

Combined Use of Cosmetic Ingredients and CO₂ at High Pressure and Very Low Temperature for the Treatment of Skin Aging

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Abstract. The industry's ability to create new devices has exceeded all expectations. However, technological progress has been directly proportional to a blurring of the lines between science and business. The technology we have tested for this paper, called CooLifting™, is based on the non-invasive administration of active ingredients by means of CO₂ pulses at very high pressure and very low temperature. The purpose of this paper is the assessment of this device.

Key words: beauty, hydration, smoothness, gloss, antiaging.

Introduction

The industry's ability to create new devices has exceeded all expectations. By including different treatment principles and technologies in compact spaces, with power autonomy and great portability, treatments which could only be imagined ten years ago are now a reality. However, technological progress has been directly proportional to a blurring of the lines between science and business: useless devices have been designed; techniques which provide lesser results but higher economic gain have been developed; and sometimes, aesthetic medicine has succumbed to marketing. This is why all devices are tested at i2e3.

The number of studies and papers published on the use of carboxytherapy in

aesthetic medicine is growing exponentially.¹ Nowadays, not only is there significant evidence of its usefulness,² but also various information regarding its application as a complement of many other treatments, such as liposuction,³ and its role in modulating physiological processes, such as the Bohr effect.⁴ Its vasodilating effect and the concomitant increase in blood perfusion have been strongly documented for over 25 years,⁵ and are excellent for stimulating tissue oxygenation, among other things.⁶

On the other hand, the deleterious effects of extreme cold on human tissues is well-known.⁷⁻⁹ However, the use of extremely low temperatures as a treatment principle is much more recent. Cold is used in myriad ways in medicine: as an anti-inflammatory, as an analgesic,¹⁰ as an

adipocytolytic,¹¹ and as a vasoconstrictor, among others. Cold is applied in isolation or combined with other physical principles.¹² Its analgesic and vasoconstrictor effects mean that it will be present in any booth, medical office, and operating room around the world.

The technology we have tested for this paper, called CoolLifting™, is based on the non-invasive administration of active ingredients by means of CO₂ pulses at very high pressure and very low temperature. The purpose of this paper is the assessment of the CoolLifting™ device.

Materials & methods

Subjects.

16 healthy women were included in this study. Inclusion criteria: a) 35 to 50 years old; b) no severe, skin, face or systemic pathologies; c) not undergoing any chronic treatment or receiving any daily medication; d) no aesthetic medical treatments or procedures during one month prior to the session.

Sample.

Every subject had measurements recorded immediately prior to the therapeutic session (control measurement, S0) and 24-36 hours after the therapeutic session (S1).

Device.

Coolifting™, BeautyGun S.L., Barcelona, Spain. It is a 1.2 kg gun-like device that is loaded with a *session-kit* provided by the manufacturer, consisting of: a) a CO₂ 33 g cartridge, and b) a 4 ml vial with the active

principles (sorghum bicolor extract, wheat protein, hyaluronic acid) and other ingredients as per the technical specifications.

Measurements.

There are valid methods to measure optical, mechanical and tactile properties of the skin¹. Data was obtained under partially controlled ambient conditions (temperature and humidity) using different test probes, cameras and diagnosis devices:

- Cutometer® MPA 580, Courage Khazaka, GmbH, Köln, Germany.
- Corneometer® CM825, Courage Khazaka, GmbH, Köln, Germany.
- Frictiometer® FR700, Courage Khazaka, GmbH, Köln, Germany.
- Glossymeter® GL200, Courage Khazaka, GmbH, Köln, Germany.
- Reveal Imager®, Canfield Scientific, Inc., New Jersey, USA.

Questionnaires

Single-question, closed-answer and self-assessed questionnaires were answered by patients 24 hours after treatment. Question posed: Have you noticed any improvement in your skin? Possible answers: No (1 point); Don't know/ Not sure (2 points); Yes (3 points); Yes, great changes (4 points); Yes, spectacular changes (5 points).

Therapeutic session

All sessions were performed by the same professional. Sessions lasted 4 minutes (parameter set by the manufacturer, cannot

be changed). A drying towel was applied to the skin prior to the session. No antiseptic agent was used. Application was performed in right and left cheek areas.

Analysis.

Descriptive statistics were used to analyze the sample. Means and standard deviations were used as central tendency and dispersion indexes, respectively. A “Shapiro-Wilk Test” was used to assess normal-distribution. Whenever it was verified, a “Student T Test” was used to compare means and determine statistical significance. When normal-distribution was rejected, non-parametrical “Wilcoxon T Test” was used to determine statistical significance and median was used instead of the mean. Two-tailed tests for paired samples were used. SPSS 17.0 for Windows® (Statistical Product and Service Solutions Ibérica, S.L.U., Madrid, Spain) was the software used for statistical analysis.

