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# Validation of Cooling and Freezing Dynamics of Cooltech® Using an Experimentally Adjusted Physical Model

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**Original Research Article**

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**Abstract:** Apoptosis of adipose tissue through cold- Cryoadipolysis/Lipocryolysis- is an aesthetic procedure that reduces subcutaneous fatty tissue. Different studies have proven that this procedure is safe and efficient; however, the use of physical-biological models to describe the cooling dynamics is becoming increasingly necessary to gain a better technological control, because it allows to optimize the temperature and time of exposure of the tissue and provides a better coverage, all of which, in turn, make the use of equipment in Aesthetics more reliable: this is the purpose of this paper. This study validates the use of models containing known substances (water and olive oil), cooled with Cooltech® hand-held devices under standard cryoadipolysis conditions.
**Keywords:** Cryoadipolysis, lipocryolysis, physical-biological model, subcutaneous fatty tissue, validation, simulation, cooltech

## INTRODUCTION

The use of physical-biological models in experimental research is essential to pursue experiments or techniques that cannot be tested directly on living organisms [1]. Models allow carrying out studies that would otherwise be hindered by ethical or logistic restrictions. There is no doubt about its substantial contribution to the advancement of knowledge. However, one of the most important issues when working with models is to understand their scope and limitations. It is not hard to understand that the quality of the results obtained using this system will be directly linked to the model chosen and how truthfully it reflects reality.

One of the biggest obstacles for models is to get results that can be extrapolated. Or, in other words, the results obtained must be useful to describe in vivo behavior of the variables included. A highly complex model will be correlated with results in humans, although it will be much harder to interpret and implement. The challenge is to find models that replicate actual results, but that can also be interpreted from a physical and biological perspective. In any case, it is clearly necessary to keep developing models that allow scaling up to human beings [2], even more so in the field of Aesthetic Medicine, where modeling-based research is virtually non-existent.

There is another inconvenient, specifically concerning the equipment used in Aesthetic Medicine: there is a limited corpus of serious, reliable and transparent evidence. It is accepted that good sources of evidence might not always yield good evidence, but poor sources of evidence promise to deliver poor evidence every time. Therefore, professionals that want to base their work on evidence will face a much bigger challenge: on one side, they will need to develop the required abilities to distinguish between good and poor evidence, and, on the other hand, they must include that good evidence in their actions [3].

The purpose of this paper is to validate the use of physical models to describe the cooling dynamics of known substances (water and olive oil), in order to use them in the next stage, where the goal is to understand the way in which human fat behaves when it is subjected to thermal insult under conditions specifically determined by the lipocryolysis technique. For this purpose, a physical model has been created and adapted for the experiments.

## MATERIALS AND METHODS

A set up has been prepared (Figure 1) to simulate the cooling of human tissues during a session with the Cooltech® device, from High Technology Products, S.L. For this, two experiments with identical design —one with water and one with olive oil— have been carried out, including: i) monitoring of time-based temperature variation; and ii) recording of middle state or phase changes. The applicator was filled with water (experiment 1) and olive oil (experiment 2), and a session of cryoadipolysis was recreated with the Cooltech® device, which basically involved placing two aluminum plates at -8 °C for a certain amount of time.

Temperature was followed up using NTC (Negative Temperature Coefficient) probes, which were inserted in three different locations of the water and oil: one in the center of each fluid (c), one very close to the aluminum plate at 2,5mm from the plate (m) and one at the plate (p).

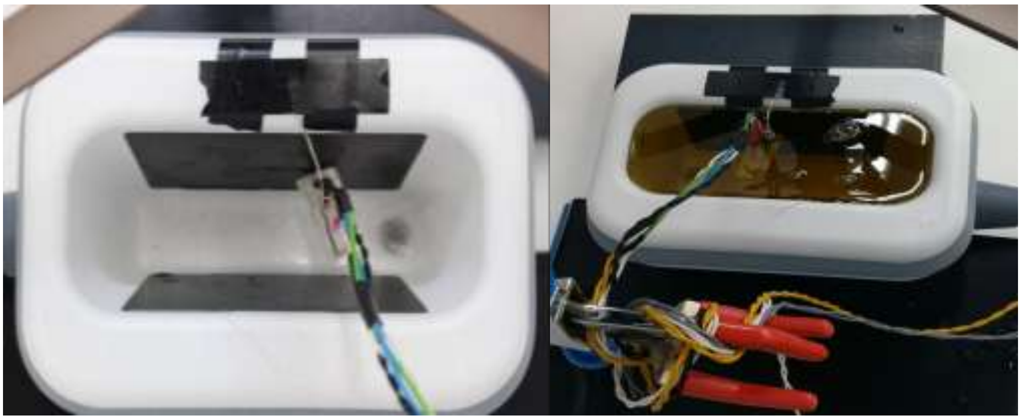

**Fig-1: Experimental set up. Cooltech® empty applicator, with temperature probes inside (above). Applicator with olive oil (below)**

