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Polarization sensitive optical coherence tomography and skin properties

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1. Invitation

You are being invited to take part in this research study because you have responded to an advertisement of the study.

2. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time.

This consent form describes the procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of this study and sign this consent form only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form.

Please take the time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

3. Who is conducting this study?

Our team is comprised of BC Cancer researchers and UBC graduate students. This study is not receiving funds from an external agency or sponsor. The co-investigators Dr. Shuo Tang and Mr. Xin Zhou are the inventors of the polarization sensitive optical coherence tomography prototype. The principal investigator Dr. Tim Lee is an inventor of the polarization speckle imaging device. He holds a patent on the device. Conflict of Interest: If this research shows that this technique is safe and effective, the inventors of these technologies may benefit financially from this study. If you would like more information, please contact the researchers or the study coordinator.

4. Background

Polarization sensitive optical coherence tomography (PS-OCT) is a new non-invasive imaging technique. It has a huge potential for medical applications. Our research team has just constructed a laboratory, research prototype. Recently, we discovered that it could be used for skin imaging, and uncovering properties of skin related to cancer diagnosis, wound healing, and aging. In particular, laboratory studies showed that the technique could measure skin surface roughness, an important clue for the diagnosis of melanoma, a form of skin cancer. However, it is not clear if the technique can measure surface roughness directly from human skin. Currently, there is no standardized non-contact skin roughness measurement method. The most well understood method is an indirect, two step technique. Skin surface is imprinted using silicone rubber and the imprint roughness is measured off-line. There are few research optical techniques for measuring skin surface roughness on human skin directly. One of them is polarization speckle imaging. This study will compare the skin surface roughness measurement between PS-OCT and polarization speckle imaging.

5. What is the purpose of the study?

The goal of this research study is to prove the practicality and the accuracy of the newly developed technique on measuring skin surface roughness. Knowledge gained from the study may be used to develop future studies on measuring skin surface properties that may benefit others.

6. Who can participate in this study?

You may be able to participate in this study if you are 18 years or older.

7. Who should not participate in this study?

You will not be eligible to participate in this study if:

- you are unable or are unwilling to give informed consent
- you cannot comfortably remain stationary for imaging
- you cannot speak or read English (Translation will not be provided due to the resource constraint of the study.)

8. What does the study involve?

If you agree to take part in this study, a research team member will measure your right forearm, right palm, forehead, and left eye corner with three non-invasive optical devices: colorimeter, polarization speckle, and PS-OCT. In addition, if you have any large moles on your forehead, cheek, forearm and/or hand, these moles may be measured too with your consent. The devices will be placed gently on the skin surface; a light will be emitted to the skin; and the returned signals will be captured by the device, which will interpret the results. For PS-OCT imaging, you have the option of allowing us to place gel on the target site to help enhance the imaging. The actual data capturing time will be less than 1 second for polarization speckle imaging and colorimeter, and about 10 seconds for PS-OCT. These measurements are painless and harmless to the skin. Each measured spot will also be photographed. The photographs will be focused only on a small patch of the skin and cannot be able to identify you. The total expected time for the procedure is approximately 60 minutes.

9. What are the possible harms and discomforts?

There are no known risks or discomforts from the procedure.

10. What are the potential benefits of participating?

There is no benefit to you from participating in this study. This study may find a practical and accurate method for measuring skin properties in the future. Data from this study may be used for commercial purposes and you will not share in any commercial value or profit derived from the use of your data.

12. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information about you already collected. You have the right to request the destruction of your information collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn, for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please send a written or verbally request to the research team.

13. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the UBC Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the Principal Investigator of the study.

Your de-identified research data may be published or deposited into a publicly accessible location at the time of publication. This data could include PS-OCT images, depolarization images, colorimeter values and skin photographs. At no time will identifying information, such as your name, birth date or street address be included in such data. This means that other researchers may analyze the data for different reasons other than those described in this consent form. Once the data is made publicly available, you will not be able to withdraw your data. The extent of the risk of you being identified through public data is unknown, but currently appears to be low.

14. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

15. What will the study cost me?

There will be no cost to you.

You will not be paid for participation.

16. If I have questions about the study procedures during my participation, who should I speak to?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Dr. Tim Lee at (604) 675-8053.

17. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598.) Please reference the study number (H19-02887) when calling so the Complaint Line staff can better assist you.

18. Study photographs

The study will photograph digitally the skin measured by the optical instruments. You will be able to review the photos taken of you at your request at the end of the imaging step. The photographs cannot be used to identify you. Only the research team will have access to the photographs, which are stored as computerized files on an encrypted, password protected computer, storage device, or hospital network server. Your photograph may be selected for scientific presentations, but no personal identification will be revealed.

19. After the study is finished

Summarized results and data that cannot be used to identify the individual will be presented in scientific journals and meetings.

Study data and photographs that cannot be used to identify the individual will be retained for future skin-related studies.

Individual results will not be returned to you; however, you can contact the Principal Investigator for information about the study at any time.

20. Signatures

Polarization sensitive optical coherence tomography and skin properties study

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I authorize access to my photographs as described in this consent form.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

_____	_____	_____
Participant's Signature	Printed name	Date

_____	_____	_____	_____
Signature of Person Obtaining Consent	Printed name	Study Role	Date

Investigator Signature

_____	_____	_____
Investigator Signature	Printed name	Date

My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant's signature was obtained.