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OBJECTIVE CLINICAL DEFINITION REPORT

Research on the liporeductive effects of a device called the “BodySculptor Intégral”, which delivers a low-frequency, low-tension current by means of 6 inductive straps placed around the arms, abdomen, thighs and calves. The inductive straps, which perfectly cover the adipose body zones, create an alternating electrostatic field on the skin surface, as well as an electromagnetic field due to current variations in the conductors and to the skin-level induced currents. The test was conducted over six weeks, with two sessions per week, on 23 adult volunteers, of which 3 were males, without any diet whatsoever.

Promoter of the study:

Cosmosoft — 95 Haussmann Boul. 75008 Paris

1/ Objective of the Study

The study consists in evaluating the specific reduction of a person's auxiliary adipose weight, in the absence of any restrictive diet, after twelve 55-minute sessions with a device equipped with 6 insulating electric straps creating weak electromagnetic and electrostatic fields.

The reduction in body fat is evaluated in weight, particularly through bio-impedance measurement at different levels of the body showing marked adipose localization.

2/ Relevance of the Test

Fatty tissues normally represent between 15% and 20% of body weight for women, which corresponds to between 50 and 80 milliard 1 adipose cells, or adipocytes.

One of the main features of the adipocytes is their faculty to change volume (between 27 and 40 times their initial size) quickly by storing fat as triglycerides. [1]

The anatomical localization of adipose tissue is a true secondary sexual character, under hormonal influence.

In men, it is predominant above the waist, at the level of the abdomen and shoulders (android-type adiposities, under the influence of androgens).

In women, it is concentrated below the waist, at the level of the lower part of the abdomen, the buttocks and the thighs (gynoid-type adiposities, under the influence of estrogens). [2]

¹ Pour l'UE, selon *Webster's third new international dictionary of the English language*. Remplacer par "billion" si le marché visé est Yankee.

Mass distribution of different body compartments [3]

Table 1

Grease	20%
Space extracellulaire	22%
Viscera	8%
Muscles and cellular mass	32%
Skin and skeleton	18%

3/ Electric Device under Evaluation

The object of the patented invention is an electric device, alleged to ensure a reduction in auxiliary adipose weight. This device consists of 6 insulating straps, meant to gird the body at the level of the arms, abdomen, thighs and calves.

The straps are equipped with a clinched conductor in successive strands, alternately oriented in either direction.

The conductor, supplied under low tension (40V) at a frequency of 50 Hz, is drowned in insulating foam with a plastic fire-protection covering.

The electric device, when used, creates an alternating electrostatic field on the strap's surface, as well as an electromagnetic field due to current variations in the conductors and to the upper-skin-level induced currents.

CNAM Professor in Industrial Technology J. Lucas [4] evaluated (April 1998) the theory behind the system of device-emitted waves, which apparently remain confined to the first layers of skin (2 to 3 mm), whereas adipocytes are generally located deeper (about 1 to 2 cm).

Therefore, one can legitimately claim that the electric device under consideration, which schematically resembles a “miniature heating blanket” and develops body-level electromagnetic fields far weaker than those put out by everyday electric installations in the home, presents no risk to those who use this device, especially over a short period (a total of twelve one-hour sessions).

4/ Volunteers

4-1 Inclusion criteria

- Age: between 22 and 60 years
- Sex: 20 females, three males
- Weight: Body Mass Index (BMI), defined as W (weight, in kg) / T^2 (size, in meters), had to be between 23 and 45. Weight was also required to have remained stable for three months prior to the study.

4-2 Non-Inclusion criteria

Pregnant or nursing volunteers

Volunteers with: acute or chronic disorders of a nature such as would affect the study; or a recent febrile illness.

Volunteers who had followed any restrictive diet or weight-reduction treatment at any time during the three months preceding the study.

4-3 Prohibitions and restrictions

The diet could not be modified at any time during the entire duration of the test, except in cases of flagrant mistakes for the individual in his/her food hygiene.

4-4 Number of volunteers

The study was conducted on 23 volunteers (20 females and 3 males), adults, presenting local or general weight overcharge.

5/ Protocol of the Clinical Study

Twenty females and three males, whose average physical characteristics are described in Table 2, participated in the clinical study, which consisted in researching the liporeductive effects of an electric device delivering a low-frequency, low-tension current, with six insulated electric straps placed around the arms, abdomen, thighs and calves, creating an electromagnetic field due to current variations in the conductors and to the skin-level induced currents, after twelve 55-minute sessions over six weeks. These 23 adult volunteers showed local or general weight overcharge, and were submitted to no imposed restrictive diet whatsoever.

