Customising the Cold Challenge: Pilot Study of an Altered Raynaud's Phenomena Assessment Method for Data Generation

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Abstract. The objective of the study is to develop a methodology for gathering data on phalanges to be utilised in wearable technology research with the potential to assist Raynaud's Phenomena (RP) sufferers. This paper gives an overview of a pilot study using a method developed from an existing medical practise called 'cold challenge', which is used in the clinical analysis of RP, and amended for data collection. Due to the alterations that differentiate the pilot study from the clinical exam, it is expected that adjustments will be required to the methodology before a full study is undertaken. The paper centres on the pilot study and the developments made through the analysis of the pilot study results for implementation in further research. The pilot study illustrates a method trialled in the early stages of R&D within PhD design research.

Keywords: Pilot study · Raynaud's Phenomenon · Medical technology research

1 Introduction

The focus of the research study is a medical condition called Raynaud's Phenomenon (RP), which 'describes excessive vasoconstriction of the digital microvasculature in response to cold exposure and emotional stress' [1]. The present pilot study aims to develop a methodology for data generation for use in design and research towards mobile technology development. Clinical analysis of RP is conducted in controlled environments and with patient information [2]. There are variations on the thermographic analysis of RP; in this study the 'cold challenge' method developed by Anderson et al. [3] was used as the framework. The cold challenge method states a single subject and includes: an environmentally controlled room to which the subject adjusts before taking the cold challenge, blood tests, an assessment of the subject's medical and family history, and the subject abstaining from smoking or caffeine intake for 4 h prior to the test.

Tests in clinical environments are carefully developed for diagnostic and clinical purposes; the anticipated outcome of this research and pilot study is not a diagnostic tool but the generation of data towards a database that would be beneficial with regard to mobile technology development. Aspects of the cold

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Fig. 1. Images of a participant's hands obtained during the pilot study. (a) Photograph. (b) Thermal image. Images by Isobel Taylor @ 2016

challenge not considered in this pilot study include fixed environments, family history, and medical data. Eliminating these factors allows for a simpler, more time efficient testing method, allowing the assessment of data for fingers from a range of subjects, regardless of their medical and family history, in quotidian situations. In this pilot study, hand submersion was carried out in containers of 15 °C water and ice. The temperature was set to 15 °C to trigger RP and cause vasoconstriction within the clinical examination of RP. Alternatively, ice is known to cause vasodilation and was also used within the pilot as a record of the effect. The research looks towards mobile outputs that create changing environments; therefore, the environment in which the test is conducted was recorded but not fixed for each group tested. Part of the overall study that will follow this pilot will involve testing specific focus groups, such as athletes and particular age groups, which is known as purposive sampling [4]. The subsequent sections of the paper outline the method used in the pilot study, the results, and the amendments to be made to the methodology for the full study. This study also acts as an example of multidisciplinary research, as it spans the fields of medicine, design, and technology.

2 Pilot Study

The participants volunteered from within the University of Porto. The session was conducted in a classroom environment at a temperature of 22 °C with the windows closed and no direct sunlight, heating, or air conditioning for the duration of the study. Participants were given information on RP and the study and an opportunity to ask questions. To the participants' knowledge, none have RP, and none have had RP diagnosed.

A container of ice cubes and a container of 15 °C water were prepared for the hand submersions. Both were stirred and their temperatures regularly checked. Participants each had a number attached to their hands (see Fig. 1), preserving anonymity whilst identifying age bracket and gender, which are known factors in RP. The FLIR ONE 2nd Gen thermal imaging camera and FLIR ONE 2nd

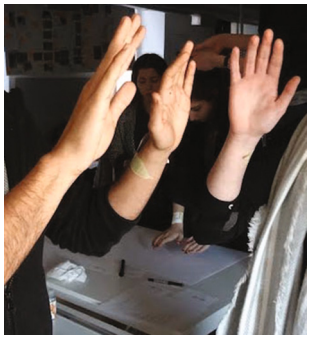

Fig. 2. Photograph hands held at chest height whilst queuing for thermal imaging. Photograph by participant no. 2

Gen iOS software were used for imaging. Participants had their temperatures taken through thermal imaging at regular intervals for 20 to 30 min following submersion. The following instructions were given to the participants. Submerse both hands, one person at a time, and form a queue for thermal imaging, looping until the time frame ends. Hold hands above the table surface for the thermal imaging to eliminate temperature contamination. Hold hands up at chest height whilst queuing and do not let hands touch anything for the duration of the test (see Fig. 2). Following the study, the participants were given a chance to ask questions & fill out a feedback form. The pilot study, gathering data on the nine participants, was completed in 1 h.

