

Cryoskin clinical study summary

BASED ON

STUDY OF THE EFFECTIVENESS OF CRYOSKIN 3.0 FIVE-SESSION PROTOCOL IN SLIMMING THE ABDOMEN ON PATIENTS PRESENTING AN ABDOMINAL CIRCUMFERENCE LESS THAN 95CM (37.4 IN.) IN WOMEN AND 102CM (40.1 IN.) IN MEN

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Introduction

- This is a brief summary of a clinical study commissioned by Prodesign and carried out by Dr Philippe Blanchmaison of the Societe Francaise d'Accreditation Sante, Paris, France
- The full paper is available on request
- This summary is for briefing purposes and does not include full clinical detail

The author

Philippe Blanchemaison, MD, has been a vascular medicine specialist in Paris, France for 28 years.

- Paris public hospital system (12 years)
- Chief editor of *International Vascular News* (8 years)
- Director at the Faculty of Medicine, University of Paris
- 264 published medical articles, 17 referenced in Medline
- 16 medical books
- Chairman or coordinator of 21 clinical trials and epidemiological studies
- Author or coordinator of research projects about vascular medicine, treatment of cellulite, vascular face rejuvenation and original protocols for Spa (creation of Aquabiking in 2001).



Summary of the study

Objectives

Main objective

Evaluate the slimming effectiveness of Cryoskin 3.0 on the abdominal area, using the standard treatment protocol

Secondary objective

Evaluate the safety of said protocol by monitoring side effects during the study

Methodology

Observational study with criteria evaluation before and after the treatment.

- Day 0: baseline visit (effectiveness criteria)
- Day 60: final visit after 5 sessions with Cryoskin 3.0, to evaluate effectiveness and side effects.

Demographic

- Subject >18 and under <70
- Waist circumference < 95cm for women and < 102 cm for men
- Stable weight for 3 months before the start of the study

Number of subjects

16 subjects

Duration

Maximum 3 months

How the study worked

Day 0: BEFORE

- Hypodermis thickness
- Weight, BMI, body fat %
- Waistline
- Digital pictures
- Satisfaction survey
- Report of adverse events

Treatment

- 5 treatments
- Every 15 days
- 34 minutes each
- Abdominal belt slimming protocol

Day 60: AFTER

- Hypodermis thickness
- Weight, BMI, body fat %
- Waistline
- Digital pictures
- Satisfaction survey
- Report of adverse events

Clinical signs

Severity of **cellulite** was evaluated and scored from **0 (no sign)** to **6 (major sign)**

There was a statistically significant improvement in all the signs measured:

- “Orange peel” without pinching
- “Orange peel” with pinching
- Fat pads
- Pain when pinching

There were further improvements as shown below:

| Effect | % of subjects showing improvement |
|---|-----------------------------------|
| Slimming (looked less fat) | 43.8% |
| Reshaping (general aesthetics) | 87.5% |
| Skin quality (toning, firmness, smoothness) | 100% |

Self-evaluation

The self-evaluation was based on a questionnaire.

| Question | Statistically significant improvement? |
|--------------------|--|
| Waist fat pad | Yes (33.3% reduction) |
| Belly fat pad | Yes (34.2% reduction) |
| Belly orange peel | Yes (30.5% reduction) |
| Smooth skin | Yes (17.4% improvement) |
| Silhouette | Yes (147.0% improvement) |
| Feeling good | No |
| Firm skin | No |
| Narrow waist | Yes (59.4% improvement) |
| Flat belly | Yes (99.0% improvement) |
| Clothes less tight | No |
| Swimsuit | Yes (51.1% improvement) |

Measurements

Waistline

- 15 subjects showed an average reduction of 1.85in. There was a significant 5.96% reduction for this group

Ultrasound

- There is a significant 18.96% (0.13in) reduction in subcutaneous fat

Weight and body mass

- There is no significant difference in weight or body fat before and after treatment

Psycho-sensory acceptability

- 94% of volunteers are satisfied with the method
- 88% of them would like to engage in regular treatments.
- 81% of volunteers judge that their time investment was worth the results achieved
- 94% of them noticing improvement of the skin,
- 75% a silhouette reshaping effect and
- 31% a slimming effect.
- 87% of the volunteers also acknowledged the relaxing effect of the method.
- 94% of the group wants to continue using this type of method and think it is more effective than other methods

Conclusions

From the study:

This technology, combined with the initial heating of the area, intensifies the thermal shock while preventing any risk of skin damage. The results are similar to suction method but without side effects.

This study, whose objective was to evaluate the effectiveness of a new slimming technique based on the use of the cosmetic device Cryoskin 3.0, demonstrated primarily a reshaping effect, in most volunteers. The reduction of the unappealing “orange peel“ aspect and the improvement of skin quality were significant.

Relevant biometrical methods, combined with a clinical study, conducted under strict medical supervision, validated the use of the Cryoskin 3.0 method for body treatments and the claim of a “reshaping effect on the silhouette”, in the context of this study protocol.

