PARTICIPANT INFORMATION SHEET

Project Title: Comparison of non-invasive instruments for tear film evaluation

Researcher(s): Mr Isaac Samuels, Ms Catherine Shon, Dr Alex Müntz, Professor Jennifer P. Craig

Researcher Introduction and Project Background:
Thank you for taking the time to read this information sheet. My name is Isaac Samuels, a 5th year medical student currently studying at the University of Auckland. I am undertaking this research project, along with colleagues Catherine Shon (optometrist) and Dr Alex Muntz (senior clinical research fellow) under the supervision of Professor Jennifer Craig who is a New Zealand registered therapeutic optometrist and head of the Ocular Surface Laboratory in the Department of Ophthalmology. This information sheet covers many study details but please feel free to contact us if you have any further questions. You are encouraged to share and discuss this information sheet with whānau, before deciding to participate in this study. This study will be conducted within the Eye Clinic, University of Auckland Grafton Campus. We have colleagues at Universities in Canada and the UK who are conducting the same project in their respective countries.

Dry eye disease is a common eye disorder. Patients typically experience gritty, irritated, sometimes watery eyes and poor vision. The diagnosis of dry eye disease is complicated, requiring a multitude of tests to diagnose, establish severity and sub-classify disease type in order to apply appropriate management for the affected individual.

Clinicians use a variety of devices to help them provide good eye care to patients. The MYAH (Topcon) is a device that has recently become available in New Zealand for helping clinicians diagnose dry eye. In this study, we aim to compare it to the more established Keratograph 5M (Oculus, Germany). It is important for us, as eye care practitioners, to know how accurately the newer device can diagnose and sub-classify dry eye disease compared to the existing method.

Study Description:
Participation in the study will involve using non-invasive devices to image your tears and ocular surface. If you respond to let us know you are interested in participating, you will be scheduled to attend a single study visit for clinical testing (lasting up to 1 hour in total) at the Grafton Eye Clinic. A small number of participants may be invited for a second visit to repeat the non-invasive tests, to allow us to test the instrument repeatability. If you’re interested in returning for a repeat clinical assessment, please advise the investigator.
Our team is committed to establishing strong partnerships which support Te Tiriti o Waitangi and an increase in positive health outcomes for all New Zealand. Eye health services are an area of health that requires greater access for Māori, and in addressing this, the current project is incorporating and applying methods of engagement to increase participation from communities which have historically been underrepresented. Collaboration and consultation with individuals and organisations to support Māori health outcomes in this area of research are integral to our work.

**Project Procedures:**
The study procedures involve noting symptoms and risk factors for dry eye disease, and assessing your tear film and ocular surface in a minimally invasive manner (non-contact wherever possible) using tests that are routinely used in clinical practice. As such, the study poses minimal risk of harm.

In this study we will:
1. Grade your ocular comfort, risk factors for dry eye, and dry eye symptoms (if any), using a brief, validated, dry eye questionnaire (taking approximately 5-10 minutes to complete).
2. Observe and grade various features of your eye’s surface using slit lamp biomicroscopy, which is used widely in eye care practices to assess eye health. This is performed with and without clinical dyes that are routinely used to highlight any issues. These are not expected to sting when applied.
3. Test how salty your tears are using a clinical osmometer - this might feel ticklish on your eyelashes but it doesn’t make direct contact with the surface of your eye.
4. Examine the tear film and the eye’s surface with two widely available clinical instruments specifically marketed for this purpose - the Topcon MYAH, and the Oculus Keratograph 5M.

**Possible Benefits:**
In taking part in this study, you will receive a thorough ocular surface review free of charge and can be provided with feedback about your ocular surface condition. Your contribution, together with those of others, will help us understand the clinical accuracy of the various instruments available in different optometry practices for diagnosing dry eye disease. You will receive a koha of $20 MTA voucher (that can be used to buy fuel, food or any other service station product) as a token of appreciation for your time in attending the clinical visit.