Method

1. Participants had a base temperature reading taken.
2. Participants submersed their hands: right hand in 15 °C water, left hand in a container of ice cubes. Group A: duration of 60 s, five participants. Group B: duration of 120 s, four participants (see Table 1).
3. Paper towels were used to dab dry hands.
4. Thermal images were taken at regular intervals for 20 to 30 min.
5. Temperature readings were gathered from the thermal imagery at the nail bed of the index and ring fingers and recorded.

Results. Tables and graphs were created for each participant, and initial data has been generated. The results for four of the nine participants are included in this paper as illustrative examples of the different variables considered in this study: one male and one female for each submersion time of 60 and 120 s. The charts include the first temperature taken before submersion; the gradient shows the drop from the base temperature to that post-submersion and the subsequent climb in temperature over time (see Figs. 3, 4, 5 and 6). The two lines in each graph show temperature taken from the nail beds of the index finger and ring

Table 1. Submersion times and temperature ranges obtained during the pilot study for four participants. All temperature data in table were taken from the index finger. Isobel Taylor @ 2016

Participant no., gender and submersion time in seconds	15 °C (right hand) base−highest–lowest, temperature in °C	Ice (left hand) base−highest–lowest, temperature in °C
No.8 Male 60 s	29.9−23.2−20.5	30.5−20.9−17.4
No.1 Female 60 s	24.2−28.5−7.9	25.1−32.8−10.2
No.6 Male 120 s	33.2−31.6−19.4	33.2−12.2−32.5
No.7 Female 120 s	33.2−24.9−18.6	24.6− 9.9−19.8

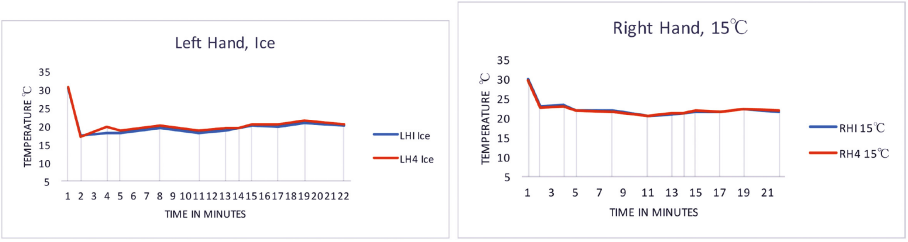

Fig. 3. Charts for participant 8: male, submersion duration of 60 s. The left hand showed a slight temperature increase following submersion in ice over 22 min, and the right showed very little temperature increase following the 15 °C submersion. Isobel Taylor @ 2016

finger of the same hand. The results show that although they can be very close in temperature, fingers on the same hand do not change temperature at exactly the same rate.

3 Amendments

Although the pilot study yielded useful temperature data results, the method requires some alterations before being conducted on a larger scale. The core changes are as follows.

3.1 Gloves

Within the pilot, the participants were asked to dab their hands dry with paper towels; however, this is problematic, as any leftover dampness alters skin temperature readings. In the Raynaud's cold challenge method, thin latex gloves are worn during the submersion and removed prior to the thermography to avoid this problem.

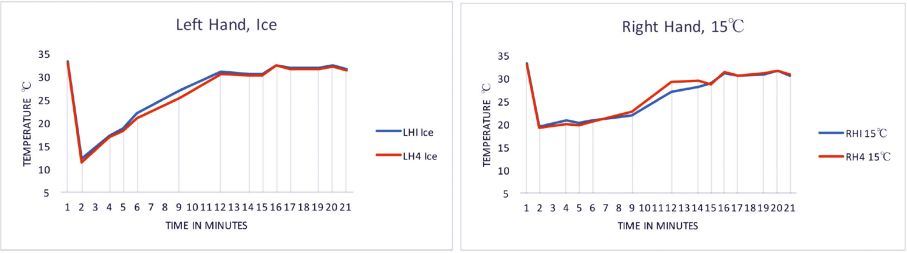

Fig. 4. Charts for participant 6: male, submersion duration of 120 s. The left hand showed a slightly faster temperature rise over time than the right hand, as expected from the vasodilation effect of the ice, and the right hand showed rewarming following the 15 °C submersion. Isobel Taylor @ 2016