The entire process was recorded and photographed using a Canon EOS700D camera, with 18-megapixel CMOS sensor and 1080p video. Physical models were created using the COMSOL Multiphysics® software. In order to efficiently model in vivo conditions, it was necessary to input the constitutive and geometrical parameters of the used hand-held device in the model. This was done with the Solid Works® software (Figure 2).

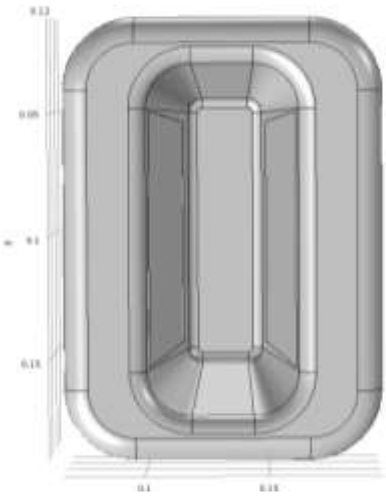

**Fig-2: Diagram of the modeled hand-held device, identical to the one used in the experiments.**

Simulations have been based on the physics of heat transfer in a liquid state. This physics solves the equation of heat transfer in liquids, and it is used to determine, in this case, the temperature on each point of the hand-held device based on time. To solve this equation, three parameters are required: calorie capacity ($C_p$), thermal conductivity (k) and density (ρ) of the liquid material.

With water, these parameters remain the same despite the change of temperature [4], but with olive oil, on the contrary, all three parameters are temperature-dependent [5]. Despite these differences, both materials should, in theory, exhibit a phase change. Logically, the latter must be included in the theoretical model, and for that it is necessary to define the initial material and an end material resulting from the state change. With water, ice parameters are widely recorded in the literature [4]. However, this is not the case with olive oil, of which there is very little reliable information about its variation after the phase change. Besides, olive oil, just like fat, is not a pure compound like water, but a mixture of several compounds, or a heterogeneous system. Therefore, each of its components is expected to experience a phase change at different temperatures, which is not observable like in the case of water, but a gradual change. To resolve this effect, olive oil's behavior will be modeled by adapting its viscosity (μ), since there is evidence of olive oil's viscosity increasing as temperature decreases (Figure 3) [6] and this change can be observed through an experiment.

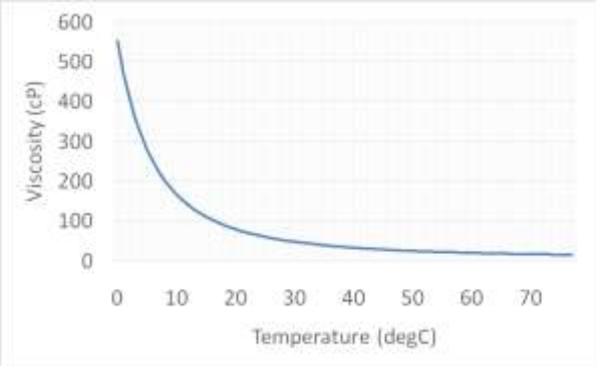


**Fig-3: Viscosity of olive oil based on temperature.**

The value of the latent heat of fusion of the material that will transform is another parameter required to carry out this model. Again, for water this value is well-established and can be obtained from the bibliography [4], but this is not the case for olive oil, so it must be deduced from known data of other oils (Table 1) [7].

To model the behavior of olive oil, a simulation was first carried out that did not take into account the phase change (Figure 5); then, a phase change to 5 ºC —because of its similarity to human fat— was modeled (Figure 6), and finally, a phase change to -6 ºC was modeled (Figure 7) [4].

**Table-1: $C_p$: calorie capacity, K: thermal conductivity, ρ: density**

| Substance | $C_p$ (J/(kg·K)) | k(W/(m·K)) | $\rho$(kg/m$^3$) | L(kJ/kg) | μ(cP) |
|---|---|---|---|---|---|
| Water | 4179 | 0.58 | 1000 | 334 | |
| Ice | 2052 | 2.31 | 917 | | |
| Oil | 1639+1.05T | 0.178-0.0000375T | 1098.8-0.636T | 80 | $\exp\left(1{,}26 - \frac{-163{,}51}{T - 240{,}64}\right)$ |

## RESULTS

### Curves Of Temperature Vs Time

***Water***

Based on temperature, water thermal parameters were considered constant. Their latent heat is known (Table 1). Figure 4 shows that the cooling obtained through simulation corresponds to the results from the experiments.

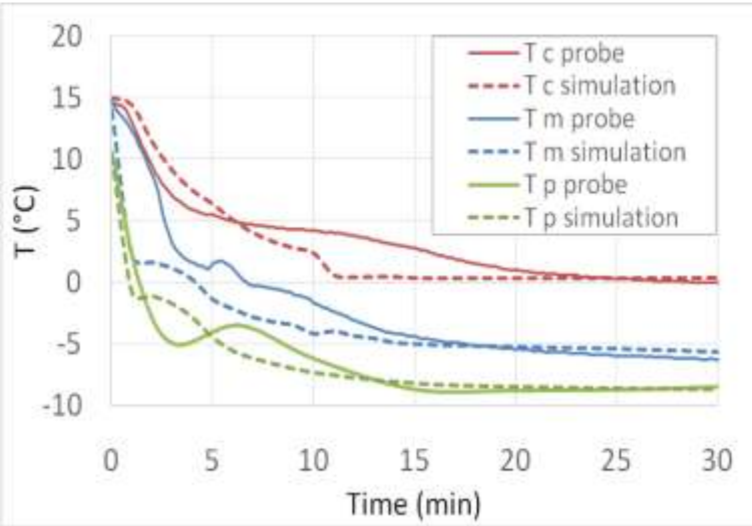


**Fig-4: Comparison of the water experiment (solid lines; Temperature values measured with probes) with the physical model (dotted lines; Temperature values simulated)**

The video recorded of the hand-held device during the 30 minutes of the experiment was compared with the video of the simulation with the physical model tested (Figure 5). Specially, the thickness of the ice layer formed in the water has been measured and compared with the simulation (Table 2). The simulation largely replicates the freezing of the water inside the Cooltech® applicator.

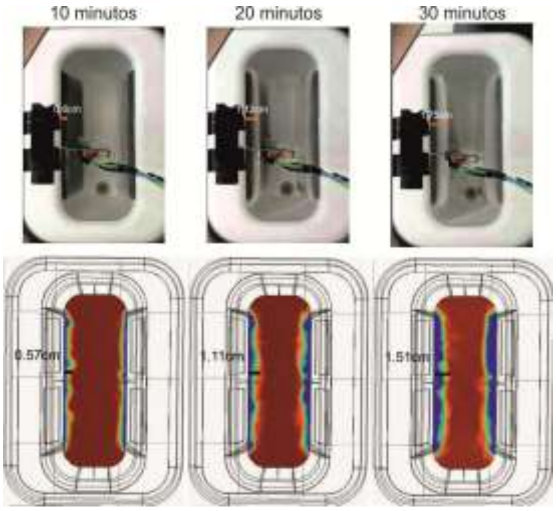


**Fig-5: Comparison of the video frames of the water experiment with images from the simulation with ice formation at 10', 20' and 30' after starting the Cooltech® process at -8 °C. The simulation images show the areas with phase changes in blue (ice) and without phase changes in red (water)**

**Table-2: Measurements of ice layer thickness of the images in Figure 5**

| | 10 minutes | 20 minutes | 30 minutes |
|---|---|---|---|
| Experiment | 0.6 cm | 1.2 cm | 1.75 |
| Simulation | 0.57 cm | 1.11 cm | 1.51 |

Figure 6 shows the ice left in the applicator after emptying it of non-frozen water, as a result of a 30-minute session of cryoadipolysis.

