

Coolifting® CoolCell®, a new group of highly effective active ingredients for the reduction of cellulite in women.

Hernán Pinto, MD, PhD[^]

[^] i2e3 Biomedical Research Institute, Barcelona, Spain.

Abstract Cellulite is a very frequent clinical condition that, despite not being serious, constitutes one of the greatest aesthetic concerns of a large number of women. In recent years, some of the technologies that have allowed the development of devices and key tools in aesthetic medicine treatments have been consolidated. The aim of this article is to test the effectiveness of CoolCell®, a new treatment for cellulite that is administered with Coolifting® technology. We included 24 women who received 8 sessions of Coolifting® CoolCell®, one per week. Thermographic measurements were taken and satisfaction questionnaires were completed.

MeSH words: cellulite, thermography, Coolifting.

INTRODUCTION

Cellulite or Gynoid lipodystrophy is a metabolic disorder of the subcutaneous tissue that affects 80-90% of adult women.¹⁻⁵ It is characterized by an alteration of the skin and subcutaneous tissue of the affected areas, mainly thighs, buttocks and abdomen, in what is commonly called orange-peel.^{2,3} It is a very common clinical condition that, although not serious, constitutes one of the greatest aesthetic concerns of a large number of women.⁵

Cellulite presents a complex and multifactorial etiology. Its pathophysiology depends on very diverse aspects such as: anatomy, genetic susceptibility, hormonal changes, efficiency of lymphatic drainage or alterations in microvasculature, extracellular matrix or adipocytes.^{2,3} Although there are various products and treatments for reduction of cellulite, none of them is definitive. For this reason and given its complexity, it is always necessary to develop new methodologies to address

this metabolic disorder¹⁻⁴ in the best possible way.

In the last years, some of the technologies that have allowed the development of devices and key tools in aesthetic medicine treatments have been consolidated.⁶ Recently, the effectiveness of a device that improves the appearance of the skin by combining the therapeutic effects of avant-garde assets, pulsatile CO₂ and cold has been proven.⁶ Both the effects of CO₂ on tissues and those of cold are well characterized. CO₂, in addition to playing an important modulating role in some physiological processes (such as the Bohr effect⁷), also increases blood perfusion⁸, stimulates tissue oxygenation⁹ and reduces adiposity.¹⁰ During recent years, numerous studies have addressed its use in aesthetic medicine,^{11,12} confirming it as a therapeutic method that is easy to apply and without significant side effects.^{13,14} On the other hand, the use of cold for therapeutic purposes is widely known in medicine, whether as a vasoconstrictor,¹⁵⁻¹⁷ anti-

inflammatory, adipocytolytic, or analgesic, among others.

The aim of this work is to test the effectiveness of CoolCell®, a new treatment for cellulite that is administered with Coolifting® technology and thus, non-invasively and through a flow of pulsed, high-pressure CO₂ and low temperature.

MATERIALS AND METHODS

24 healthy women from 35 to 50 years of age were included. Inclusion criteria: without systemic, severe or skin pathologies and not receiving chronic treatment. 8 sessions of Coolifting® CoolCell® were carried out at the rate of one per week. Each session lasted 10 minutes, in which 1 CoolCell® kit was applied: 2 Coolifting® CO₂ cartridges, two CoolCell® active vials and a specific topical product. The session did not require any special preparation. All sessions were performed by the same professional and in the same areas: thigh and abdomen.

Coolifting® device (BeautyGun S.L., Spain) was used to apply the treatment. This is a 1.2 kg gun that is loaded with a 33gr CO₂ cartridge and a 4 ml vial. In this work, the effects of the active ingredients that make up the CoolCell® product have been evaluated, according to technical specifications.

Thermographic measurements were taken with the Cell Meter® professional kit (International Product & Services S.R.L., Italy) immediately before the first therapeutic session (control measure, S0) and 2 months after the 8th session (S1). The Thermoplate®30 was used under controlled temperature and humidity conditions. Thermographic images were analyzed with the Knime analytics software (Knime GmbH, Switzerland). With this software, thermographies' colors were

separated by RGB channels (figure 1). Once labeled and grouped in the correct way, variations of the colors green, blue, red and black could be analyzed.

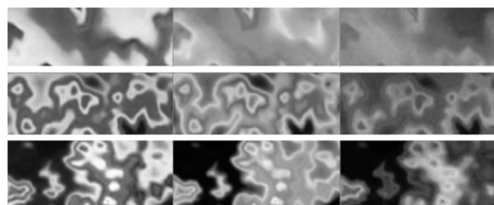


Figure 1. Color analysis. Channels obtained with Knime® Software.

