Wearable Technology in the Study of Raynaud's Phenomena
Ascertainment of the Potential Impact of Wearable Technology on Raynaud's Phenomena Utilizing Data

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1 RESEARCH PROBLEM

Can wearable technology aid in the study of Raynaud's Phenomena?
Raynaud's phenomena (RP) affects 3-20% of the Population worldwide (Nhs, 2015). RP is the vasoconstriction of the microvascular system in the extremities, such as the digits, in response to cold exposure or emotional stress. The prime quotidian problems for sufferers are: ischemia to the extremities, the pain this causes, loss of fine pincer movements and the aesthetics (Fig 1.). The initial symptom of an RP attack is often numbness; this is not always noticed by the individual with RP.The faster the attack is identified the sooner the individual can attempt to re-establish blood flow, therefore shortening the time the tissue has been starved of nutrients. Current options include Pharmaceutics which have side effects from headaches to bleeding in the brain along with problems in cross drug interactions. Pharmaceutics also come at a cost, not just of the drug but also the time spent with the Doctor which can be regular if a drug that suits the individual is not easily found. Whilst available wearables such as ski gloves and heat focused garments limit function and dexterity they also have a lack of data of the impact these have. The presupposition is that a wearable data collection device could create a database to aid in the understanding of the condition itself as well as any wearable or pharmaceuticals impact. The PhD research continues from the researcher's MRes in Digital Media that questioned whether an RP attack could be detected with a temperature sensor. The study showed positive results which included taking the skin surface and environmental temperatures of predicting attacks initiating from data changes. The research will be advanced by focusing on data gathering, for an accurate device, improving the calculations involved. The aim is to create a device/ system to extract data from the skin concomitant with external data including weather reports and geo location incorporated through exploitation of a smart phone for data gathering and assessment over time. Interest also lies in how a designer can impact the implementation of the research. The research will centre on Primary Raynaud's Phenomena, PRP, in the fingers with the potential this could be used in cases of Secondary Raynaud's Phenomena, SRP, and other effected extremities.

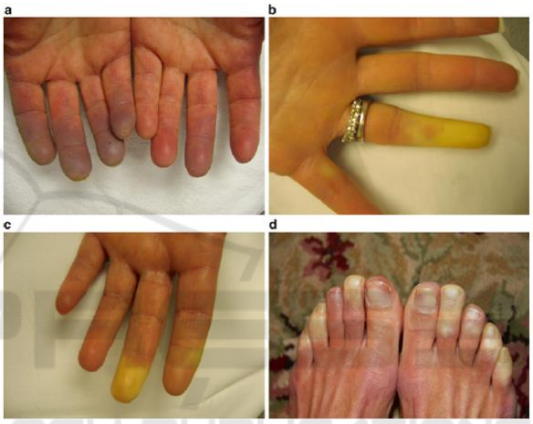

Figure 1: Example of RP in fingers and toes. a. showing the blue hue from the inadequate blood supply, ischemia, the yellow/white pallor's in b, c & d the initial loss of blood flow from the vasoconstriction. (Wigley, 2015).

2 OUTLINE OF OBJECTIVES

- Ascertain if wearable technology can aid in the study of symptoms of Raynaud's Phenomena.

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- Ascertain if predictions of attacks can be made from routines, weather reports and geographical data. Information with the potential to be utilized by the individual through e.g. a smart phone, as well as a database for quantitative analysis.
- Create a model from the research for further implementation in wearable technology, design for health and wellbeing purposes.
- Report on the role of the designer as part of development in medical/ wellbeing technology within the field of wearable technology. Focusing on wearable technology for health teams, backgrounds and dates.
- Create a collection of information gained from the PhD study on RP into a report.

3 STATE OF THE ART

This section describes:

3.1 Raynaud's Phenomenon; the medical condition,
3.2 Technology and wearables; the state of technology & multidisciplinary wearable technology developments
3.3 current market; products and research.

