PARTICIPANT INFORMATION SHEET

Project Title: Effect of age on the ocular surface

Researcher(s): Assoc. Prof. Jennifer P. Craig, Dr. Simon J. Dean, Dr. Alex Müntz, Ms Karien Nel, Ms Catherine Shon, Mr Saia Manase

Researcher Introduction:

Thank you for taking the time to read this information. We are researchers from the Ocular Surface Laboratory within the Department of Ophthalmology at the University of Auckland. Associate Professor Jennifer Craig is a clinical researcher and NZ-registered optometrist, Dr Simon Dean is an ophthalmologist and honorary clinical senior lecturer, Dr Alex Muntz, Karien Nel and Catherine Shon are clinical researchers, and Saia Manase is a nursing student undertaking summer research under the supervision of A/P Jennifer Craig.

Project Description:

You are invited to participate in our project which aims to help us better understand how the surface of the eye changes with age, and help us better understand such changes in relation to dry eye. Dry eye is a common condition that results in chronic irritation symptoms. We would like to find out more about this condition because it can have an adverse impact upon quality of life. You do not need to have symptoms of dry eye in order to take part in the study.

Ocular surface characteristics we will investigate included the stability and volume of the tear film (the fluid layer covering the surface of your eye) and the quality of the oil glands within the eyelids. We are interested to find out if the characteristics show similar results within each of 5 different age groups (<20, 20-29, 30-39, 40-49, 50-59 years). Your participation will require you to attend a single visit (of 20 - 30 minutes), at Grafton campus Eye Clinic or Manukau Superclinic.

In taking part in this study, you will receive a full ocular surface review and can be provided with feedback about the status of your ocular surface condition, without cost. Your contribution might also help dry eye patients in the longer term if we can better distinguish changes due to dry eye from changes that are simply age-related. There is the possibility that your data could contribute to a large-scale international epidemiological study, where similar data are collated from many individuals from many countries. Any data used for this purpose will be entirely de-identified so that your identity cannot be traced from the data.
Project Procedures:

Various measurements of your anterior eye health will be recorded at a single visit, using standard, clinical techniques. The test procedures are largely non-contact (don’t touch your eye) and pose minimal risk of harm. The procedures include:

1. Grading of ocular comfort, risk factors for dry eye, and dry eye symptoms (if any), using brief, validated, dry eye questionnaires (taking a total of 10 minutes to complete).

2. Examination of the anterior eye, including the eyelids and ocular surface, using a slit-lamp biomicroscope, the instrument found in all eye examination rooms, and the Oculus Keratograph 5M. These are used routinely in the clinical setting and do not directly touch your eye.

3. Grading of the tear film quality with one or more of the Medmont E300 topographer, the Kowa DR-1 and the Tearsceince Lipiview (as available). This does not involve direct contact with your eye.

4. The quantity and quality of the eyelid gland contents will be assessed following gentle pressure applied to your closed lower eyelid (equivalent to that of a forceful blink).

5. Clinical evaluation of tear osmolarity, which might feel ticklish on your eyelashes but doesn’t touch the ocular surface, may be performed. These are recognised clinical tests performed regularly to assess the tear film.

6. Evaluation of the ocular surface quality with standard clinical dyes to confirm the health of your eye’s surface. There is no stinging sensation when the dyes are applied.

It is anticipated that the results of this study will be presented at national and international conferences and will be submitted for publication in the scientific literature. You will not be individually identifiable in any report from the study.

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 from any other clinicians, today or in the future. 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.

There are a number of reasons you might not be suitable for this project. These include:

- Use of eye medications (other than lubricant eye drops). Drops must not have been instilled for at least 2 hours prior to eye examination
- Contact lens wear – contact lens wearers are eligible as long as the contact lenses have been removed at least 12 hours previously.
- Ocular surgery in the last 3 months in either eye
- A systemic condition, disease or trauma judged by the investigator to be incompatible with participation in the study
- 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) will be stored in a secure cabinet at the University of Auckland for six years (for publication purposes) before being securely destroyed. Electronic data will be de-identified immediately following collection and stored indefinitely to allow comparison to future data sets.

Consent Forms will be held by the Department in a secure location, separate from the research data for a period of six years.

High magnification digital images of your eye will be taken. These are used for analysis only and you are not identifiable from them. They will be deleted 2 weeks after your clinical examination.

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.

Anonymity and 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 along with the raw clinical data after 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.

Possible benefits

Participation in this study is unlikely to benefit you directly, but will provide an opportunity to participate in a scientific study which could help researchers better understand the aging eye and ultimately improve patient care. You will also be eligible to enter into the prize draw to win a $50 Westfield voucher. Withdrawal from the study does not preclude you from entering the prize draw.

Risk of Harm

The risk of harm during the clinical assessments, as stated above, is minimal, and is the same level of risk you would be exposed to during contact tonometry, a procedure routinely performed during a conventional 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.

**Contact Details and Approval:**

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

Assoc. Prof. Jennifer P. Craig PhD FCOptom FAAO (Optometrist and Principal Investigator)
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For any queries regarding ethical concerns you may contact:

The Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711. Email: [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz)