

**Title:** Study for the evaluation of the efficacy of Lipocryolysis (EEEL).

**Authors:** Hernán Pinto<sup>1</sup>, Raúl Pinto<sup>2</sup>, Graciela Melamed<sup>3</sup>

Center: <sup>1</sup>Age Back Barcelona, <sup>2</sup>Pinto Institute Buenos Aires, <sup>3</sup>MEG Group Buenos Aires

**Abstract.** Since ancient times human beings have faugh to conceive methods that could help them reduce the accumulation of undesired fat tissue in their own bodies. Lipocryolysis has already been recognized as an effective therapy: localized fat reduction can be achieved by means of a combined, regulated and controlled heat extraction and vacuum in a single therapy. This study was design to quantify and measure this claimed reduction of local adiposities. For this purpose, 16 volunteers were recruited. The evidence suggested that Lipocryolysis is an effective therapy for localized adiposities reduction and that the reductions obtained are measurable and significant.

**Key words.** Lipocryolysis, adipocytes, triglyceride cristalization, localized adiposities.

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**Objetives.**

Primary: analyze and quantify the efficacy of Lipocryolysis in localized adiposities reduction.

Secondary: settle down the methodological basis to achieve future standard therapeutic protocols.

**Hypothesis.**

It is possible to reduce local adiposities by means of a combined, regulated and controlled heat extraction and vacuum in a single therapy known as Lipocryolysis.

## **Introduction.**

Since ancient times human beings have faugh to conceive methods that could help them reduce the accumulation of undesired fat tissue in their own bodies. In the last decades, the excessive body fat storage (obesity) has seen major breakthroughs in its treatment thanks to several clever devices manufactured and lots of therapeutic advances. We have witnessed the splendour of bariatric surgery, intra-gastric balloons, gastric bands and hundreds of diets. But on the other hand, methods that claimed effectiveness for local adiposities reduction were much less. And this number grew even thinner when considering only non invasive ones.

Few years ago, Manstein & Anderson et al from the Wellman Center at Massachussets, settled down the modern bases of the heat extraction for local adiposities reduction (6). Now-a-days, Lipocryolysis has been recognized as a valid and effective therapy (2) (4) and has already been accepted by many public health regulatory offices: FDA, HC, CE.

Before heat extraction, when starting a Lipocryolysis procedure, the machine

generates vacuum. By doing so it assures, in first place, the correct tissue positioning in the treatment unit and, in second place, the local blood flow reduction with the obvious loss of the its heat providing effect. This last is mandatory, for we need to be able to reduce adipose tissue temperature down to Lipocryolysis therapeutic range. Lipocryo® machine reduces the epidermic temperature up to 3,1 °C, an absolutely safe temperature that takes care of epidermal, dermal and every other surrounding tissue (3). Superficial temperature correlates perfectly well with the temperature achieved inside the adipocytes (real therapeutic goal). With the 3,1 °C in epidermis during the unavoidable 25 minutes or more that will last any session, an intra-adipocytary temperature below 10,2 °C will always be achieved. At these temperatures, not only saturated fatty acids inside adipocytes suffer physical changes (cristalization) but also unsaturated fatty acids whose cristalization temperature is lower. Biological messages occur. And these messages unleash the apoptotic stimuli that will finally destroy the cell in the incoming days or weeks.

## **Materials & methods.**

*n.*

Sixteen (16) volunteers were included in this trial. All of them were women between eighteen and fifty-five years old, with no systemic pathologies diagnosed, under no medication, not pregnant nor in lactancy period and with no specific Lipocryolysis contraindications: Raynaud's disease or phenomenon, cryoglobulinemia, local (application zone) lesions, recent scars, any type of wound, swelling, dermatitis, "cold hives", prominent varicosities.

Subjects must also had a BMI index ( $IMC = \text{weight}/\text{height}^2$ ) between 26 and 31 at trial beginning, for Crylipolysis did not appear to be effective in obese patients as in localized adiposities patients (4).

From 30 days prior to the first session until 60 days after the last Lipocryolysis session, subjects committed not to undergo any fat reduction treatment, not local nor general, like, among others, the following: diets, reducing products and cosmetics, liposuctions and other surgical procedures, detergent injections (eg: phosphatidylcholine, sodium

deoxycholate.), mesotherapy, or carboxitherapy among others.

### *Experimental groups.*

The whole sample were sixteen women ( $n=16$ ) that were randomly assigned to one of two groups of 8 subjects each. Aleatorization was performed by a simple aleatorization system. All subjects received the treatment in the same way, though each group received a different number of sessions. Subjects in the first group (G1) got a single Lipocryolysis session, while subjects that belonged to the second group (G2) received two Lipocryolysis sessions separated 45 days from one another. For proper data management, every subject was characterised with two numbers. The first number was according to the group of the subject and could be 1 or 2 for subject belonging to group 1 or 2 respectively. The second number was in accordance to the order in which the subject was included in its group: 1, 2, 3, 4, 5, 6, 7 or 8.

