# Novel Approaches to the Non-invasive Treatment and Symptom Quantification of Raynaud's Disease: Comparison of Heat Retentiveness of Materials and Infrared Thermography and Warmth Provocation

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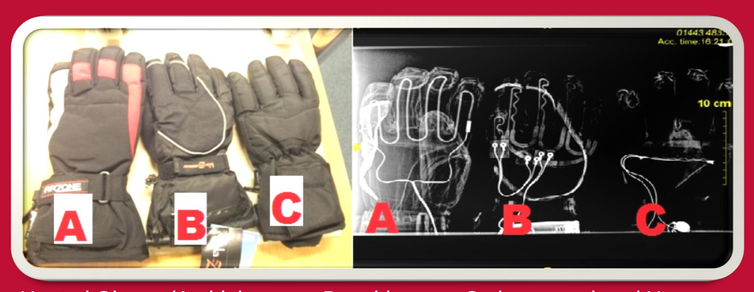
## 1 Background

Raynaud's disease is a debilitating microcirculatory disorder which causes extreme cold and numbness, particularly in the hands and fingers[1].

Gloves are commonly used non-invasive treatment modalities, but to this author's knowledge only "Thermoflow" far infrared (FIR) gloves have research evidence to substantiate their claims of effectiveness[2].

Heated gloves have elements within materials, yet they are often reported as ineffective and bulky due to the need for large battery packs[3]. Furthermore when considering current vascular research, there are potentially very specific anatomical sites of endothelial destruction responsible for the disease[4]. By assessing these specific points it is possible for strategic deployment of heated elements, specific to the patient's needs, potentially reducing the required power and battery size whilst preserving dexterity and maximising effectiveness.

Infrared thermography is a useful non-invasive tool for assessing Raynaud's symptom severity and location[5]. Typically assessment is made based on forced symptom-manifestation, following a period of cold provocation. Measurements are taken from the dorsal nail bed to the metacarpophalangeal (MCP) joint, known as the distal-dorsal difference (DDD)[6]. To this author's knowledge, the DDD has not been assessed via symptom-alleviation following a period of warmth provocation – which if clinically significant could provide a safer and more ethically sound testing procedure for future researchers.




Heated Gloves (A= high range, B= mid range, C= low range) and X-ray Image of the Internal structures. Note the diffuse placement of elements..

## 2 Methods

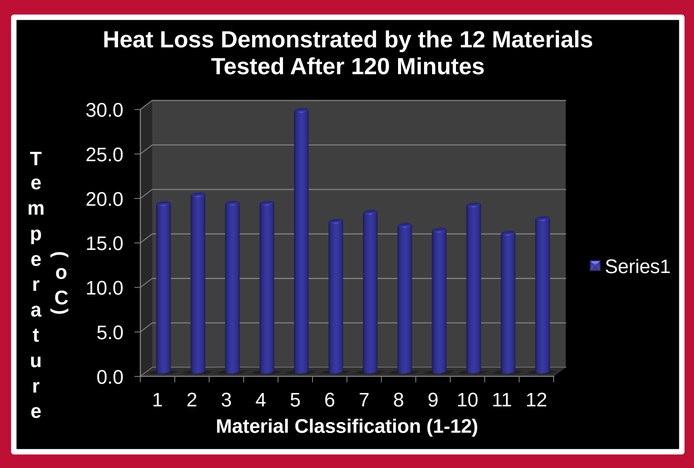
Two key areas of study created two novel methodologies:

•**One**: Materials were sourced and tested for heat-retentiveness, by using calibrated temperature sensors and comparing the changes in temperature inside a given material, over a period of 150 minutes per test. Sodium-acetate phase change heat pads were used as the heat source. This aspect of the project compared a total of 12 different materials and combinations of materials, over a total of 72 tests.

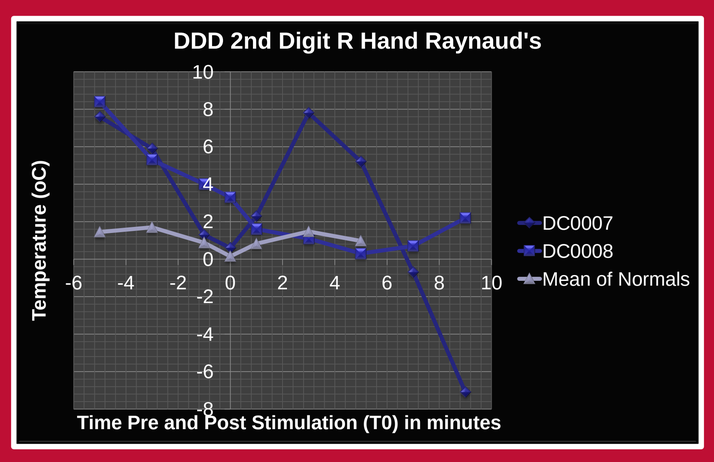
•**Two**: Subjects (n=6, 4m, 2f) were invited to take part in an ethically approved pilot study to visualise the effects following a 2 minute warmth provocation. All subjects signed consent and had an acclimatising period of 15 minutes in a room at controlled temperature of 23ºC (±1ºC). Subjects then placed both hands under an incubator maintained at 29ºC (±1ºC). Temperatures were recorded every minute for 5 minutes pre-stimulation commencement and up to 10 minutes post-stimulation cessation, using Infrared thermography with off-line analysis. 2 of the female subjects reported a history of extreme coldness and numbness in the fingers, but did not have a Raynaud's disease diagnosis.