Protocol used

1. Coating of zones which will be in contact with the straps with Softslim's Gel Anti-Capitons, then wrapping in stretchable plastic film.
2. Twelve 55-minute sessions with the BodySculptor Intégral.
3. Kneading of the treated zones using the LipiDrainor vibratory draining device, and Softslim's Gel Anti-Capitons, for 20 minutes.
4. Classical slimming massage for about 10 minutes.
5. Taking measurements.

body } *sculptor*
Integral



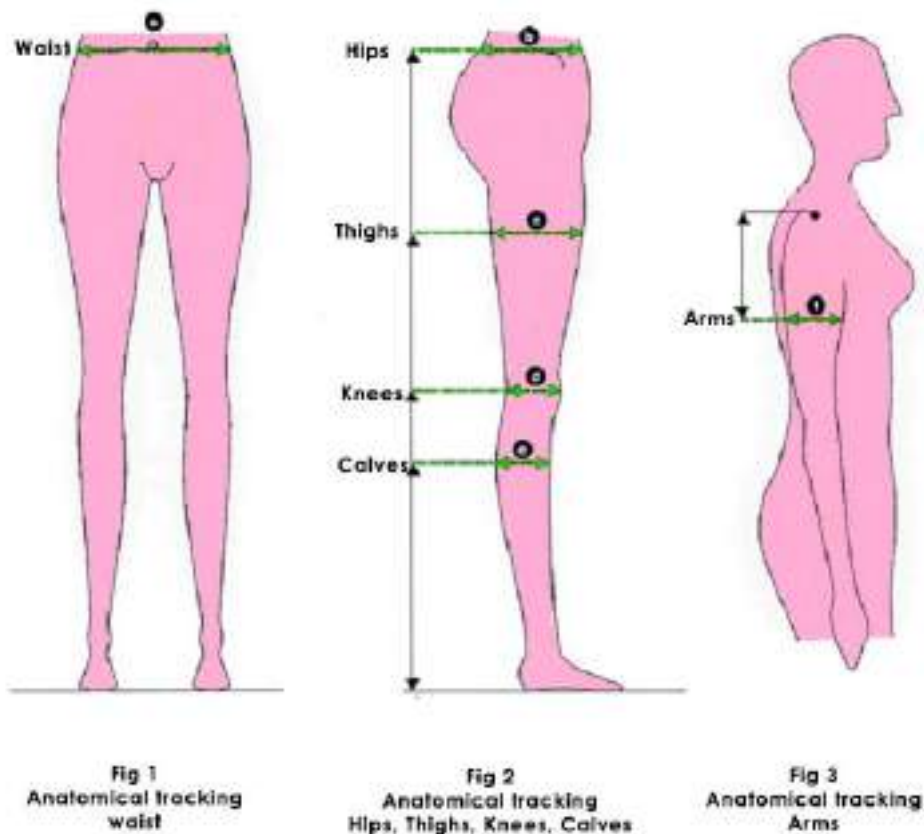
Experimental assessments

- Weighing of each volunteer (with empty bladder)
- Evaluation of circumferences, in centimeters, with a self-rewinding, constant-tension tape measure, at individual reference points for the waist, hips, thighs (right and left), knees (right and left), calves (right and left), and arms (right and left). (Cf. Figure 1.)
- Bio-impedance measurement, in order to evaluate body fatness (Tefal's Silhouette impedance bridge).

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

Evaluation of circumferences, in centimeters

Figure 1



Data analysis and interpretation of results

Averages obtained for each tested zone were calculated from individually determined values carried to all test subjects.

- Values obtained when measuring circumference after 12 sessions with the electric device were compared to initial values using Student's "t" test for matched sets, significance for which starts at $p < 0.05$.
- A synthesis of these analyses has allowed the interpretation of the results.

6/ Results of the Clinical Study

6-1 Physical characteristics of volunteers at the start of the test (Table 2)

Results of clinical test of BodySculptor Integral

23 individuals / 12 sessions

Table 2

Pseudo	Sexe	Age	Waist(m)	Initial Weight(kg)	Loss Weight(kg)	Initial fatty mass (kg)	Loss fatty mass(kg)	Initial BMI (kg)	BMI after 12 sessions
FABS	F	47	1,62	74,1	3,0	29,5	4,5	28,2	27,1
INBA	F	32	1,64	66,6	3,0	22,9	3,9	24,8	23,6
MYKE	F	28	1,70	82,6	3,2	33,3	4,2	28,6	27,5
NOEL	F	39	1,70	81,3	5,2	32,8	5,8	28,1	26,3
IMBR	F	31	1,60	85,2	6,0	39,9	7,1	33,3	30,9
RIHA	M	25	1,66	105,6	6,0	37,5	4,9	38,3	36,1
FRAL	M	57	1,72	131,6	9,6	60,6	10,2	44,5	41,2
NAEL	F	58	1,55	105,2	1,2	55,6	1,6	43,8	43,3
NABO	F	60	1,63	74,2	5,0	28,9	5,4	27,9	26,0
GABE	M	34	1,68	97,1	8,4	31,2	8,6	34,4	31,4
BOMH	F	45	1,60	91,8	3,2	45,9	4,4	35,9	34,6
AMHA	F	43	1,67	99,3	7,1	50,5	7,7	35,6	33,1
THAT	F	31	1,57	83,4	6,4	38,8	6,6	33,8	31,2
NEBA	F	38	1,65	69,3	2,1	24,1	2,9	25,5	24,7
AMCH	F	35	1,67	75,1	5,9	28,8	6,1	26,9	24,8
AZEL	F	24	1,72	69,7	4,9	23,4	4,9	23,6	21,9
LAAA	F	34	1,60	68,3	6,7	25,8	6,5	26,7	24,1
YOTE	F	36	1,65	74,0	7,7	28,5	7,0	27,2	24,4
SAEL	F	44	1,68	88,0	5,8	39,2	6,1	31,2	29,1
ANMR	F	22	1,61	78,2	4,8	32,0	5,3	30,2	28,3
MYTR	F	27	1,69	68,9	3,6	23,2	3,7	24,1	22,9
HEHM	F	30	1,69	66,4	2,3	21,8	3,3	23,2	22,4
OLBS	F	35	1,67	73,9	4,6	28,1	4,9	26,5	24,8
Average		37	1,65	83,0	5,0	34,0	5,5	30,5	28,7
NEBA	F		38	1,65	69,3	2,1		24,1	2,9
AMCH	F		33	1,67	75,1	5,9		28,8	6,1
AZEL	F		26	1,72	69,7	4,9		23,4	4,9
LAAA	F		34	1,60	68,3	6,7		25,8	6,5
YOTE	F		36	1,65	74,0	7,7		28,5	7,0
SAEL	F		44	1,68	88,0	5,8		39,2	6,1
ANMR	F		22	1,61	78,2	4,8		32,0	5,3
MYTR	F		27	1,69	68,9	3,6		23,2	3,7
HEHM	F		30	1,69	66,4	2,3		21,8	3,3
OLBS	F		35	1,67	73,9	4,6		28,1	4,9
Average			37	1,65	83,0	5,0		34,0	5,5

23 volunteers, averaging 37 years of age and 83 kg, were selected.

Average Body Mass Index (BMI) was 30.5, indicating pronounced average obesity for all volunteers.

In fact,

- **4 volunteers show a normal BMI, between 18.5 and 25, i.e. 17% of subjects;**
- 9 show overweight, with BMI's between 25 and 30;
- 8 show obesity, with BMI's between 30 and 40; and
- 2 show severe obesity, with BMI's above 40.
- Average body fat of the 23 test subjects is 34 kg.

6-2 Evolution of the stoutness, weight and body fat parameters during the test (Tables 2, 3, and 4)

