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LIPOREDUCTION EFFECTIVENESS TEST ON

body sculptor
exCell⁺
EXPRESS TREATMENT

The « Bodysculptor ExCell » Class 1 medical device has been the subject of a technical advancement designated "Bodysculptor ExCell+" and intended to improve the performance of the first appliance in the field of drainage and extraction of fatty acids released by the basic technique.

The different research goals at the outset of this test were therefore:

- To **check the effectiveness of this advancement of the product** .
- To **reduce the length of the trial**, usually spread over 6 weeks, to 2 just weeks, in order to check whether the effectiveness is preserved in express treatment.
- To highlight **the extension in effectiveness of the medical device in the time after the cessation of treatment**.

Study sponsor:

COSMOSOFT - 95, bd. Haussmann -75008 PARIS

1- EQUIPMENT TRIAL

It concerns a low-frequency bio-magnetic wave generating device, for the slimming process, combined with a mechanical cellular lipid extraction system, by controlled cutaneous micropressure. The two techniques work in parallel, with the help of:

- Two micropressure boots and one micropressure belt incorporating the bio-magnetic wave system to treat wrapped areas (waist, hips, buttocks, thighs and calves)
- Two bio-magnetic inductive straps for the arms
- A bio-magnetic inductive mask to cover the oval of the face

1-1 The Bodysculptor technique

The electrical device tested is characterised by its creation, during use, of an alternative electrostatic field on the surface of the strap and an electromagnetic field due to fluctuations of the current in the conductor as well as the inductor currents in the first layers of the skin.

A study carried out by Professor LUCAS of CNRS (National Centre for Scientific Research) showed that the waves emitted by the Bodysculptor technique only reach the upper layers of the skin, thereby allowing the stimulation of keratinocytes, nerve endings and capillary loops leading to the release of mediators which, after migration, in their turn stimulate lipolysis at the adipocyte level (cf. bibliographic references below)

[1] J. LUCAS, CNAM -April 1998

[2] SCHALLREUTER K.U.(1997). Epidermal adrenergic signal transduction as part of the neuronal network in the human epidermis. *J Investig.Dermatol Symp. Proc.*, 2, 37-40

[3] SCHALLREUTER K.U. Lemke K.R., Pittelkow M.R., Wood J.M., Korner C and Malik R. (1995). Catecholamines in human keratinocyte differentiation. *J.Investig.Dermatol.* 104, 953-957

[4] BOSTON B.A. (1999). The role of melanocortins in adipocyte function. *Ann NY Acad. Sci.* 20, 75-84

[5] AKESSON L., AHREN B., EDGREN G and DEGERMAN E. (2005). Vpac2-R mediates the lipolytic effects of pituitary adenylate cyclase-activating polypeptide/vasoactive intestinal polypeptide in primary rat adipocytes. *Endocrinology*, 146, 744-750

[6] CHANG X, QIN K and LU Y. (2001). The study of effects of static magnetic field on SP-mRna in trigeminal ganglion in rats. *Hua Xi Kou Qiang Yi Xue Za Zhi*, 21, 235-237

The bio-magnetic waves emitted by Bodysculptor are at a frequency below 100 Hz at 40 volts. These waves, which are found at the bottom of the electromagnetic spectrum, correspond to inductor currents which are totally harmless to the skin and the human body. Thus we can prove that the electrical device studied, which broadly resembles a "mini electric blanket" and which creates electromagnetic fields, at a body level, infinitely weaker than domestic electrical installations surrounding us everyday, presents no risk to subjects using the equipment, especially for short-term use (12 x 1 hour in total).

1-2 The lipid extraction technique by controlled cutaneous micropressure

Coupled to the Bodysculptor inductive straps, controlled cutaneous micropressure provides:

- A sufficient mechanical pressure allowing successful extraction of fatty acids liberated by the bio-magnetic waves from the adipose cell
- An effective evacuation of extracted fatty acids, through the vascular system
- A general sensation of well-being and relaxation.