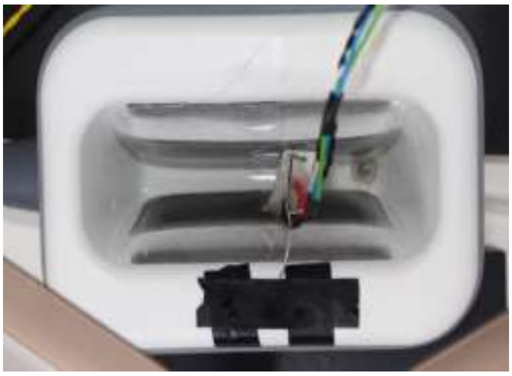

**Fig-6: Frozen water in aluminum plates 30 minutes after starting the experiment.**

***Olive oil***

First, a simulation was performed taking into account a physical model without a phase change. The result of the simulation is clearly different from experimental data (Figure 7). If the temperature of the central probe (red curves) is observed, the simulated temperature (red dotted curve) has a slower decrease than real temperature. This indicates that the physical parameters of thermal conductivity and calorie capacity of the simulation are wrong.

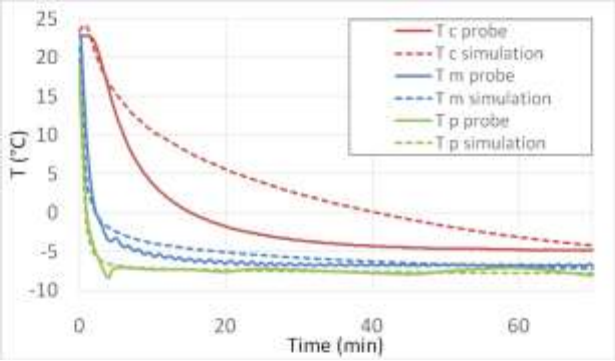


**Fig-7: Comparison of experimental data (solid line) and simulation without phase changes (dotted line).**

The second simulation included a phase change of olive oil to 5 °C, because of its similarity with human fat. Figure 8 shows the result. It is not consistent with experimental data either, since a phase change to 5 °C would imply that the temperature inside the fluid must reach 5 °C during the process (red dotted curve). However, the experiment shows a higher decrease in temperature (red solid curve).

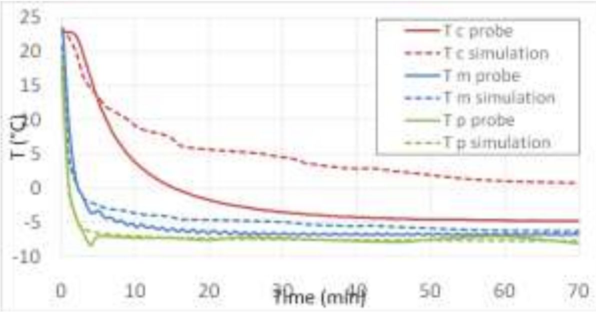


**Fig-8: Comparison of experimental data (solid line) and simulation of phase change adjusted to a phase-change temperature of 5 °C (dotted line)**

During the experiment, it was not fully possible to observe the freezing of olive oil, but there was an observable change in transparency, denoting a process of gelification or a variation in viscosity (Figure 9).

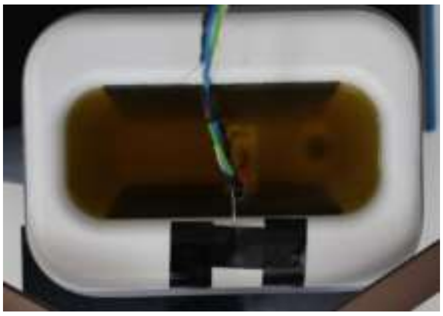

**Fig-9: Olive oil 70 minutes after starting the experiment. A change in transparency, obtained at a low temperature, is observed**

The coefficient relating the viscosity of a substance with its thermal conductivity and calorie capacity is known as the Prandtl number (1) [8].

$$Pr = \frac{C_p \cdot \mu}{k} (1)$$

To adjust the simulation to the results of the experiments, the $C_p$ and K parameters were modified, although its quotient remained constant. This was done to preserve the Prandtl relation. Besides, only the independent term of temperature of both parameters was changed, so not to affect its thermal behavior. In this model, an oil phase-change temperature of -6 °C has been considered [4], and the values obtained in the simulation are well adapted to the results from the experiments as long as the quotient between the calorie capacity ($C_p$) and the constant (K) equals 2,857.