Results of clinical test of BodySculptor Integral

Table 3 23 individuals / 12 sessions

Pseudo	Waist(cm)		Hips (cm)		Thighs(cm)		Knees(cm)		Calves(cm)		Arms(cm)	
	Initial value	Loss(cm)	Initial value	Loss(cm)	Initial value	Loss(cm)	Initial value	Loss(cm)	Initial value	Loss(cm)	Initial value	Loss(cm)
FABS	92,5	6,5	107,6	7,1	63,9	3,4	38,4	2,1	39,0	1,2	29,7	2,7
INDA	84,5	9,3	109,9	8,9	60,8	3,2	35,7	2,5	34,6	1,0	32,6	1,7
MYKE	93,6	8,3	111,0	10,8	61,8	5,1	49,5	4,0	39,2	2,5	28,5	2,9
NOEL	98,9	9,5	112,9	11,9	62,0	4,6	48,0	3,0	38,5	1,9	32,4	5,5
IMBR	99,8	7,4	121,4	9,5	63,9	3,3	48,4	2,0	38,3	2,7	35,7	2,0
RHHA	109,5	8,5	114,7	8,9	56,4	2,9	69,0	-	-	-	30,0	2,8
FRAL	150,5	11,3	137,5	10,8	62,4	4,4	-	4,3	-	-	38,2	4,2
NAEL	114,2	6,8	148,4	8,4	69,0	4,3	52,4	3,9	43,7	2,2	37,1	2,7
NABO	94,3	5,6	107,6	7,8	58,6	3,4	52,5	2,2	36,7	0,4	27,7	3,7
GABE	116,8	8,7	114,6	8,6	69,2	4,9	-	-	-	-	34,7	4,6
BOMH	114,2	11,8	127,4	10,8	66,6	3,2	49,8	2,2	36,2	0,8	36,0	2,7
AMHA	105,4	10,1	117,2	11,4	67,1	7,5	68,2	4,5	40,6	3,4	36,6	5,2
THAT	110,5	9,7	116,4	16,1	66,7	5,7	49,1	2,5	37,2	1,9	31,8	2,6
NEBA	76,5	7,4	110,2	9,0	59,0	5,5	66,6	3,8	39,7	1,7	29,8	2,8
AMCH	90,5	7,7	116,8	8,4	64,3	3,3	62,0	2,4	41,8	1,4	35,7	1,8
AZEL	77,5	6,5	108,5	7,4	57,9	3,5	49,5	2,0	35,7	1,2	28,7	2,7
LAAA	95,2	7,8	111,6	9,5	65,0	6,3	65,7	4,0	48,7	2,6	36,4	4,0
YOTE	98,4	8,2	104,5	7,6	52,4	4,3	42,8	3,3	33,7	1,3	28,8	2,2
SAEL	100,8	7,5	121,6	8,4	65,1	4,2	49,4	3,4	37,9	3,1	30,8	3,4
ANMR	96,5	7,4	119,0	9,0	67,0	5,2	48,0	3,2	39,7	1,8	32,4	2,9
MYTR	78,9	6,8	109,9	7,2	59,8	4,0	42,2	2,4	36,6	1,2	28,7	1,1
HEHM	83,7	5,6	102,4	5,4	56,2	2,1	44,3	1,8	26,4	1,3	24,4	1,8
OLBS	97,5	7,0	111,0	9,1	59,8	6,9	44,1	5,5	34,7	2,8	32,0	4,8
MOYENNE	99,1	8,1	115,9	9,1	62,4	4,4	47,0	3,1	37,3	1,8	33,1	3,0
AMCH	90,5	7,7	116,8	8,4	64,3	3,3	62,0	2,4	41,8	1,4	35,7	1,8
AZEL	77,5	6,5	108,5	7,4	57,9	3,5	49,5	2,0	35,7	1,2	28,7	2,7
LAAA	95,2	7,8	111,6	9,5	65,0	6,3	65,7	4,0	48,7	2,6	36,4	4,0
YOTE	98,4	8,2	104,5	7,6	52,4	4,3	42,8	3,3	33,7	1,3	28,8	2,2
SAEL	100,8	7,5	121,6	8,4	65,1	4,2	49,4	3,4	37,9	3,1	30,8	3,4
ANMR	96,5	7,4	119,0	9,0	67,0	5,2	48,0	3,2	39,7	1,8	32,4	2,9
MYTR	78,9	6,8	109,9	7,2	59,8	4,0	42,2	2,4	36,6	1,2	28,7	1,1
HEHM	83,7	5,6	102,4	5,4	56,2	2,1	44,3	1,8	26,4	1,3	24,4	1,8
OLBS	97,5	7,0	111,0	9,1	59,8	6,9	44,1	5,5	34,7	2,8	32,0	4,8
MOYENNE	99,1	8,1	115,9	9,1	62,4	4,4	47,0	3,1	37,3	1,8	33,1	3,0

* Measures not taken: at these levels, modifications in men were not significant.