2- VOLUNTEERS

2-1 Inclusion criteria

- Age : from 21 to 75 years
- Sex : 22 female subjects
- Weight : body mass index (BMI), defined as the ratio P (weight in kg)/ T^2 (height, in metres), had to be between 23 and 45

Weight also had to be stable for the 3 months preceding the study.

2-2 No Inclusion criteria

- Pregnant or nursing women
- Volunteers wearing pacemakers
- Volunteers presenting with:
 - An acute or chronic condition having an unacceptable characteristic for the study concerned;
 - A recent feverish condition
 - Deep vein thrombosis
 - An infection (erysipelas, lymphangitis)
 - Severe arteriopathy
 - Cardiac insufficiency
 - Haemophilia
 - Capillary fragility
- Volunteers having undertaken a weight-loss diet or a conventional slimming treatment in the previous 3 months.

2-3 Prohibition and restriction

The diet must not be modified during the trial, excluding obvious errors in dietary health by the subject herself.

3- TEST PROTOCOL

22 female subjects participated in the clinical study which consisted of research into the liporeductor and lipodrainer effects of BodySculptor exCell+, after 12 sessions, without follow-up massage, of 60 minutes duration, spread over 12 days at one session per day.

These 22 adult volunteers presented with localised or generalised excess weight and were not subject to a restrictive diet.

3-1 Protocol used

- 1- Preliminary application of Spas Sérums Osmosculpt to the areas in contact with the straps (anti-cellulite on the body and anti-age on the face)
- 2- Positioning of biomagnetic arm straps and face mask.
- 3- Positioning of micropressure boots and belt incorporating biomagnetic straps
- 4- Carrying out 12 x 60 minute sessions



3-2 Experimental evaluations

3-2 Experimental evaluations

- Weighing of each volunteer (empty bladder)
- Measurement in centimetres of circumferences taken with an automatic rewind and constant tension tape measure in relation to individual reference points at the: waist –hips –thighs (right and left) –knees (right and left) –calves (right and left) –arms (right and left) (cf. figure 1)
- Measurement of bio-impedance with the aim of evaluating body fat (Impedance meter scales Silhouette by Tefal)

NB: All the measurements were taken by the same person throughout the study

Taking the measurements

MEASUREMENT IN CENTIMETRES OF CIRCUMFERENCES

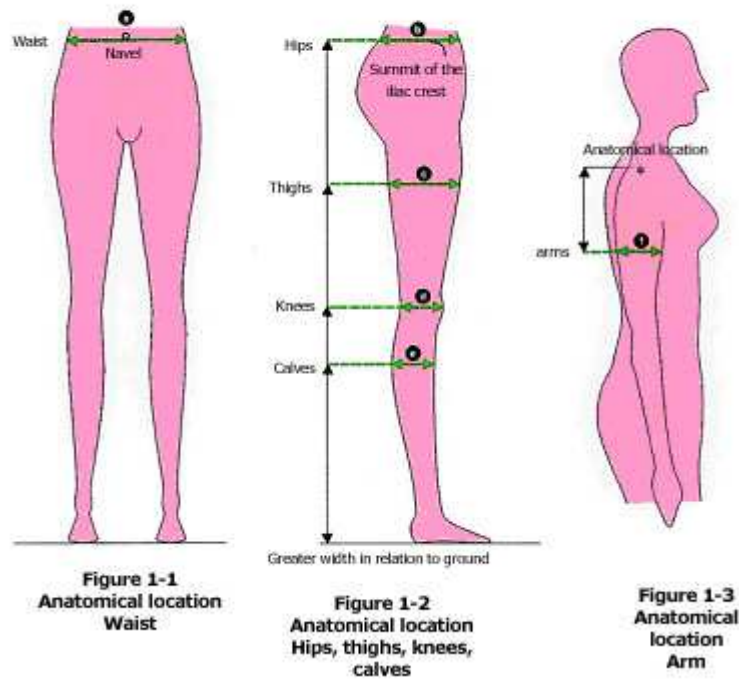


Figure 1

3-3 Analysis of data and interpretation of results

The averages obtained in each of the areas tested were calculated from the individual values recorded from all the panellists.