**How the Data will be Used:**
Deidentified data collected at three independent sites across the world by collaborating researchers (the University of Waterloo in Canada, Aston University in the UK and here, at the University of Auckland) will be collated for analysis. No identifiable information will be shared and you will not be individually identifiable in any report from the study. Topcon, the study funders, will receive a report describing the final outcomes, but not the raw data. They have no influence over how the study is designed, conducted, analysed, interpreted or reported. The intended outcome of this work is a peer-reviewed scientific publication, and the outcomes which are important to eye care clinicians may be presented at national and international conferences.

**Participation:**
Participation in this study is voluntary which means you are under no obligation to take part. Neither your refusal nor agreement to take part will affect the clinical care you receive, from the researchers or any other clinicians, today or in the future. If you are a patient of the Eye Clinic, you may contact the Clinic Director should you feel that this assurance has not been met. Similarly, if you are a student at the University of Auckland, your decision to participate or not participate will not influence your academic progress in any way, and nor will it impact on your employment status as a staff member. As a student or staff member, you may contact your HoD should you feel that this assurance has not been met.
Eligibility:
There are a few reasons you might not be suitable for this project. These include:

- If you are not willing or able to refrain from using eye drops, other dry eye treatments or contact lenses for at least 24 hours before you attend the study visit.
- The history or presence of any ocular disorder or condition in either eye that would likely interfere with the interpretation of the study results.

Incidental Findings:
Any abnormalities noted incidentally during the examination of your eye will be discussed with you and you will be offered advice about management and/or referral consistent with normal clinical care by registered health practitioners. If you do not wish to be advised of incidental findings, you will not be eligible to take part.

Data Storage/Retention/Destruction:
Clinical data (paper copies) and consent forms will be stored in a secure cabinet at the University of Auckland for six years before being securely destroyed. Electronic data will be de-identified immediately following collection and stored indefinitely on the University of Auckland Research drive and subsequent collated with the de-identified data from the other sites in Canada and the UK.

Right to Withdraw from Participation:
If you change your mind about participating, you have the right to withdraw from the study at any time, without providing a reason. You are also at liberty to withdraw any data traceable to you, up to two weeks after your clinic appointment.

Confidentiality:
All participants will be assigned a unique alpha-numeric identification code to protect confidentiality. A document linking the code with your name will be stored independently of the clinical data and will be available only to the researchers. All clinical data will be collected, recorded, stored and analysed under your unique code. The linking document will be destroyed following completion of the study and raw clinical data will be destroyed after a period of 6 years. If the results of this study are to be published in the scientific literature or presented at a conference, as with the study report, you will not be individually identifiable.

Risk of Harm:
The risk of harm during the clinical assessments is minimal, and is the same level of risk you would be exposed to a routine eye exam. The investigators are trained to carry out these procedures safely. You will be given detailed instructions during the test procedures to minimise risks as far as possible. The investigators are trained to anticipate patient movements, however, in the unlikely event you move suddenly or unexpectedly during the test procedure, there is a small risk that contact could be made with your eye surface, and an abrasion could occur. This would usually take several hours to fully resolve, during which time your eye could be slightly uncomfortable. The abrasion would be treated, and you would be followed up, according to standard clinic protocols.
Compensation:
This investigator-initiated study arose from the academic interest of the researchers in dry eye diagnostics. Topcon have since offered to provide support for the study via equipment loan and a contribution to the research costs but are not the sponsors of the study. As research is not being conducted for the benefit of a commercial sponsor, patients may be eligible for compensation via ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001.

Contact Details and Approval:
For any queries or concerns about this study please contact one of the following researchers:

Professor Jennifer P. Craig (Project Supervisor)
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Professor Charles N. J. McGhee (Head of Department of Ophthalmology)
Email: c.mcghee@auckland.ac.nz
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If you require Māori cultural support, you are encouraged to talk to your whānau in the first instance. Alternatively, you may contact Iwi United Engaged consultant Dr Kevin Roos by emailing kev@iue.net.nz.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Approved by the Auckland Health Research Ethics Committee on 19 July 2021
for three years. Reference number AH22082