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PARTICIPANT INFORMATION SHEET

Project Title: Characterising the lid margin in meibomian gland dysfunction (MGD)

Researchers: Prof Jennifer P. Craig, Dr Alex Müntz, Dr Kalika Bandamwar, Catherine Shon

Project Background:

Thank you for your interest in our research. You are invited to take part in a project aiming to develop a method to better understand and ultimately treat meibomian gland dysfunction (MGD), a common ocular condition that you may or may not be affected by. You have either told us about your MGD (as diagnosed by your eye care practitioner or as a participant in one of our previous research studies), or you are suspected to have MGD based on typical signs and symptoms or you are a current contact lens wearer who experiences contact lens discomfort. If you are healthy (non-MGD) you are invited to contribute to this study as a control.

Meibomian gland dysfunction is the most frequent cause of dry eye disease (DED), a condition affecting hundreds of millions of patients worldwide, and around 30% of the New Zealand population. MGD commonly involves the *keratinisation* of the eyelid margin. The skin on our fingertips, foot soles, or the inside of our cheeks commonly keratinises (i.e. toughens) when exposed to various mechanical, thermal, chemical stressors. The eyelid margin is no different, but at the ocular surface, the keratinisation process is poorly understood, and this limits the options for treating MGD. Better methods of characterising changes at the lid margin are needed. Therefore, **in this study we aim to develop a novel method for measuring keratinisation levels at the lid margin.**

Researcher introduction:

We are researchers from the Ocular Surface Laboratory in the Department of Ophthalmology, at the University of Auckland. Our team includes Professor **Jennifer Craig**, a clinical researcher, NZ-registered optometrist and principal investigator in the Ocular Surface Laboratory, along with trained co-investigators **Catherine Shon**, a NZ registered optometrist and researcher, Dr **Alex Müntz** and Dr **Kalika Bandamwar**, research fellows in the Ocular Surface Laboratory, who will be performing the clinical investigations in this research project.

Project description

This project involves a single study visit of one-hour duration. The visit will take place at the Grafton Eye Clinic, at the University of Auckland. The clinical measurements conducted at the study visits are outlined below. The study is observational only – there are no treatments applied to your eyes.

Project Procedures:

Various features of the eye's surface will be observed using standard clinical techniques that are performed routinely by eye care professionals. These 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 5 minutes to complete).
2. Examination of the tear film and the eye's surface with the Oculus Keratograph 5M.
3. Examination of the anterior eye, including the eyelids, eyelashes and ocular surface, using a slit-lamp biomicroscope, the instrument found in all eye examination rooms.
4. Evaluation with standard clinical dyes that confirm the health of your eye's surface. There is no stinging sensation when the dyes are applied.
5. Clinical evaluation of tear osmolarity, which might feel ticklish on your eyelashes but doesn't touch the ocular surface.
6. Evaluation of keratinisation by applying a sterile membrane and/or spatula to the outer lid margin skin, just next to your eyelashes. This will feel similar to brushing a cotton tip swab along your eyelid margin. A drop of ocular anaesthetic temporarily numbs your eye, for comfort. The numbness will resolve within a few minutes, your pupil will not dilate (widen) and it will be safe for you to drive. We will later assess the membrane, and any material wiped away from your lid margin on the sterile spatula, in the laboratory.
7. Oils will be gently expressed from the meibomian glands by pressing the outer lid margin skin, underneath the eyelash line, for assessment later in the laboratory.
8. Clinical evaluation of lid margin sensitivity using a dual temperature non-contact aesthesiometer where temperature-controlled air puffs are directed to your lid-margin and you will be asked if you felt them.

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. 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 if you are a staff member. If you feel this assurance has been breached, you are advised to contact the Head of the Ophthalmology Department.

Eligibility

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

- Ocular surgery in either eye in the 3 months prior to baseline measurements or during the study
- 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.

- Contact lens wear – current contact lens wearers are eligible as long as the contact lenses are not worn on the day of study participation.
- Certain medications (topical or systemic, including eye drops and dietary supplements) – please inform the investigator of any medication you may be taking.
- Eye cosmetics – please discuss your eye cosmetic use with the investigator.
- You have been a participant in a clinical trial within the last 30 days.

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. We will ask if you would like us to contact any of the health professionals who provide you with health care. If you would like us to do so, we will ask for their contact details and request your permission to contact them on your behalf to let them know about your participation in the trial.

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 on password-protected computers to allow comparison with 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.

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 final clinic visit.

Data use and confidentiality

This study has been initiated and designed by the researchers at the University of Auckland. Industry funding may be sought to support research costs. If this is successful our industry partner will receive a copy of the overall study outcomes, but it is important for you to know that they will have no influence over the study design, its conduct, or its publication after completion, regardless of the findings. It is anticipated that the results of this study will be written up and presented orally at national and international conferences and submitted for publication in the scientific literature. You will not be individually identifiable in any report arising from the study.

Benefits

In taking part in this study, you will receive an ocular surface review free of charge and can be provided with feedback about your ocular surface condition. You are helping us learn about MGD and how it translates to dry eye disease. As a token of our appreciation for your participation in the study, you will receive a $20 petrol/retail voucher to thank you for your time.

Risk of harm

The risk of harm during the clinical assessments and procedures, is minimal, and no greater than the risk you would be exposed to during a regular 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

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non--earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury.

If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation..

Contact Details and Approval:

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

Name	Contact details	Role
Prof Jennifer Craig	jp.craig@auckland.ac.nz Ph: 09 923 8173	Principal Investigator
Dr Alex Müntz	a.muntz@auckland.ac.nz	Co-Investigator
Dr Kalika Bandamwar	kalika.bandamwar@auckland.ac.nz	Co-Investigator
Catherine Shon	catherine.shon@auckland.ac.nz	Co-Investigator
Prof Charles McGhee	c.mcghee@auckland.ac.nz Ph: 09 923 6712	Head of Department

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: humanethics@auckland.ac.nz

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 27 NOV 2019 FOR 6 YEARS, REFERENCE NUMBER 024055