- The values obtained from measurement of circumference after 12 application sessions of the electrical device were compared to the initial values using Student test "t" in matching series, the statistical significance of which is obtained from $p < 0.05$.
- The synthesis of these analyses allowed the results to be interpreted.

3-4 Satisfaction survey

At the end of 12 treatment sessions, the following questionnaire was submitted to all volunteers to collect the personal findings of each person.

QUESTIONNAIRE « Express Treatment » <i>BodySculptor Excell⁺</i>
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Name : _____ Date : _____

Comments collected from panellists.

- At the end of each session, did you observe a general feeling of relaxation ?
Yes No
- During each session, did you observe sustained sleep?
Yes No
- After each session, did you observe a feeling of lightness, particularly in your lower limbs ?
Yes No
- Do you have circulatory problems?
Yes No
- If yes, have you noticed an improvement, especially in your legs?
Mild Medium Considerable
- At the end of treatment did you note any firming-up of your body?
Mild Medium Considerable

In your opinion, did use of the FaceSculptor face mask lead to

- A lessening of adipose overload to the face and neck?
Mild Moderate Considerable
- A firming-up of the skin of the face and neck?
Mild Medium Considerable
- At the end of each session, did you observe a general feeling of well-being
Yes No
- How satisfied are you following this BodySculptor ExCell + treatment?
Unsatisfied Satisfied Very satisfied

4- RESULTS OF THE TEST

The 22 volunteers who participated in this express treatment presented on average with obvious excess weight. So, 50% were obese, having a BMI of over 30.

At the end of the test, this percentage had gone from 50 to 27%, representing an improvement of almost 50%. In the same time, volunteers with a normal BMI went from 9 to 18%, also representing a 50% improvement.

The 22 volunteers at the beginning presented an average weight of 79.2 kg with average body fat of 42% of the average weight.

At the end of the test, the average weight loss, admittedly modest as an absolute value (3.1 kg), corresponded to an up to 70% loss of fatty tissue (2.2 kg).

The initial circumference measurements of the 22 volunteers were taken, in centimetres, at the waist, hips, knees, calves and arms, according to the precise anatomical locations in figure 1.

The measurements of the 22 volunteers taken at the end of this 12 day express treatment showed an average reduction in absolute terms from, according to the parameters of corpulence under consideration, 1.8 cm, at the calves and arms, to 7.5 cm and 7.2 cm, at the waist and hips.

A loss of 2.7 cm was also observed at the knees, and of 3.9 cm at the thighs. $P < 0.01$ (table 1)

Measurements in centimeters two weeks after the end of the test

11 of the 22 people tested, for whom the initial measurement parameters are incorporated into the results above, were subjected to further measurement, two weeks after the end of the treatment.

The results then, suspected but never quantified, were surprising since the additional losses achieved were 22 to 47% according to area

The new centimetre reductions ($p < 0.01$) were then:

- 0.8 cm for the arms and calves being in total -2.6cm
- 1.7cm and 1.4cm for the waist and hips, being in total respectively -9.2 and -8.6 cm
- 1.4 and 0.9 cm for the thighs and knees, being in total respectively -5.3 and -3.6 cm.

The results are absolutely in line with those of previous tests already carried out over 6 weeks instead of 2 as in this instance.

The statistics gathered on the variation of corpulence parameters (arms, hips, waist, thighs, calves) thanks to Student test "t", which seems the most appropriate, considering the number of volunteers, uses rough, non- standardised values.