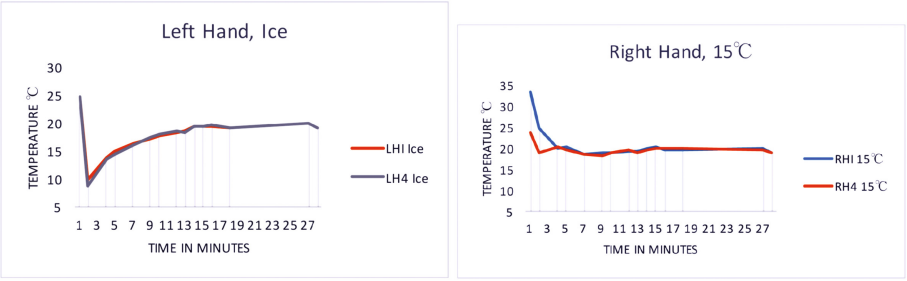

Fig. 5. Charts for participant 7: female, submersion duration of 120 s. The right hand showed very little temperature rise over time, and the base temperature of the ring finger was higher than that of the index finger. Isobel Taylor @ 2016

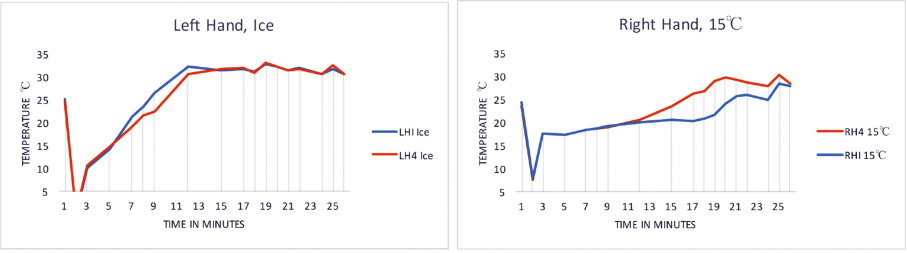

Fig. 6. Charts for participant 1: female, submersion duration of 60 s. This not only showed the faster rewarming following ice submersion but also a final finger temperature that was higher than the base temperature in the same hand. Isobel Taylor @ 2016

3.2 Back Drop

A thick piece of white matte paper was used to avoid the reflection of temperature from the table. In Raynaud's cold challenge and medical thermography, black cloth is used [5]. This will be incorporated in subsequent studies.

3.3 Submersion Temperature

The pilot used 15 °C water and ice. Ice has been used in historic examinations but has been rejected more recently because ice submersion causes vasodilation rather than triggering a Raynaud's attack. Ice submersion was included in the pilot to obtain a record of the effect of vasodilation. The problem with conducting two tests on one person is that their body is likely to be effected by both hands; therefore, within the pilot, neither measurement is a reading of the response to 15 °C water or ice but a measurement of the effect of one hand in each temperature.

3.4 Environment

The temperature of the room the participants were acclimatised to was recorded; however, a more accurate device is needed for reliable results. Considerations such as wind speed, time of year, temperature, and climate will be recorded when using outdoor environments.

3.5 Thermal Imaging

The battery on the thermal imaging device (FLIR ONE 2nd Gen) is short. Because of this, the data contains a gap from when the device required charging. For future studies the FLIR will remain connected to a power supply during the study to keep it charged [6].

3.6 Target Group and Participants

For the pilot test, the age ranges of the pilot study participants were 21–30 (eight participants) and 31–40 (one participant). In future work, a larger range of ages will be included. The dominant hand and hand strength should also be noted to evaluate whether this has any relation to the temperature readings. This information may be useful based on advice currently given to RP sufferers that exercise is beneficial [7]. Therefore, hand strength will be measured to determine if participants with stronger hands show any unique temperature patterns compared with participants with weaker hands. Although the labels on the participants' hands were legible, they were not easy to read. In future studies, participant labelling should be clearer. Amendments to the explanation of the exam given to the volunteers identified from the pilot study include the following addition to the information sheet based on the question most commonly asked by the participants: 'What happens if it turns out I have or may have RP?' From

this, a section will restate that this test is not a diagnosis but is aimed at data collection and that if the condition has not previously affected the participants, this study will not change that.

4 Conclusion

The pilot study was successful in recording temperature ranges when exposing hands to specific stimuli and the identification of improvements for the full study. The data collected is clear and usable, and additional information, such as hand strength information, has been identified for inclusion in further studies. As a designer working across disciplines, I have found creating this pilot study to be highly beneficial as a crash course in obtaining a more in-depth understanding of RP not just from papers and discussions but from live testing and observation. As this pilot is the early stages and research is ongoing, the results of how this pilot and the method of study it informs are inconclusive, as they cannot be fully evaluated until the study is further developed. The test and results will also be discussed with medical experts for feedback and further alterations.

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