For this analysis, only 80% (approximately) of the area represented by the thermographic photo was taken into account. The colors outside the frame were not included in the analysis (figure 2).

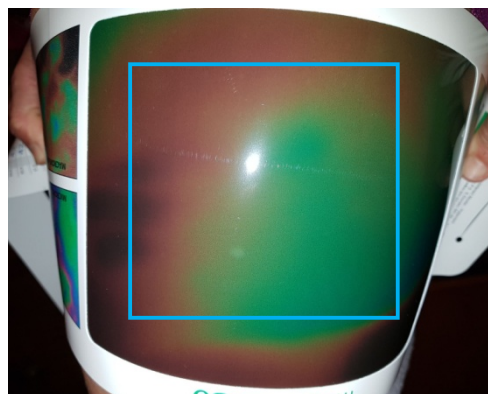


Figure 2. Thermography of the thigh. Blue frame: inside, the area included in the colorimetric analysis.

Additionally, both the patients and the professional who made the applications completed satisfaction questionnaires, with only one closed-ended question. The question was: Have you noticed any improvement in the treated skin? The possible answers were: No; I do not know/ I'm not sure; Yes; Yes, great changes and Yes, spectacular changes.

For the description of the sample, means and standard deviations were the respective indexes of central tendency and dispersion selected. For the comparison of

means, Student's T was used (paired samples and two tails).

RESULTS

Of the 24 women who started this treatment, only one had to interrupt it. The interruption was not due to any side effect. Of the 23 women who received the 8 sessions, 1 (4.34%) reported not being sure of having noticed improvements in her skin; 4 (17.39%) reported noticing the changes, 11 (47.83%) reported noticing great changes and 7 (30.44%) reported spectacular changes.

The color variation of black, red and blue was not statistically significant (figure 2). The variation to green went from 51% (20.25) pre-treatment to 62.25% (17.01) after treatment. This difference was statistically significant: $p = 0.043$.

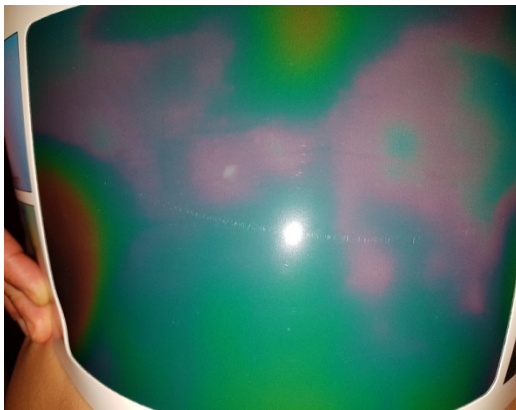


Figure 2. Abdominal thermography (left flank). Range of colors displayed with the Thermoplate®30 (standard): blue, red and green.

DISCUSSION

In this work we have tested the effectiveness of the Coolifting® device with the new CoolCell® active ingredients for the reduction of cellulite (although without taking into account cellulite sub-classifications). Future designs should

corroborate or rule out a greater or lesser action when one or another physiopathological component (eg.: edema, adipose tissue) primes.

A healthy thermographic picture, without cellulite, is homogeneous. The exact color of this situation of normality will be in the central area of the thermographic scale, but will depend on the plate used and the general conditions of the environment in which the measurements are taken. In this case, the homogeneous color seen in patients without cellulite was light green. The quantification of the color channels of the thermographic images showed some non statistically insignificant differences, but also significant and important color variations. The non-significant variation of the colors red and light blue is understandable, while these two colors represent intermediate categories in the thermographic scale. That is to say, that the decrease of a certain color (eg.: pink to green) can be compensated by the variation of another color (eg.: purple to pink). On the other hand, this study shows a significant variation towards the green and towards the homogeneity of the color. This, clinically, results in an improvement of cellulite and a reduction in edema, which is typically visualized as images of large, diffuse spots. These edematous spots and micro-nodules were visualized with different shades of red, purple and light blue.

On the other hand, the results of the questionnaires carried out are very positive, with 78.27% of the patients reporting great or spectacular changes. However, the fact that these data have been obtained in a self-referential manner is subjective and far from an ideal condition. Future studies should confirm these findings, using objective

methodologies to obtain the data. All in all, this type of information is very useful.

The results presented in this work indicate that the Coolifting® CoolCell® is an effective method for the treatment of cellulite. However, it will be necessary to carry out additional studies with a larger number of subjects and a robust methodology to confirm these findings. On the other hand, the CoolCell® effect was monitored until 2 months after the eighth

session. In the near future, it would be interesting to extend the monitoring of the results up to 6 months. Finally, although cellulite mainly affects women, it is important to emphasize that the conclusions of this work can only be extended to the female population. A study that includes men would allow extrapolation or discard the findings of this work.

