PARTICIPATE IN RESEARCH

Information for Prospective Participants

Visual performance with customised scleral contact lens in keratoconus

Research team

Principal Researcher: David Atchison, Professor, Optometry and Vision Sciences

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What is the purpose of the research?

The purpose of this research is to investigate how customising the front surface design of the scleral contact lenses influence the aberrations of the eye and visual performance following a short period of wear in keratoconus.

Keratoconus is a condition where the clear, dome-shaped front part of the eye (the cornea) becomes thin and bulges into a cone shape. This change in the shape of the cornea makes it harder for the eye to focus properly, causing blurry or distorted vision (aberrations).

Aberrations are imperfections in the way the eye focuses light. These imperfections can cause blurry, distorted, or unclear vision. Ocular aberrations can be due to irregularities in different parts of the eye, such as the cornea with keratoconus.

Scleral contact lenses are large-diameter special contact lenses made of rigid plastic material that sit on the white part of the eye (the sclera). They create a smooth and regular surface over the cornea, which can help improve vision in individuals with keratoconus. Because they are bigger, they are more comfortable and stay in place better than regular contact lenses.

Are you looking for people like me?

The research team is inviting individuals between the ages of 18 and 40 years to participate in this research project that requires two groups of participants: (1) individuals with healthy eyes and normal vision with or without spectacles/soft contact lenses (non-keratoconus), and (2) individuals with keratoconus.

The suitability for your participation will be determined through a case history and a screening eye examination.

What will you ask me to do?

You will be required to attend the Ophthalmic and Visual Optics Research Laboratories (Room no. Q503A and Q504) at Q-block, QUT Kelvin Grove Campus. Complimentary reserved parking will be provided at the campus premises. You will also be required to pause wearing your contact lens (if any) for at least 24 hours before visiting the laboratories to participate in this research project.

At visit 1, all participants will undergo a screening for suitability for participation (~30 minutes), and the baseline ocular measurements (~1 hour). If you are identified to have keratoconus, a trial scleral contact lens will be fitted into your right eye to determine the required lens parameters such that the lens would not touch the sensitive front part of your eye (cornea) (~30 minutes). The trial lens will be removed from your eye once the lens parameters are finalised.

At visit 2, only the keratoconus participants will be called to fit the customised spherical and aspherical scleral contact lenses into the right eye, and the tests will be repeated that will take ~4 hours in total. The fellow eye (left eye) without a contact lens will be occluded with an opaque eye patch to avoid potential visual imbalance. You will be given a rest break of 10 minutes in between the lens fit. At the end, you will be asked to fill out the scleral lens satisfaction questionnaire and the scleral lens discomfort questionnaire.

During the measurements, you will be required to look towards a fixation target inside the instrument for most of the tests, and outside the instrument for a few other tests. All procedures and tests that will be done before and after fitting contact lenses are completely safe and do not involve any touching or contact with your eyes. The lenses and eye patch will be removed from your eyes once all required ocular measurements have been obtained.

Are there any risks for me in taking part?

The research team does not believe there are any risks beyond the normal risks of an eye examination and a contact lens fitting. However, the likelihood of these risks in this research is extremely low given that (1) all participants will be initially screened for their suitability for participation, (2) hand hygiene, lens hygiene, and infection control protocols will be strictly followed, (3) all measurements will use standard clinical instruments that pose no risk to participants, and (4) appropriate breaks will be provided in between the eye tests and lens wear.

You can drive immediately after the lenses and eye patches are removed.

You will receive advice on your eye health and any necessary eye care including follow-up as a consequence of the study will be provided at no cost at the QUT Optometry Clinic.

It should also be noted that if you do agree to participate, you can withdraw from participation in this research project without a comment or a penalty at any time via verbal discussion with the researchers or via email.

Are there any benefits for me in taking part?

It is expected that this research project will not benefit you directly. However, it may benefit the scientific community by providing insights into understanding of how scleral contact lens parameters influence central and peripheral aberrations. The outcomes of the study will help clinicians determine what asphericity should be put on the front surface of scleral lenses to minimise aberrations. This would be beneficial in improving the visual performance of patients with keratoconus.

During the study, any information regarding the outcome of measurements of your eyes that the investigator feels may be of particular interest to you will be shared.

Upon request, a summary of the research outcomes will be provided to you via email after the completion of the study.

Will I be compensated for my time?

We would very much appreciate your participation in this research. If you are included into the study, the research team will reimburse you with a gift card of $50 per visit (total of $100 for two visits) upon the completion of data collection to contribute toward any out-of-pocket expenses incurred during your involvement in this research (e.g. travel costs) as a token of appreciation for your time and contribution to the study.

I am interested – what should I do next?

If you are interested in participating in this study, for details of the next step, please contact one of the listed researchers:

Mr. Satish Gupta	**satishkumar.gupta@hdr.qut.edu.au**	**07 3138 6161 or 0450 669 232**
Prof. David Atchison	**d.atchison@qut.edu.au**	**07 3138 6152**
Prof. Stephen Vincent	**sj.vincent@qut.edu.au**	**07 3138 0415**
Assoc. Prof. Andrew Carkeet	**a.carkeet@qut.edu.au**	**07 3138 5703**

Study site: QUT Q Block – IHBI, 60 Musk Avenue, Kelvin Grove, Brisbane, QLD – 4059, AUSTRALIA

Alternatively, please scan the following QR-code and fill in the given form to express your interest.

You will be provided with further information to ensure that your decision and consent to participate is fully informed.

Thank You!

QUT Ethics Approval Number: 8695