, magazines or journals.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study. I also consent to the collection, use and disclosure of my personal health information and study data from this study. I acknowledge that I have received a copy of this information and consent form. I am aware that by signing this form I do not waive my legal rights.

\_\_\_\_\_  
Signature of participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of participant

\_\_\_\_\_  
Signature of person explaining consent

\_\_\_\_\_  
Date