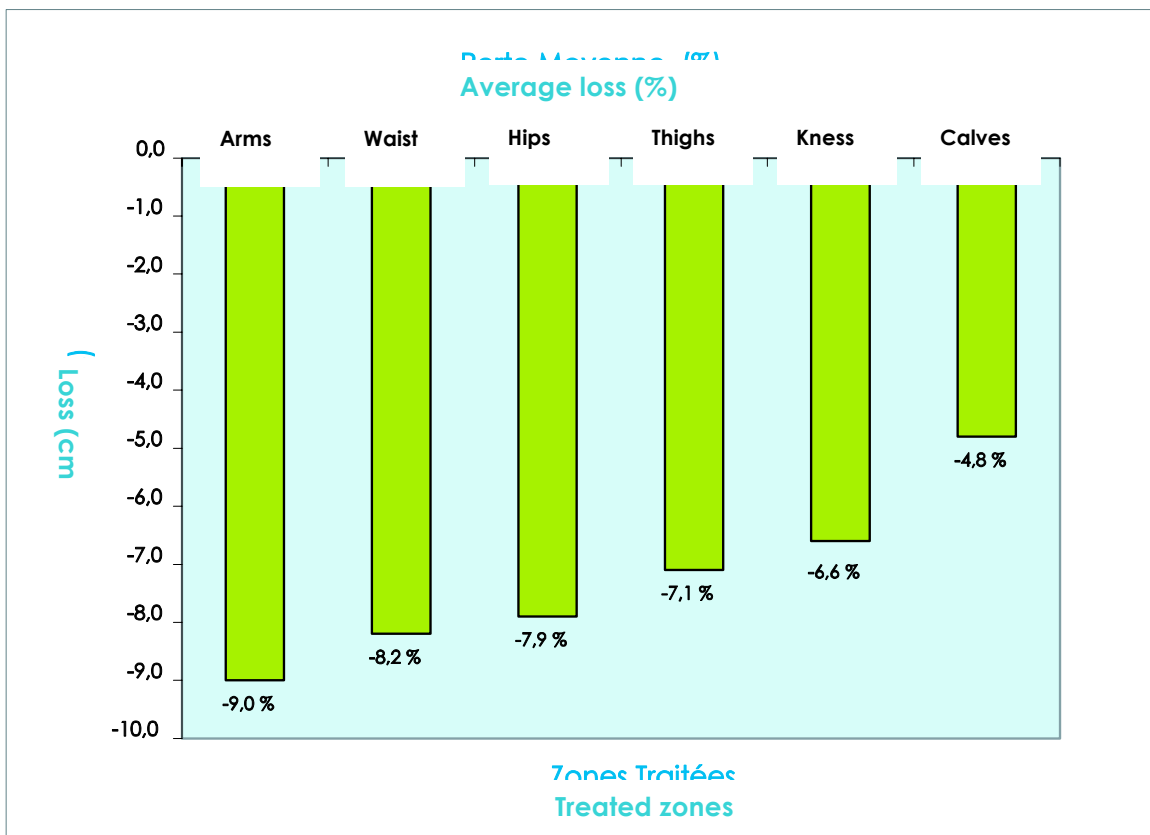
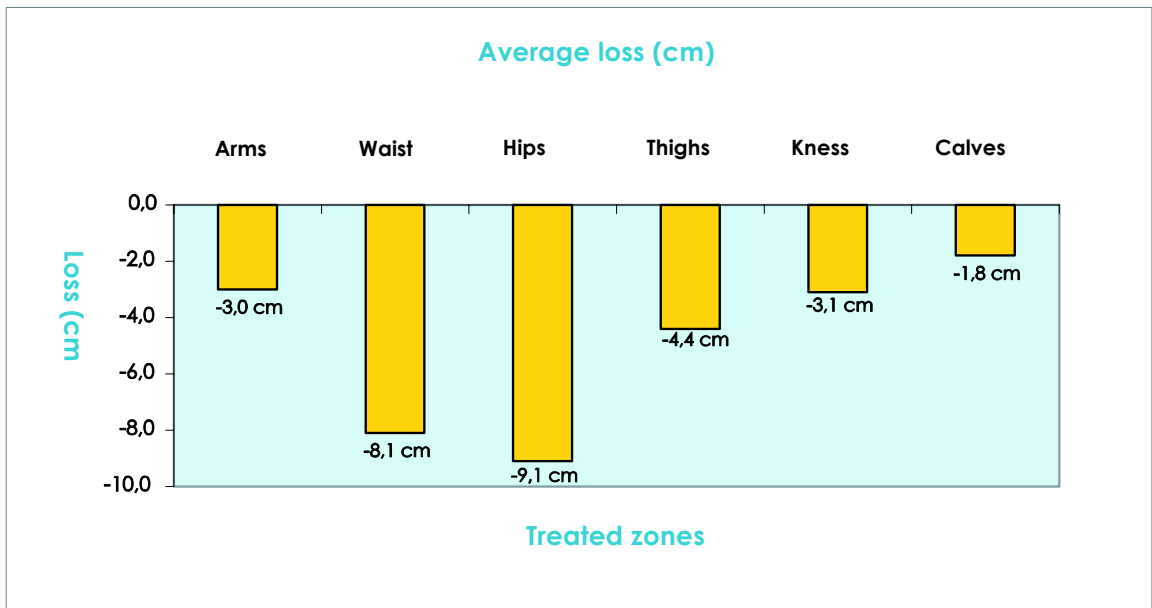
Measures of initial circumferences in centimeters are taken of the 23 volunteers, at the waist, hips, knees, calves and arms, following the anatomical reference points indicated in Figure 1.