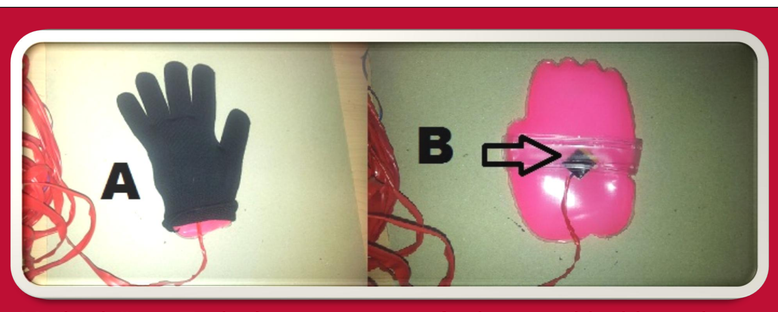
## 3 Results

**Experiment 1:** On average, material 9 and combination of materials 11 lost the least heat over 120 minutes.




**Experiment 2**: Subjects with a history of Raynaud's (DC0007 + DC0008) had different recovery profiles following warmth provocation, when compared to the mean recovery times of normal hands.




Method One: Typical arrangement of a heat pad inside a glove (A). The sensor was held in place using the heat pad "built in" strap (B).


Method Two: The typical set up of the infrared camera for viewing hands (A). Images B and C show the hands of one of the subjects as viewed by the naked eye (B) and through IR imaging 5 minutes following provocation(C). NB this subject had neurofibromatosis.

## 4 Conclusions

•**One** - materials with high heat retentive capabilities consistently retained more heat than materials with low capabilities. New materials were compared and one new material (material 9) outperformed all others. Material 9 was combined with another material to create a prototype (material 11), which performed better than any other combination of materials (1-4 and 12). Recommendations have been made to TONUS Europe, and gloves are due to go into production later this year; due to be tested by volunteers with Raynaud's and comparisons made with placebo glove(s).

•**Two** - The 2 subjects with Raynaud's symptoms experienced a different recovery profile when compared to normal hands. Subject DC0007 continued to normalise after provocation, yet after 7 minutes began to increase the DDD again. Subject DC0008 was hyper-responsive immediately following provocation, until 3 minutes later when the DDD plummeted and became a negative number. This profile could potentially be considered diagnostically relevant when assessing the DDD. A larger study is currently underway involving 42 subjects, and initial results are encouraging.

## 5 References

1. Silman, A., Holligan, S., Brennan, P., Maddison P. (1990). Prevalence of Symptoms of Raynaud's Phenomenon in General Practice. *BMJ,* **301**: 590-592.
2. Ko, G.D., Berbrayer, D. (2002). Effect of Ceramic-Impregnated "Thermoflow" Gloves on Patients with Raynaud's Syndrome: Randomized, Placebo-Controlled Study. *Alternative Medicine Review*, **7(4):** 328-335.
3. Mawdsley, A. H. (2011). Letter detailing feedback on currently available gloves from the chief executive off the Raynaud's and Scleroderma Association (UK), dated 23rd February, 2011.
4. Kim, Y.H., Siew-Weng, Ng., Heung, S.S. and Hee, C.A. (2011). Classification of Raynaud's Disease Based on Angiographic Findings. *Journal of Plastic, Reconstructive and Aesthetic Surgery,* **xx**: 1-9.
5. Wright, C.I., Kroner, C.I., Draijer, R. (2005). Non-invasive Methods and Stimuli for Evaluating the Skin's Microcirculation. *Journal of Pharmacological and Toxicological Methods*, **54**: 1-25.
6. Anderson, M.E., Moore, T.L., Lunt, M. And Herrick, A.L. (2006). The 'Distal–Dorsal Difference': a Thermographic Parameter by Which to Differentiate Between Primary and Secondary Raynaud's Phenomenon. *Rheumatology*, **46:** 533-538

**Acknowledgements: Chris Groves (TONUS Europe); KESS**