3.1 Raynaud's Phenomenon

(RP) describes excessive vasoconstriction of the digital microvasculature in response to cold exposure and emotional stress (Pauling, 2013). This causes vessels in the extremities to constrict, stopping blood flow, short term this can be painful, longer term damaging, long term can cause irreversible damage. Raynaud's comes in 2 forms, Primary, PRP, and secondary, SRP. Primary Raynaud's is idiopathic, a condition in itself, secondary RP is a symptom of another condition. Amputations are not common but do occur in RP patients; amputations occurring from vascular diseases, which includes RP, counts for the highest number of amputations in the developed world (Ziegler-Graham, 2008). Current solutions for patients leave a lot to be desired; medical prescriptions have substantial side effects, effects from headaches to bleeding in the brain. Along with the main non-pharmaceutical suggestion is 'avoid the cold' (Raynauds, 2009). The research predicts gathering detailed quotidian data will aid in research and further illuminating the details of RP by taking recordings including temperature readings; usually only taken in clinical environments whereas RP attacks take place at home, at work, when traveling. The utilization of individual and local data will have great potential in the improvement of the wellbeing of those with the condition on a quotidian basis. For the purpose of the PhD research I will be focusing on the hands and ensuring the outcome can be adapted for the other effected extremities; toes, nose, ears. Medically the focus will be on Primary Raynaud's though in many cases the outcome is likely to inherently be of use to those with Secondary Raynaud's. From observations at the 2015 Raynaud's and Scleroderma conference UK it became evident that the patients were not satisfied with the current methods of coping with the ailment. A search of current medications and devices revealed problems, listed in the research problem, highlighted by patients interviewed before and during the conference. [The 2016 Raynaud's conference was much the same in regard of the patients finding the current options lacking].

3.2 Technology and Wearables

There has been a growing increase in the space for designers to collaborate in science, health and technology, particularly noticeable in wearable technology teams. Wearable technology has and is able to bring together designers, scientists and engineers to incorporate the technology into a form fitting for the identified user and purpose. This has been a rare occurrence in history from Leonardo da Vinci [1452 - 1519]; design, art, medicine, science and engineering, James L. Acord [1944 - 2011]; art, nuclear science, Eduardo Kac [1962-]; art, biology. An example of a current wearable technology team is Studio XO with founders Benjamin Males, engineer, and Nancy Tilbury fashion design, (Studio, 2016). Wearable technology as a field has hit mass media with its own reality TV show, founded by Intel: 'America's greatest makers' (Americasgreatestmakers, 2016). Although a relatively young field, in regard to fields such as biology and chemistry, this in part goes to show the increase in interest and popularity. The most common focus for wearable technology regarding wellbeing is in sports, fitness and elderly care, "As of September 30, there were 266 wearable devices on the market (including 118 fitness wearables)" (Herz, 2014). This is not to say wearable technology is the universal answer to healthcare problems; *"Potentially, these devices could give patients direct access to personal analytics that can contribute to their health, facilitate preventive care, and aid in the*

*management of ongoing illness. However, how this new wearable technology might best serve medicine remains unclear. "(*Piwek, 2016) Wearable technology is on the rise, yet not all who purchase/ obtain devices will keep up use and devices may not work with accuracy; "*This systematic review indicated higher validity of steps, few studies on distance and physical activity, and lower validity for energy expenditure and sleep. The evidence reviewed indicated high interdevice reliability for steps, distance, energy expenditure, and sleep for certain Fitbit models. As new activity trackers and features are introduced to the market, documentation of the measurement properties can guide their use in research settings. "*(Evenson, 2015). Reliability of the technology is of great importance, particularly with a medical condition focused device.

3.3 Current Market and Research

The financial market of wearable technology in health is on the rise. According to a report by Pira International (now called Smithers Pira, 2012) by 2021 the smart material market will be worth just under €2,000 million, medical and healthcare making up just under 1/3rd of the market (Wilson, 2011).