Average initial body fat (34 kg, i.e. 41% of average initial body mass) reveals the existence of a considerable average auxiliary adipose weight on all test subjects.

The measures taken of the 23 volunteers after 12 55-minute sessions show an average reduction in absolute value, depending on the stoutness parameters considered, of between 1.8 cm for calves and 9.1 cm for hips. Losses of 3.1 cm for knees, 4.4 cm for thighs, and 8.1 cm for waists can also be seen (Table 4)

Evolution of measures during the test

Table 4



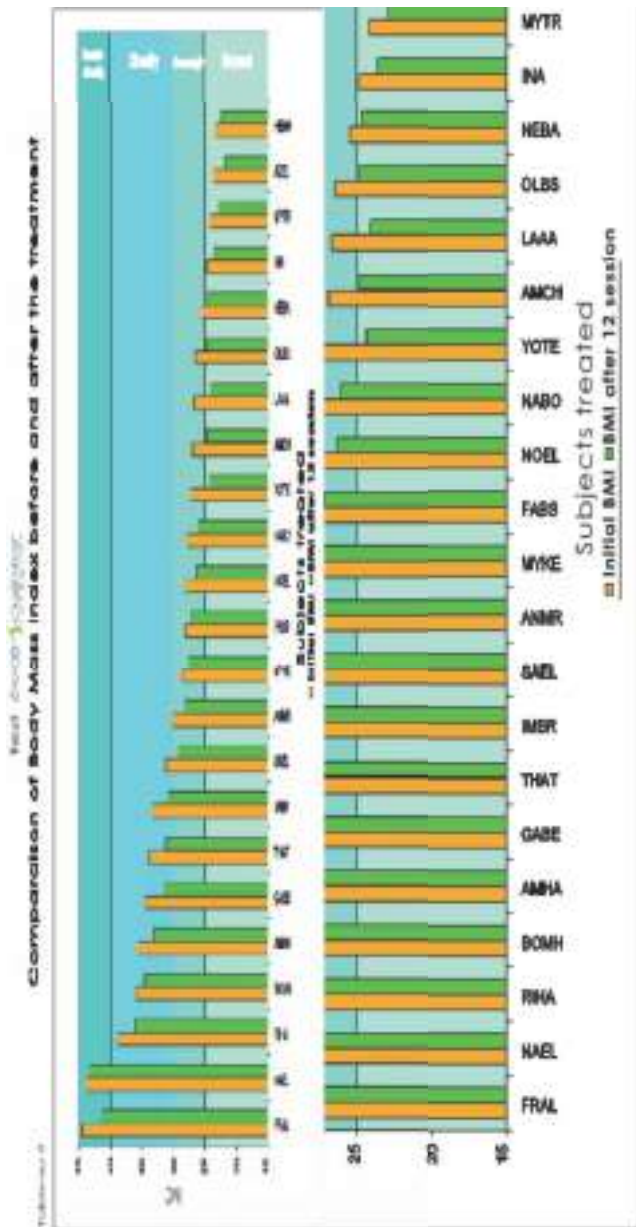
The statistical analysis of the variation of stoutness parameters (arms, hips, waist, thighs, calves), made using **Student's "t" Test**, which seems the most suitable considering the number of volunteers, uses non-normalized raw values.

The differences which were noted are very significant ($P < 0.01$).

The weight and body fat measures taken of the 23 volunteers after 12 55-minute sessions reveal average losses of 5 kg (weight) and 5.5 kg (body fat). Average BMI during the test (Table 5) dropped from 30.5 to 28.7, resulting in 5 subjects moving from a state of obesity to one of overweight.

In fact, by the end of the test:

- **9 subjects (against 4 at the start) had a normal BMI, i.e. 40% of test subjects against 17%.**
- 6 subjects against 9 had a BMI translating into overweight.
- 6 subjects against 8 had a BMI translating into obesity.
- 2 subjects still presented severe obesity, which nevertheless showed marked improvement.



7/ DISCUSSION

1- A critical look at the comparative weight and body-fat loss curves for all subjects treated (Table 6) shows that both are quite similar. Thus, as the test result table (Table 2) clearly demonstrates, average weight loss (5.0 kg) generally corresponds to body-fat loss (5.5 kg). The small difference between both is due either to low degree of precision in the technique used for measuring body fat ($\pm 10\%$) or to a variation in total water.