The differences observed are highly significant ($P < 0.01$)

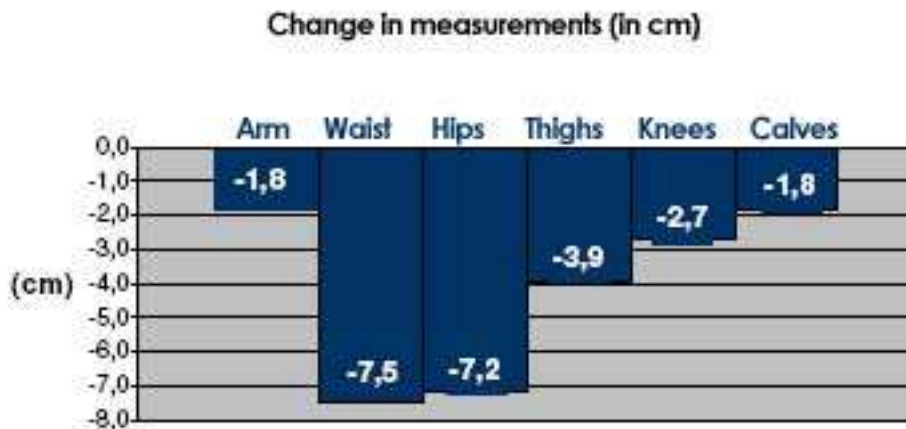
RESULTS OF THE EXPRESS TREATMENT

Change in measurements (in cm)					
Arm	Waist	Hips	Thighs	Knees	Calves
-1,6	-5,7	-6,2	-4,0	-2,6	-0,8
-2,5	-7,4	-8,7	-3,8	-3,0	-1,2
-2,4	-8,7	-12,2	-4,5	-4,3	-2,0
-1,7	-4,6	-4,2	-2,7	-3,1	-0,8
-1,1	-6,5	-10,1	-4,3	-3,3	-2,7
-2,4	-10,9	-11,4	-4,3	-3,9	-3,0
-1,2	-5,8	-5,5	-2,7	-2,0	-4,0
-2,3	-13,2	-7,1	-4,1	-2,0	-1,1
-1,7	-7,5	-7,1	-3,7	-2,3	-0,6
-2,6	-11,0	-6,4	-5,4	-2,5	-1,5
-2,7	-11,1	-10,6	-4,2	-3,2	-2,0
-1,4	-8,9	-7,7	-4,5	-3,3	-2,3
-2,6	-7,9	-6,8	-5,0	-2,8	-2,1
-2,1	-6,7	-4,8	-2,9	-2,3	-1,8
-1,6	-7,2	-5,5	-3,2	-2,2	-1,2
-1,2	-7,9	-6,2	-3,6	-3,4	-2,5
-1,8	-7,6	-7,2	-4,3	-1,5	-0,7
-0,8	-4,7	-4,2	-3,5	-2,5	-2,4
-1,3	-5,2	-6,4	-4,8	-2,3	-1,5
-1,6	-8,3	-8,4	-4,2	-2,7	-1,4
-2,3	-4,4	-6,9	-3,3	-2,5	-2,1
-2,1	-3,8	-4,6	-3,5	-2,4	-2,2
-1,8	-7,5	-7,2	-3,9	-2,7	-1,8

Change in weight	
S1	S12
61,0	59,0
66,5	63,2
91,8	87,3
70,9	69,3
75,5	72,7
91,6	87,2
63,3	60,4
93,4	87,9
73,2	70,1
70,6	66,7
65,9	61,6
100,3	96,2
86,6	83,4
77,1	74,8
69,8	67,8
79,7	76,8
84,5	82,3
70,0	67,6
86,9	84,7
76,2	74,0
119,2	115,5
67,9	66,7
79,2	76,1

Change in body fat	
S1	S12
19,4	18,1
24,3	22,4
44,0	40,5
26,9	26,1
28,8	26,7
38,4	35,4
19,5	17,8
46,8	40,9
26,6	24,6
29,1	25,2
22,7	19,0
50,3	47,5
35,2	33,2
27,7	26,5
25,1	23,7
32,6	31,1
40,4	38,6
25,2	23,9
37,4	35,2
33,6	31,8
67,5	64,1
25,4	24,3
33,0	30,8

