

Investigation of zonular insufficiency using a novel device

QUT Ethics Approval Number 5741

Research team

Principal Researcher:	Prof Michael Collins	Principal Investigator
Associate Researchers:	Dr Alyra Shaw	Associate Investigator
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	Dr Hosein Yazdi	Research Associate
	Mr Brett Davis	Research Associate
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Why is the study being conducted?

The purpose of this project is to collect clinical data with a new instrument, the ZoFIA device, used to capture light reflections from the eye from which movement (wobble) of the eye's lens can be calculated. The research team is looking for healthy adult participants aged over 50 years with a variety of eye conditions including zonular insufficiency (weakness of the fibres supporting the lens inside the eye) and cataract (cloudiness of the lens inside the eye). The research project is funded by Cylite Pty Ltd (an Australian company based in Melbourne).

What does participation involve?

Participation in this project will first involve a brief eye examination, where you will undergo standard tests like those you receive during a typical eye examination with your optometrist. This will help the investigators determine whether your eyes are suitable for inclusion in the project.

Three measurements will then be taken with the ZoFIA device. To have these measurements taken, you will simply need to place your chin on the instrument's chin rest and look at a dim light inside the instrument. Proper alignment of your face/eye with each device may take 1-2 minutes, and then capture of the actual measurement may take another minute. These measurements are non-invasive, don't touch the eyes, and should not cause you any discomfort.

It is expected that your participation in the project, including the pre-measurement screening examination and the measurements on the ZoFIA instrument will take approximately 1 hour.

Your participation in this research project is entirely voluntary. If you do agree to participate you can withdraw from the research project without comment or penalty. You can withdraw anytime during the study. Your decision to participate or not participate will in no way impact upon your current or future relationship with the research team, the School of Optometry and Vision Science, or QUT.

What are the possible benefits for me if I take part?

It is expected that this project will not benefit you directly. During the study, the investigator will share with you any information regarding the measurements and images of your eyes that may be of interest to you.

To compensate you for your contribution of time should you choose to participate, the research team will provide you with gift cards (Coles/Myer) to the value of \$40.00 per hour (\$10 per 15 minutes) for participating in the study as compensation for your time. The same rate of compensation will be used for participation in screening visits, even if you are ineligible for the study. When available, free parking will be provided adjacent to the research laboratory or you will be reimbursed for your out-of-pocket travel expenses associated with the visit to the O Block, KG laboratories (parking fees or public transport fees).

At the conclusion of the entire study, you will be provided with a summary of the study outcomes.

What are the possible risks for me if I take part?

There are minimal risks associated with your participation in this project.

It is extremely unlikely that the light of the instrument could exceed the amount, which is considered safe for the eye, as the instrument has been designed with fixed illumination intensity which cannot be altered. Thorough testing of the instrument light sources ensured that it the Maximum Permissible Exposure to the eye is in accordance with the safety standard DIN EN ISO 15004-2:2007-06: Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection.

Other less serious risks are the potential for eyestrain following exposure to the light sources incorporated in the clinical instruments, however these all use visible or infrared lights which are at intensities which are far below those that could cause a hazard, and less than one would experience outdoors on a clear day.

During screening, fluorescein (a yellow dye routinely used in optometric practice) will be placed into the eye and used to assess the corneal (front surface of the eye) health. There is a minimal risk of allergic reaction, which will be further minimized by asking if you have ever had eye drops as part of an eye test in the past.

Standard Operating Procedures are in place in the laboratory for addressing Covid-19 safety of the participants and researchers.

During assessment of the eye, if any findings indicate a serious underlying condition, you will be immediately discontinued from the study and provided with appropriate management by the Chief Investigator and research team, that includes registered, therapeutically endorsed optometrists. If required a referral letter will be provided for the QUT Optometry Clinic or an optometrist of your choice.

It should be noted that if you do agree to participate you can withdraw from participation at any time during the project without comment or penalty.

What about privacy and confidentiality?

All data will be coded (i.e. it will be possible to re-identify you). A re-identifying code stored separately to personal information and will only be accessible to the research team.

Any personal information that could potentially identify you (name, initials, date of birth, ethnicity) will only be accessible to the research team. Any personal information that could potentially identify you will be removed or changed before files are shared with the study sponsor. The measurement files (including images of eye structures and their measurements) saved from each instrument will be transferred to the sponsor and will be coded only with a four-digit code (2 letters and 2 numbers).

Any data collected as part of this research project will be stored securely as per QUT's Management of research data policy. Data will be stored for a minimum of 15 years and can be disclosed if it is to protect you or others from harm, if specifically required by law, or if a regulatory or monitoring body such as the ethics committee requests it.

The research project is funded by Cylite Pty Ltd (an Australian company based in Melbourne), and they will receive the data collected in this study, but they will not have access to personally identifying information about you that may be obtained during the research project.

How do I give my consent to participate?

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

What if I have questions about the research project?

If you have any questions or require further information please contact one of the listed researchers:

Catherine Foster	c.foster@qut.edu.au	07 3138 5731
Alyra Shaw	aj.shaw@qut.edu.au	07 3138 8285

What if I have a concern or complaint regarding the conduct of the research project?

QUT is committed to research integrity and the ethical conduct of research projects. If you wish to discuss the study with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the QUT Research Ethics Advisory Team on 07 3138 5123 or email humanethics@qut.edu.au.

Thank you for helping with this research project. Please keep this sheet for your information.