Specifically regarding RP; most heated gloves and socks on the market have been ski or fishing based with a smaller number for hiking and motor bikers. RP sufferers at the SRUK conferences cite use of hand warmers and normal thick gloves and socks but none have cited use of any RP specific made product apart from silver gloves. Silver gloves and socks whilst marketed as an aid to RP have very little scientific evidence to prove this. RP also has a particularly high rate of the placebo effect. However, although RP sufferers have cited use of silver products none have given any particular feedback on their use other than a thin glove being useful at times and the ability to use touch screens, both of which could be achieved with a non-silver glove. This is not to say silver is not useful: evidence does show antibacterial properties and conductivity that will be assessed as part of the material options in practical developments (see methodology). Also, these devices do not collect data or make predictions. Current devices in research specifically for RP include 2 groups from Universities Nottingham Trent and Virginia Commonwealth. Nottingham Trent have funding from the Raynaud's and Scleroderma society UK (Sruk 2016) for developing a heating glove, previously they have developed a thread for monitoring temperature within socks to test for ulcers in patients with diabetes. At the Virginia Commonwealth university an engineering student developed a 2-layer glove to heat fingers and hands in regard to RP (Ugincius, 2016). If the Virginia group collect and use data, as the mediation seems to suggest, the interest to this research project will lie in what data they collect and how they use it. Clinical analysis of RP is conducted in controlled environments and with patient information (Murray, 2015). Wearable technology allows data to be collected over prolonged periods of time at the patient's home. This data collected and processed could show patterns such as times of day RP attacks are most common, temperatures that trigger RP attacks, sudden loss of blood flow. Within clinical environments tests to study RP include the cold challenge which examines temperature of the fingers following exposure to 15°C water submersion for 60 or 120 seconds over 25 minutes using a thermal imaging camera. Within the challenge the specialist looks for the rate the finger temperature changes over 25 minutes. The research will broaden this temperature reading study to days, weeks, months and more. Including the ability to record attacks that may be related to weather conditions as well as temperature levels in the locations that matter most to the patients as managing their condition in the locations the attacks occur.

4 METHODOLOGY

The presupposition is that the answer will be found in the field of wearable technology; this field enables real time data capture and analysis concomitant with an external direct impact on the affected area/s. Real time data includes human and external such as finger temperature, weather reports and geo location. The aim is to achieve this through qualitative practice-based research by use of the appropriate materials, currently being identified, in articulation with syntax capable of learning and adapting and with the capability of prediction to alert the user. Research initiates with a foundation of literature and market research focusing on the users; interviews and surveys with doctors, specialists, patients and relevant agents.

The overall methodology being followed is represented by the following action research cycle:

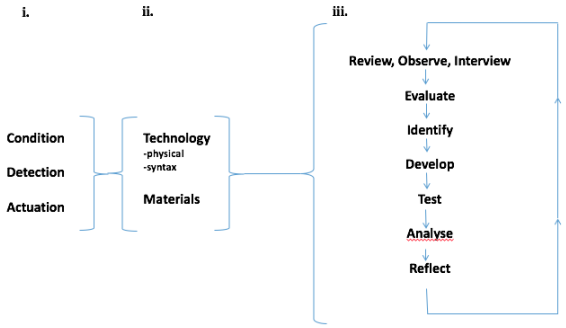

Figure 2: Methodology diagram, based on the general action research cycle diagram.

(Fig. 2) When iii. is the evaluations of i. and ii. then iiii. is the specific testing of prototypes and finalisation of the research.

The research focuses on collecting data for the individual user and for an overall study towards RP research.

The method will test usability and performance of a wearable device for collecting data and software for mobile phones for gathering and communication. To be completed through finding, developing and if need be synthesizing optimum materials and parts for detecting and code for mobile software. This research will be principally compiled with primary and secondary research utilizing key academics, medical doctors and researchers, in addition to secondary research based on extensive archived material, internet sources, published papers, patents, market reports, company websites, conference reports, magazines, newspapers and newsletters.

A series of user aims/criteria are being compiled including; How safe is it? And Durability? forming a flow chart to analyse the developments and final device.

Resources; material laboratories and time, executing this research in Porto means access to material science academics and laboratories for developing the physical device. Within the researchers MRes physical parts and materials were obtained through samples issued by companies on request and meeting any additional costs, expectation is that this method of compiling parts for research will carry forward.