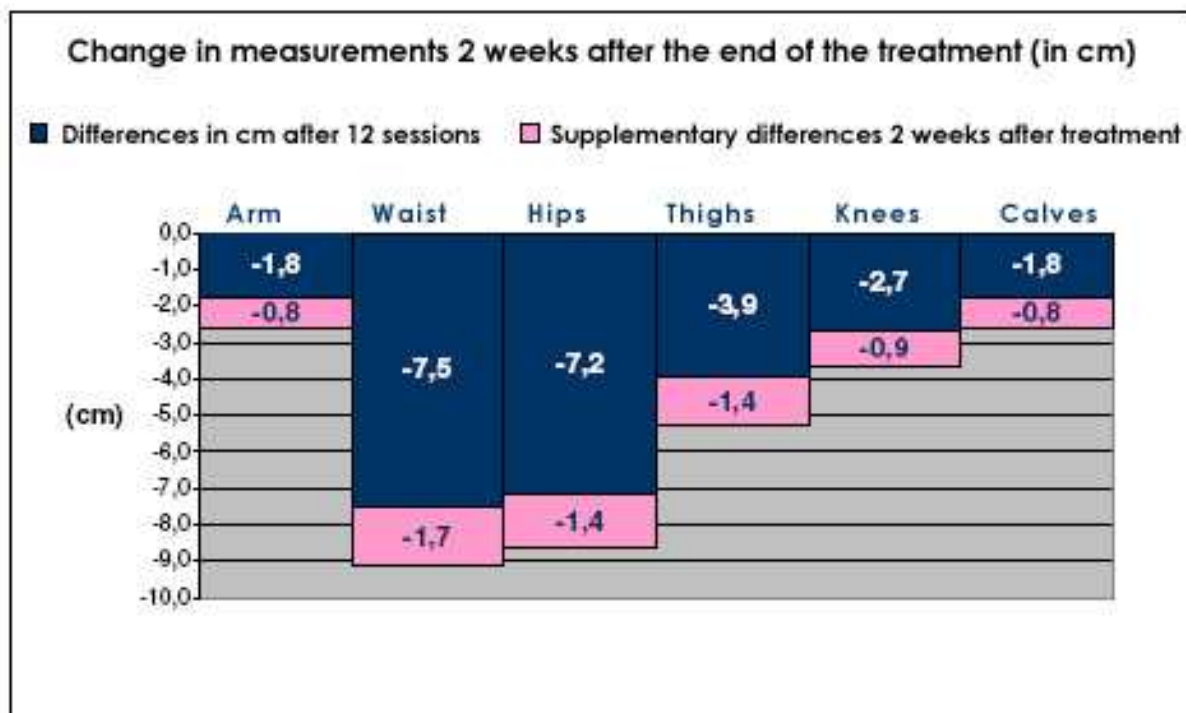
Diff. (kg)	S1	S12	Diff. (kg)
Weight	79,2	76,1	-3,1
Body Fat	33,0	30,8	-2,2



RESULT TWO WEEKS AFTER THE END OF THE EXPRESS TREATMENT

Change in measurements (in cm)					
Arm	Waist	Hips	Thighs	Knees	Calves
-0,7	-0,8	-0,9	-2,5	-1,4	-1,3
-0,7	-0,8	-1,2	-1,2	-0,8	-1,0
-1,2	-2,6	-2,6	-0,5	-0,7	-0,6
-0,8	-0,9	-1,2	-0,6	-1,1	-0,9
-0,9	-0,8	-0,9	-0,5	-0,1	-1,1
-0,6	-1,0	-1,7	-1,8	-0,9	-0,9
-0,9	-1,8	-1,0	-1,4	-1,0	-0,7
-0,7	-0,9	-1,0	-1,2	-1,0	-0,6
-0,5	-0,7	-1,1	-0,8	-0,6	-0,8
-0,9	-3,2	-1,4	-2,2	-1,2	-0,9
-1,1	-4,7	-2,9	-2,4	-1,5	-0,6
-0,8	-1,7	-1,4	-1,4	-0,9	-0,8