### *Samples.*

Every subject had the adipose panicle

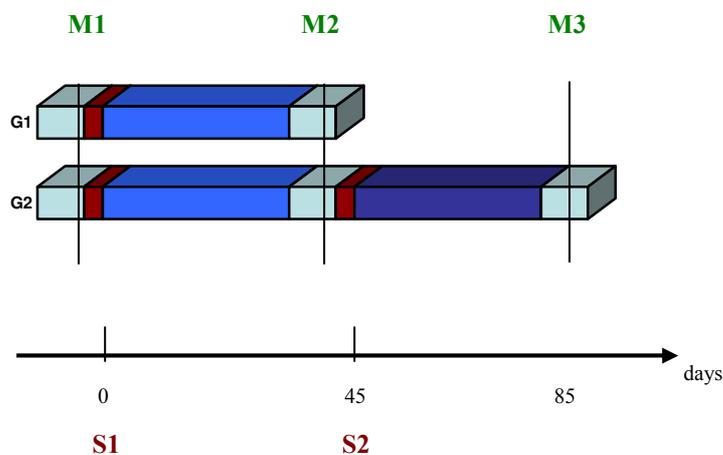
of the treatment zone measured three times. Two zones were assessed: right peritrochanteric area and left peritrochanteric area. First measurement (M1) -base or control measurement-, was performed 10 days prior to the first therapeutic session (S1). The second measurement (M2) was performed 40 days after the first therapeutic session (S1). And the third measurement (M3), was performed 40 days after the second therapeutic application (S2) (Fig. 1).

- maximum measurement: 80 mm
- precision: 99%
- grades: 0,2 mm
- measurement pressure: 10 gms/mm<sup>2</sup> (constant)
- repetibility: 0,2 mm

Plicometry was the measurement method chosen for it has already been very well proved the direct relationship between skin folds and subcutaneous adipose panicule thickness. A “Harpenden Skinfold Caliper” was used. Main technical specifications:

Pictures of every treated zone were taken. Every patient got 3 picture sets for every zone and session, P1, P2 and P3, that where taken at the same moment of sample plicometry (M1, M2, M3). For image recovery a Nikon Reflex – D5000 camera of 10,8 mmp with an AF-S Nikkor 15-80 lense was used. Plicometry measurements, pictures and all Lipocryolysis sessions were carried out by the same person.

**Fig. 1**



**Figure 1.** Session schedulle (S1 and S2) and data recovery vs. time. Control measurement (M1) and 40 days after 1st (M2) and 2nd (M3) therapeutic session.

*Therapeutic session. Cryolipolysis.*

Subjects were treated in each session with therapeutic combination of vacuum and cold. Lipocryo® machine from Clinipro S.L. was used. Main technical data and features:

- dimensions: 20 x 50 x 55cm
- weight: 24 Kg
- power source: 100-240 V/50-60 Hz
- max. power: 150 W
- touch screen VGA 10,4"
- Windows CE.Net
- contact dimensions of treatment unit: 17x5 cm
- max. vacuum system automatic regulation: 800 mbar
- max. automatic cooling energy: 150mw/cm<sup>2</sup>
- control circuits in base and treatment unit with RISC microcontrollers
- extraction and cooling energy representation, min. safety temperature in real time and with double control system
- liquid refrigeration

In every session, the application area was divided into two Lipocryolysis zones: right and left peritrochanteric. A session consisted in a single application for every zone. The procedure lasted between 24 and 32 minutes for each zone. The time variation was due to differences in the adipose panicle thickness of each patient. It is necessary to introduce this parameter manually. To assess this data a "Harpenden Skinfold Caliper" (identical to the one described above) was used. The acting protocol of every session was as follows:

- turn on and autocheck Lipocryo®
- pre-treatment photography
- plicometry
- parameter set up
- treatment zone cleaning
- treatment zone marking
- treatment zone gel application
- Lipocryolysis applicaion
- Treated zone cleaning
- Posttreatment photography

**Results.**

We have observed a reduction in the adipose panicle of the treated zones. The subjects of G1 experimented an average skin fold reduction of 7,18 mm for their single session. This represented an 18,26 % reduction of the skin fold thickness of the trochanteric areas (Fig. 2). The subjects of G2 experimented an average skin fold reduction of 6,06 mm for the first session. This represented a 17,48% reduction of the skin fold thickness of the trochanteric areas and an average reduction of 4,38 mm for the second session, that represented an additional reduction of 14,50% of the remaining thickness of trochanteric area skin folds 40 days after the first session (Fig. 3).

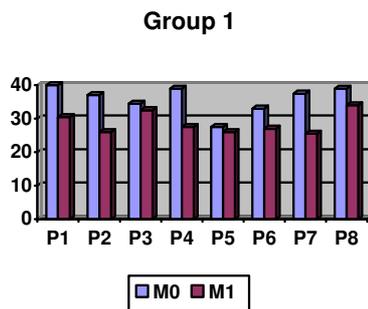


Fig 2. Pretreatment measurement (M0) and 40 days postsession (M1) of the eight G1 subjects.

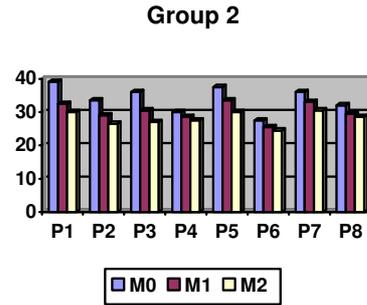


Fig 3. Pretreatment measurements (M0), 40 days post first session (M1) and 40 days post second session of the eight G2 subjects.

**Conclusion.**

Lipocryolysis is a very effective way of combining the therapeutic properties of vacuum and a specific way of extracting heat from adipose tissue. Every subject included in this protocol, experimented a reduction in the skin folds of their treated area. In the majority, this reduction was statistically significant. The group that received a second Lipocryolysis session got better results than the group that received a single session. The reduction obtained with the second session was minor than the reduction obtained with the first session but was still significant. The evidence suggests that Lipocryolysis is an effective therapy for localized adiposities reduction and that the administration of this therapy in two sessions separated by 45 days is more

effective than a single session treatment.

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**Interest declaration:** Dr. Hernán Pinto is medical consultant for Clinipro, S.L.

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