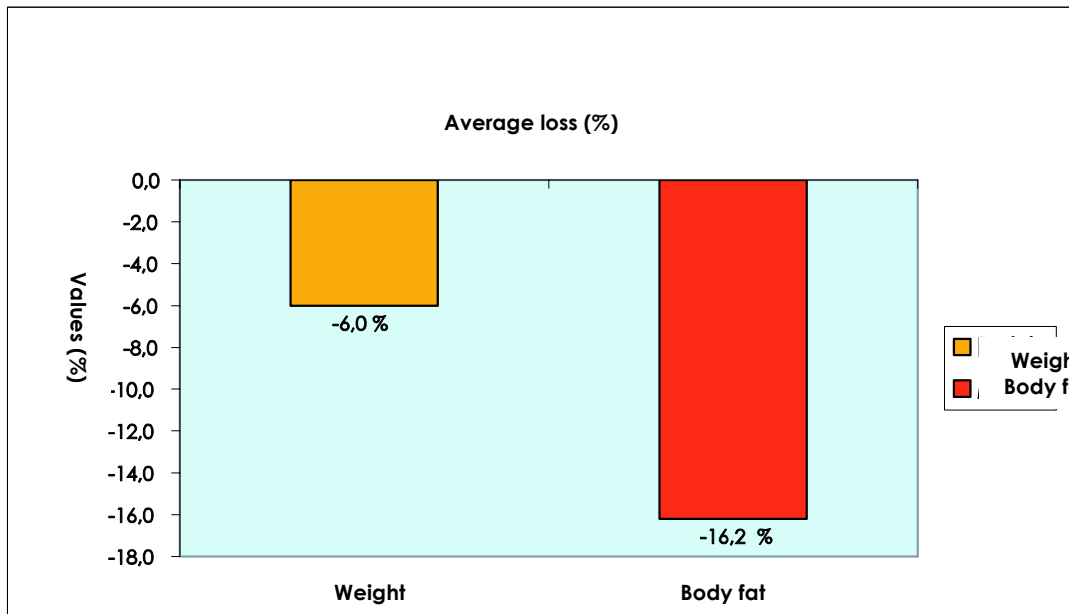
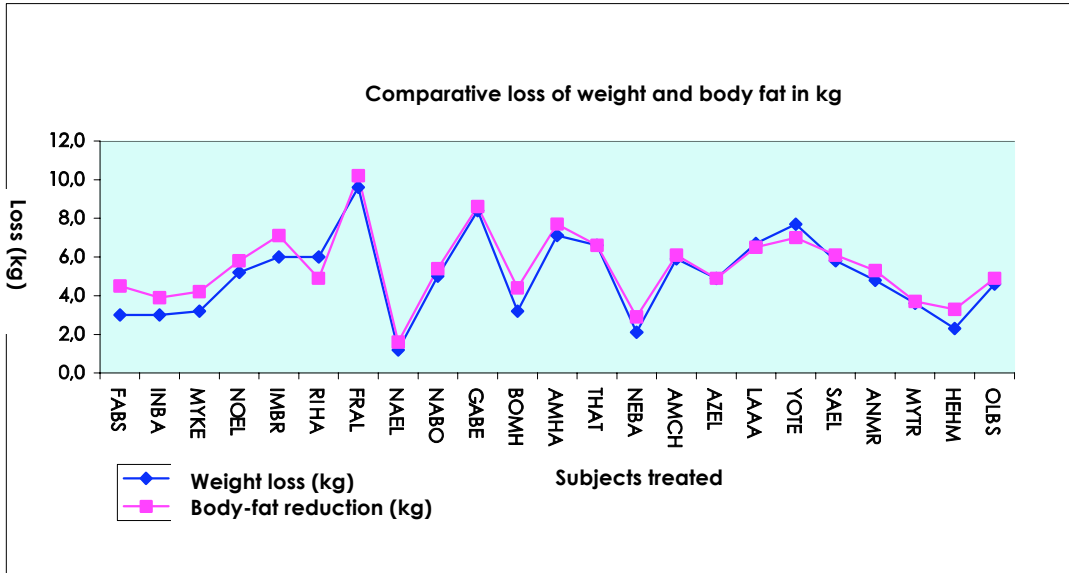
Be that as it may, it thus appears that the “BodySculptor Intégral” technique allows reducing body fat almost specifically, with no significant modification

in lean body mass. It is therefore, properly, a slimming process, not a weight-loss process, affecting only the auxiliary adipose weight.