	Arm	Waist	Hips	Thighs	Knees	Calves
Differences in cm	-1,8	-7,5	-7,2	-3,9	-2,7	-1,8
Additional losses 2 weeks after treatment	-0,8	-1,7	-1,4	-1,4	-0,9	-0,8
% optimisation 2 weeks after treatment	45%	22%	20%	35%	34%	47%
Total losses 2 weeks after treatment	-2,6	-9,2	-8,6	-5,3	-3,6	-2,6



Results of the satisfaction survey

To questions put to the panellists at the end of the BodySculptor ExCell + express treatment they responded:

- At the end of each session, did you observe a general feeling of relaxation?
Yes 100%
- During each session, did you observe **sustained sleep**
Yes 82%
- After each session, did you observe a **feeling of lightness**, particularly in your **lower limbs**?
Yes 95%
- If you have **circulation problems**, have you noticed an **improvement**, notably in **your legs**?
Considerable 78
Mild 22%
- At the end of treatment did you note any **firming-up** of your body?
Considerable 36%
Medium 64%
- In your opinion, did use of the FaceSculptor face mask lead to a **lessening of adipose overload to the face and neck**?
Considerable 14%
Moderate 46%
Mild 40%
- In your opinion, did use of the FaceSculptor face mask lead to a **firming-up** of the **skin** of the **face and neck** ?
Considerable 18%
Modéré 56%
Mild 26%
- At the end of each session, did you observe a **general feeling of well-being**?
Yes 100%
- How **satisfied** are you following this BodySculptor ExCell + treatment?
Very satisfied 50%
Satisfied 50%

The results of this survey are completely in line with the figures for the express treatment

5- DISCUSSION

- The « BodySculptor exCell + » technique allows the almost-specific reduction of body fat without significant modification of the lean tissue. So, it acts well as a slimming process, and not for weight-loss, which is only concerned with excess fat
- The average loss of centimetres from the body, after a 12 consecutive day express treatment, corresponds to an average loss of two clothes sizes.
- The results seen immediately after the express treatment are optimised, in the two weeks following, by 34% on average.

The issue of slimness is not purely of an aesthetic nature, but is found above all in the wider field of health.

So the WHO and the national cholesterol education program have retained the waist-size measurement as one of the criteria for metabolic syndrome, which is a determining cause of type 2 diabetes and of cardiovascular diseases.

The maximum waist size tolerated is 88 cm for women and 102 cm for men.

Very recently, 21 scientific experts from the Fond Mondial de Recherche contre le Cancer (the World Cancer Research Fund), having evaluated the results of 7000 worldwide studies carried out over the past 50 years, placed slimness in first position in a list of recommendations to reduce the risks of a cancer appearing.

(Fonds Mondial de Recherche contre le Cancer-18th December 2007)

In this context, the contribution of a medical device such as the BodySculptor exCell+ which allows a selective and significant reduction of body fat can only be positive.

6- CONCLUSION

It was demonstrated by this study that an intensive 2 week treatment had broadly similar results to those achieved with a traditional 6 week treatment.

- The test panel were aged between 21 and 75. The results were equally convincing regardless of age.*
- No unwanted secondary effects were reported or observed, even among elderly patients or those with metabolic pathologies.*
- The BMI and body fat measurements confirm the specific action of BodySculptor exCell+ on the release of adipocyte fats.*

These results improve by 34%, two weeks after the end of the intensive treatment.

- Among patients displaying adipose overload to the face, the facial strap has been particularly valued for its refining results.*
- A clear improvement in quality and tone of the skin was noticed.*
- Well-being, relaxation and lightness have been experienced and appreciated by all the patients.*

They were all equally satisfied and motivated at the beginning and the end of the treatment.

In conclusion, the BodySculptor exCell+ proved effective and free from risk in the intensive two week treatment for excess body fat deposits.

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