Then, the minimal variation of the independent term of $C_p$ and K was estimated to fulfill the relation mentioned before, and the following coefficients were determined: $C_p$ = 749.33 + 1.05T and K = 0.26 -

0.0000375T, where T is the temperature in K. Figure 10 shows the data from the experiment and the simulation, taking the estimated dependencies of $C_p$ and K. The physical model was found to adapt the experimental data with very high accuracy.

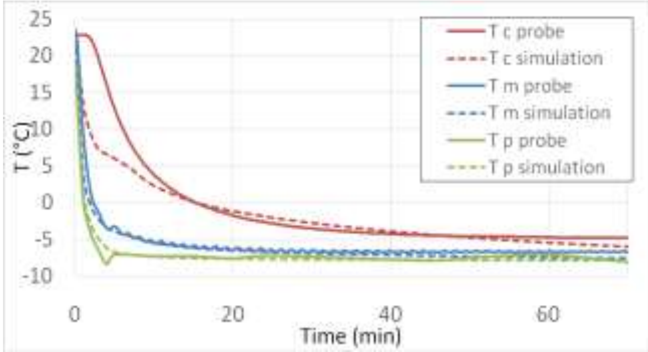


**Fig-10: Comparison of experimental data (solid line) and simulation of phase change adjusted to a phase-change temperature of -6 °C (dotted line) and latent heat of 80 kJ/kg**

As in the case with water, the whole cooling process of oil was recorded with a video camera, observing a change in transparency that can be attributed to a change in viscosity. To simulate this state change in oil, its viscosity was estimated based on temperature. A video with the change in viscosity of oil inside the Cooltech® applicator has been recorded and compared with actual images (Figure 11). Again, it is observed that the simulation with viscosity can be correlated with the change in transparency of oil inside the applicator.

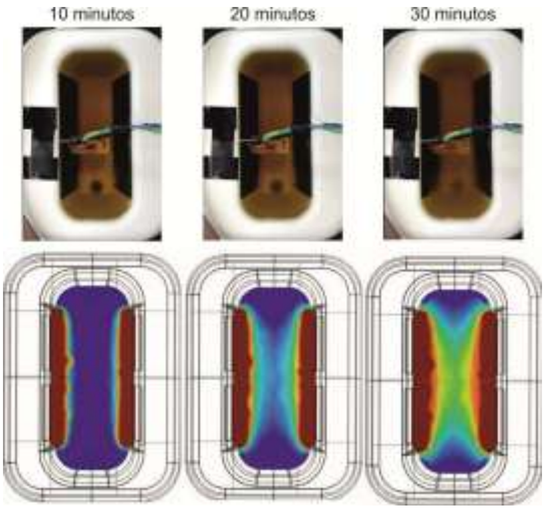


**Fig-11: Comparison of the video frames of the olive oil experiment at 10', 20' and 30' after starting the cryoadipolysis process with images from the simulation of viscosity, illustrated by a change of color from blue to yellow**

## DISCUSSIONS

These experiments have brought to light the possibility of using physical models and simulations to predict the behavior of Cooltech® Cryoadipolysis applicators (used in Aesthetic Medicine) for the cooling and freezing of substances like water and olive oil. But they have also brought to light the great importance of checking any physical model suggested through experiments. In this study, modeling the behavior of olive oil without considering a phase change or uploading in the model the data of a phase change to 5 °C would have been a mistake, making it impossible to understand how the behavior of this material affects a living being. On the other hand, and as expected, creating models with the data recorded in literature (phase change to -6 °C) gives more consistent results. However, these data had to be interpreted by means of the variation of another parameter, viscosity, since the actual phase change could not be observed.

Parameters had to be deduced and adapted to establish the suggested physical model. First, the latent heat of olive oil had to be deduced from the information about that same parameter for other similar oils. Second, although the relations between the adapted parameters (Prandtl number) remained the same, they had to be logically, although arbitrarily, changed. Finally, it is worth noting that the material used in the experiment (olive oil) is very similar to human fat due to its content of fatty acids, but it is also different from a physiological point of view.

However, this study has proven that it is possible to generate physical models enabling to simulate the cooling dynamics of a Cooltech® applicator containing a known substance.

Future studies will carry out experiments with fat to irrefutably confirm the coherence and consistency of the ideas underlying this study and the robustness of the suggested model.

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