The action research cycle will be addressed in 3 segments;

4.1 Foundation,
4.2 Core,
4.3 Finalisation.

4.1 Foundation

The foundation is formed from comprehensive understanding of the condition itself and the problems that restrict daily function. The outcome of this segment will be a list of criteria enabling the assessment of a device for RP, in order to ensure that the designed and developed outcome meets the needs it is intended for and to comprehensively answer the research question. To form this criteria, the methods being used are as follows: Interviews and surveys with RP patients, Information from medical specialists, observations made from the researcher in reviewing the information and literature review. These will include interviews and observations of persons without RP as a person with RP may not know or remember the difficulties in certain situations even without RP. These potential findings are not to be ignored as if there is an aid to the problem it will still be of use to the RP sufferer but it is important to distinguish what it helping in regards to RP and what is helping RP aside. This section includes the literature and market review. Within the literature the topic spans many disciplines including: medicine, data processing, product design, engineering and technology. Although most of this is being accomplished within the early stages of the PhD research, this work will remain ongoing throughout as the information may be updated and crucial elements may be found at any time throughout the research time frame. A list of criteria the device should meet will be formed from section 4.1; the list is to be updated as and when new information is obtained for the outcome to be assessed against.

4.2 Core

The core of the PhD will lie in the prototyping, data collecting, analysis and developments. Although focus lies on the data and algorithms the device will use to inform the user and aim to predict attacks.

However, materials and technology used are also highly important. Materials used must allow the outcome device to be comfortable to wear, functional, durable, aesthetic and in many ways above all desirable. A device that is highly functional for its use but not desirable will not be used sufficiently and will ultimately fail at its purpose. The desirability will be evaluated throughout the process from materials, designs, shape, comfort, static, sound and feel against other materials, not just skin. The device prototypes will use temperature sensors with Bluetooth to transmit

to a mobile app. The mobile app will also be developed in this segment to tie the wearable sensors, weather data and communication to the user together for assessment.

The outcome of this segment will be: The identification of risk factors employable in wearable technology and how to record the risk factors, physical prototypes, a mobile app to assess the location of the user utilising online weather data and routines found through correlations of temperature drops over the course of a day.

4.3 Finalisation

This section concerns trials, testing and evaluation. Prototypes are to be tested against the developed criteria. Prototypes to be tested on RP patients to gain feedback and alterations to be made for further developments. Accuracy of the data the prototypes record to be assessed and tested. Also mass scale development to be assessed, questioning how the prototype could be developed in a factory setting. This also entails a costing evaluation to compare current methods in managing the condition against the potential of the prototype to aid in understanding of when the attacks are problematic to aid the user in adaption in their daily routines. Software will also be written to collect data from individuals to create a large database for finding patterns in RP attacks and environmental changes that effect RP.

5 EXPECTED OUTCOME

- A report on whether wearable technology, in the form of the prototypes developed, can aid in research and prediction of symptoms of Raynaud's Phenomena.
- Various prototypes using human biological data to understand when an attack takes place, showing designs tested and evaluated.
- An app for prediction and prevention with the ability to work with the wearable technology prototypes.
- A study ascertaining the potential difference a wearable device, with and without use of the developed app, can make to someone with a medical/wellbeing condition. Highlighting the gain of control over the personal data and environment.
- A database of temperature findings, both from literature reviews and case studies. / Database of finger temperatures, 'normal' exposed to particular environments and recovery
- A model from the research for further implementation in wearable technology, design for health and wellbeing purposes.
- A report on the role of the designer as part of development in medical technology within the field of wearable technology. Focusing on teams working on wearable technology for health, their backgrounds and dates.
- A model from the research for further implementation in wearable technology, design for health and wellbeing purposes.

6 STAGE OF THE RESEARCH

At the current stage of the research criteria is being extracted from the foundation research for the prototype assessment. This includes literature review of RP from the medical field, recent wearable technology devices aimed at RP patients and data on continued use of wearable technology for generating personal data regarding health, wellbeing and fitness. The core of the research is under way in testing what materials will be most favourable to establish the form of the wearable and tie in with the sensors needed. Algorithms are being drafted to analyse the data from the wearable and weather data to process into easily readable charts. As part of the ongoing foundation review on the RP condition conferences are being attended including the SRUK annual patient conference bringing together RP experts, doctors and patients. Surveys are being developed to gain a more personal understanding of how RP effects sufferers during their daily lives. These will be sent out to the SRUK members, the Scleroderma and Raynaud's association UK. RP patient's groups within Porto will also be sought to compare results between different geographic locations.

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