Indeed, average weight loss over the test equals 6.0% (which corresponds, in percentage, to the losses in centimeters), whereas body-fat loss stands at 16.2%, revealing a very obvious drop in auxiliary adipose weight. (Table 6)

Evolution of weight and body fat during the test

Table 6



2- The evolution of the measurements during the test illustrates the “body-sculpting” effect in terms of localized auxiliary weight. Thus, Table 4 shows average circumference reductions in the more enveloped zones, as follows:

- Up to 9.1 cm for the hips, i.e. an average loss of 7.9% ($p < 0.01$);
 - Up to 8.1 cm for the waist, i.e. an average loss of 8.2% ($p < 0.01$); and
 - Up to 4.4 cm for the thighs, i.e. an average loss of 7% ($p < 0.01$)
- **This slimming corresponds, in practice, and in terms the subjects can note objectively, to a 2-size reduction in clothes (1 size = 4 cm).**
 - The evolution of average arm and knee measures is on the same order: respectively 9% and 6.6% ($p < 0.01$).
 - As for calves, generally a less adipose zone, the drop is not as pronounced: -4.8% ($p < 0.01$).

3- This overall slimming effect is quite evident in the before-and-after-treatment comparison in Body Mass Index (BMI) of the subjects under treatment (Table 5).

Thus, a general tendency towards a return to BMI normalcy on all treated subjects can be seen (40% of them had a normal BMI by the end of the test, as opposed to 17% at the start). The average decrease in BMI, which drops from 30.5 to 28.7, indicates passage from a state of obesity to one of overweight.

4- Considering average losses in percentage, Table 4 reveals that the most significant losses measured are to be seen in the arms and waist

This distribution corresponds to an android distribution of fatty tissues, to which morbidity-mortality studies associate cardiovascular and metabolic complications resulting from obesity.

Before coming to a favourable conclusion regarding the observed, statistically-significant lipolytic effect of the “BodySculptor Intégral”, a few reflections on the presumptive operation of the device are in order.

Knowing that the power of the emitted waves does not allow them to reach deeper than the outer layers of the skin (i.e. a few millimeters at best), [4] whereas adipocytes are often located far deeper, Bioalternatives Laboratories, [5] after in vitro evaluations, have theorised that in this case, stimulation of the lipolysis would not be done directly at the adipocytes level, but rather indirectly, thorough 3 types of targets located in the outer layers of the skin:

- The kératinocytes of the epidermis; [6] [7] [8]
- The vascular endothelial cells of capillary loops located in the dermis; and
- The nerve endings located in the dermis and epidermis. [9] [10]

Messengers would then be transmitted from these cells to the adipocytes, triggering the observed lipolysis.

Following the study, fourteen subjects agreed to participate in an interview to gather their impressions. The answers most often given reflected:

The manifestations felt during the sessions:

→ Sensation of overall well-being during or after the sessions:

- Feeling of relaxation
- Improvement in sleep
- Sensation of lightness
- Sensation of heat (only one subject was bothered by this, but sessions were conducted over the summer)

→ Feeding modifications:

- They were moderate in most subjects, who corrected the most evident mistakes they recognized on their own (nine of the subjects had previously followed straight diets, partial or total recovery or increase in weight).

→ Pronounced and beneficial effects were noted particularly regarding:

- Slimming
- Silhouette
- Improvement in skin elasticity
- Also mentioned were:
- Smoothing of stretch marks
- Feeling of well-being and lightness.
- Overall impressions of satisfaction were unanimously positive, with expressions of high degrees of satisfaction.

8/ Conclusion

After treatment on 23 subjects, consisting of twelve 55-minute sessions, one may conclude that the tested electric device, the “BodySculptor Intégral”, allows a net reduction in auxiliary adipose weight, as evaluated by measuring the subjects’ body fats, and by the reduction in circumferences noted in different parts of the body.

It thus appears that the tested device, using a safe and non-aggressive physical process, allows an almost specific drop in body fat, equally distributed throughout the body. It can therefore be considered as a slimming process, with no significant, undesired reduction in lean body mass.

Furthermore, the process is a painless one, non-traumatic for tissues. There are no obvious counter-indications for a healthy subject.

The process can be accompanied by a low-calorie diet for greater efficiency with overweight or obese subjects. It may also prove to be an essential motivating factor for them, as it acts perceptibly on their measurements.

This complementarity should empower them to take more effective measures in dealing with their problem, outside of the slimming effect, as do subjects with normal weights.

Finally, the observed action, which is more pronounced on fatty reserves in android distribution, may have a beneficial effect on obesity-related risk factors.

Done on this day, December 11th, 2005

Dr. S. FARGEON

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