Results

The sample analyzed consisted of 16 women ($n=16$) with a mean age of 41.875 (SD 2.825) years old. S0 stands for the control pre-treatment measurement and S1 for the final 24 hours post-treatment measurement.

Questionnaire

Table 1 shows the answers to the question *Have you noticed any improvement in your*

skin?

| <i>Answer</i> | <i>n</i> |
|-----------------------|----------|
| No | 0 |
| Don't know / Not sure | 0 |
| Yes | 10 |
| Yes, great | 5 |
| Yes, spectacular | 1 |

Table 1. Questionnaire answers. “n” represents the number of patients that provided that answer.

Corneometry.

S0 mean hydration: 60.934% (SD 8.474). S1 mean hydration: 66.337% (SD 7.649); $p=0.068$.

Fricitiometry.

S0 mean smoothness: 525,125 (SD 201.772). S1 mean smoothness: 391.012 (SD 167.628); $p=0.049$. Fricitiometry scale 1 to 1000 points (according to manufacturer device set-up).

Glossymetry.

Variable 1: total gloss. S0 mean gloss: 4.582 (SD 1.171). S1 mean gloss: 5.567 (SD 1.476); $p=0.048$.

Variable 2: isolated gloss, after DSC (diffuse scattering correction). S0 mean gloss: 2.536 (SD 1.084). S1 mean gloss: 3.419 (SD 1.508); $p=0.008$.

Cutometry.

Data was obtained from 19 variables (table 2).

| | n | Pre treatment (SD) | Post treatment (SD) | <i>p</i> |
|----|----|--------------------|---------------------|----------|
| R0 | 16 | 0.349 (0.091) | 0.333 (0.106) | >0.05 |
| R1 | 16 | 0.132 (0.056) | 0.107 (0.049) | >0.05 |
| R2 | 16 | 0.65 (0,077) | 0.711 (0.085) | <0.05 |
| R3 | 16 | 0.424 (0.112) | 0.400 (0.130) | >0.05 |
| R4 | 16 | 0.223 (0.083) | 0.204 (0.078) | >0.05 |
| R5 | 16 | 0.377 (0.107) | 0.396 (0.100) | >0.05 |
| R6 | 16 | 0.514 (0.136) | 0.474 (0,010) | >0.05 |
| R7 | 16 | 0.249 (0.055) | 0.266 (0.047) | >0.05 |
| R8 | 16 | 0.220 (0.060) | 0.202 (0.039) | >0.05 |
| R9 | 16 | 0.078 (0.030) | 0.071 (0.033) | >0.05 |
| F0 | 16 | 11.460 (3.584) | 10.493 (2.735) | >0.05 |
| F1 | 16 | 0.097 (0.186) | 0.830 (0.096) | >0.05 |
| F2 | 16 | 1.343 (0.452) | 1.355 (0.435) | >0.05 |
| F3 | 16 | 7.803 (1.789) | 7.662 (1.849) | >0.05 |
| F4 | 16 | 15.521 (4.173) | 14.155 (3.449) | >0.05 |
| Q0 | 10 | 63.644 (14.068) | 61.911 (11.229) | >0.05 |
| Q1 | 10 | 0.574 (0.071) | 0.566 (0.054) | >0.05 |
| Q2 | 10 | 0.411 (0.073) | 0.410 (0.051) | >0.05 |
| Q3 | 10 | 0.163 (0.041) | 0.157 (0.015) | >0.05 |

Table 2. Cutometry variables: comparison before and after treatment. “n” number of patients. SD: standard deviation. *p*: statistical significance. “R” variables: linear measurements, “F” and “Q” variables: area measurement.

Reveal Camera

This device performs standard and polarized pictures and shows a mexametric pigment distribution: melanin and haemoglobin. It was not possible to observe clinical differences though some pictures seemed to show a slight difference in melanin distribution (Fig. 2).

Discussion

Aesthetic treatments are applied seeking both instant and long-term effects. The

former (“flash” effects) are deemed qualitative and are usually due to tissue changes mostly associated with changes in a physical variable, such as water retention or light reflection. These changes may occur almost instantly and, as discussed in this paper, have statistical and clinical repercussions. Not only have gloss ($p=0.048$; $p=0.008$) and smoothness ($p=0.049$) increased in a statistically significant degree, but also all patients have noticed a change subjectively. 100% of

patients have reported a real and noticeable improvement: 31.25% rated it as a “great” improvement, and one patient rated it as a “spectacular” improvement. Although this information is subjective, it is of great importance in aesthetic medicine. Further research will be necessary in order to explore this subjective component adequately.