REFERENCES

- 1.Christman MP, Belkin D, Geronemus RG, Brauer JA "An Anatomical Approach to Evaluating and Treating Cellulite." *J Drugs Dermatol.* 2017 Jan 1;16(1):58-61.
2. Hexsel D, Mazzuco R. Cellulite. In: Tosti A, Hexsel D, editors. *Update in Cosmetic Dermatology.* Mumbai: Springer-Verlag Berlin Heidelberg; 2013. pp. 21–32.
3. Zerini I, Sisti A, Cuomo R, Ciappi S, Russo F, Brandi C, D'Aniello C, Nisi G "Cellulite treatment: a comprehensive literature review." *J CosmetDermatol.* 2015 Sep;14(3):224-40. doi: 10.1111/jocd.12154.
4. Alizadeh Z, Halabchi F, Mazaheri R, Abolhasani M, Tabesh M *Int J EndocrinolMetab.* "Review of the Mechanisms and Effects of Noninvasive Body Contouring Devices on Cellulite and Subcutaneous Fat." 2016 Jul 3;14(4):e36727. doi: 10.5812/ijem.36727. eCollection 2016 Oct.
5. Luebberding S, Krueger N, Sadick NS. "Cellulite: an evidence-based review." *Am J ClinDermatol.* 2015 Aug;16(4):243-256. doi: 10.1007/s40257-015-0129-5.
6. Pinto H. Combined Use of Cosmetic Ingredients and CO₂ at High Pressure and Very Low Temperature for the Treatment of Skin Ageing. *Aesthetic Medicine.* 2015; 1(2): 68-72
7. Sakai Y, Miwa M, Oe K, et al. A novel system for transcutaneous application of carbon dioxide causing an "artificial Bohr effect" in the human body. *PLoS One.* 2011; 6(9):e24137.
8. Hartmann B, Drews B, Bassenge E. CO₂-induced acral blood flow and the oxygen partial pressure in arterial occlusive disease. *Dtsch Med Wochenschr.* 1991; 116(43):1617-21.
9. Ito T, Moore JI, Koss MC. Topical application of CO₂ increases skin blood flow. *J Invest Dermatol.* 1989; 93(2):259-62.
10. Brandi C, D'Aniello C, Grimaldi L, Bosi B, Dei I, Lattarulo P, Alessandrini C. Carbon dioxide therapy in the treatment of localized adiposities: clinical study and histopathological correlations. *Aesthetic PlastSurg.* 2001 May-Jun;25(3):170-4.
11. Millán E. Carboxytherapy in Pinto H, *Principios de Medicina Estética*, Ed. Ruiz del Amo, 2013.
12. Koutna N. Carboxytherapy: a new non-invasive method in aesthetic medicine. *Cas Lek Cesk.* 2006; 145(11):841-3.
13. Brandi C, D'Aniello C, Grimaldi L, Caiazza E, Stanghellini E. Carbon dioxide therapy: effects on skin irregularity and its use as a complement to liposuction. *Aesthetic Plast Surg.* 2004; 28(4):222-5.
14. Pianez LR1, Custódio FS1, Guidi RM2, de Freitas JN3, Sant'Ana E4. Effectiveness of carboxytherapy in the treatment of cellulite in healthy women: a pilot study. *ClinCosmetInvestigDermatol.* 2016 Aug 22;9:183-90. doi: 10.2147/CCID.S102503. eCollection 2016.

15. Patel R, Halem M, Zaiac M. J. The combined use of forced cold air and topical anesthetic cream for analgesia during the treatment of palmar hyperhidrosis with botulinum toxin injections. *J Drugs Dermatol*. 2009; 8(10):948-51.
16. Pinto H, Ricart-Jané D, Pardina E. X-ray diffraction analysis confirms intra-adipocitary lipid crystallization after a lipocryolysis-like stimulus. *Cryoletters*. 2013;34(6):619-23.
17. Pinto H, Melamed G. Contrast lipocryolysis pre and post session tempering improves clinical results. *Adipocyte*. 2014; 3(3)212-4.
18. Roure R, Oddos T, Rossi A, Vial F, Bertin C. Evaluation of the efficacy of a topical cosmetic slimming product combining tetrahydroxypropylethylenediamine, caffeine, carnitine, forskolin and retinol, In vitro, ex vivo and in vivo studies. *Int J Cosmet Sci*. 2011 Dec;33(6):519-26. doi: 10.1111/j.1468-2494.2011.00665.x. Epub 2011 May 13.