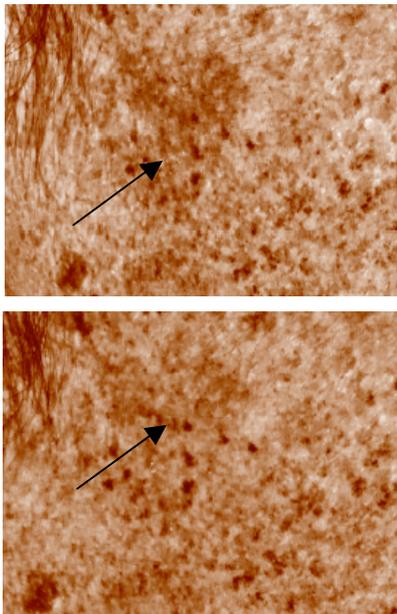


Figure 2. Melanin distribution. Top: pre-treatment. Bottom: post-treatment. Black arrow shows a slight change in colour.

The situation is different when it comes to assessing those tissue properties which depend on the number of cells performing a certain function or the greater or smaller degree of synthesis of certain molecules. These are quantitative properties, whose paradigmatic example is elasticity. Other examples may be the other mechanical properties of skin, such as distensibility or the depletion of the adaptation response to mechanical stress. These properties will be

affected by multiple different variables. However, for this example in particular, they will depend mostly on the quantity, quality, and layout of skin fiber proteins. Observing the clinical impact resulting from changes in processes where protein synthesis is stimulated is neither easy nor quick. When the purpose is to make physiological changes which will have an effect on tissue such that they can be noted macroscopically, patience is required.

Such is the case of cutometry. Although the R2 variable has resulted in positive and statistically significant changes ($p=0.041$), the fact that significance was isolated means that we should think that this finding is important but has no great impact on global cutometry analysis. Undoubtedly, much more attractive than the statistical significance of R2 is the overall trend of all 19 cutometry variables as a whole. R0 represents the passive behaviour of the skin when force is applied to it. It is the first maximal amplitude, the highest point of the first curve, and finds correlation with skin firmness. R2 represents the portion of the elasticity curve between the maximal amplitude and the skin re-deformation capability. This is the elasticity of the skin and the closer the value gets to 1, the more elastic the tissue is. R5 also correlates with elasticity, but analyzes the elastic component solely, not anchoring it to the viscous component. Another elastic variable that was analyzed was R6. It represents the elastic part of the visco-elasticity curve. The smaller the value, the higher the elasticity. R7 represents the relation between the elastic portion of the elasticity curve and the complete curve: the

closer the value is to 1 (100%), the more elastic the curve is. “F” and “Q” parameters are “areas” and are highly dependent on the maximum amplitude of the curve.

All cutometry variables have evolved positively, indicating greater elasticity and firmness, and lower depletion in response to mechanical stress. This will surely be a promising approach for this treatment in the future. However, the design of this study is not sensitive to the small and quick changes in the mechanical properties of skin. The second sampling is so immediate (24 hours post-treatment) that the phenomenon does not have enough time to reach significant levels. The pulsed mechanical stimulus, the action of CO₂, and even the release of NO^{xxx} may partly explain this phenomenon. Future research with serial application protocols and medium-term follow-up is recommended. These designs may assess whether the positive trend in the skin’s mechanical properties observed in this study will materialize into statistically significant changes.

Hydration has improved from a clinical standpoint, although the improvement has not been statistically significant. This observation may have been partly biased, as initial mean hydration was 60.934%. These values are relatively good and much more difficult to improve than lower values, such as those from which we have started in other studies.^{xx} An explanation for this apparently better initial hydration may be found in sample selection: The 16 volunteers were women between 35 and 50 years old with no pathologies. However, this fact has made it possible to confirm the

interesting improvement of this treatment on skin smoothness. In previous studies, we have had to deal with an uncomfortable fact: the spectacular improvement in hydration conditions biased the interpretation of frictiometry.¹³ A corneal layer with higher water content opposes more greatly to friction than a dryer one. In other studies, we witnessed that patients with poor initial hydration levels greatly improved their condition, misleading frictiometry results and interpretation. Further investigations with layered initial comparable hydration-level groups will be required to confirm these observations.

The overall conclusions of this study regarding the test of the CooliftingTM device are:

- i) It can achieve significant skin beauty enhancement in the very short term by improving tissue gloss ($p < 0.05$).
- ii) It can achieve significant skin beauty enhancement in the very short term by improving tissue smoothness (C).
- iii) It can probably achieve significant skin beauty enhancement in the very short term by improving tissue hydration (correct tendency, $p = 0.068$).
- iv) It can probably achieve significant skin beauty enhancement in the long term by improving skin mechanical properties such as elasticity and firmness (correct tendency, only R2 $p < 0.05$).
- v) It can possibly have a role in skin beauty enhancement in the long term by improving pigment distribution (isolated observations). Since it is logical to assume to some extent a dose-dependent effect, further studies with higher exposure protocols and long-term follow-up may provide new evidence.

Also, designs that include male subjects will be necessary to extrapolate these results to the general population.

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