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Groupe de Recherche et d'Evaluation en Dermatologie et Cosmétologie

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CLINICAL EVALUATION
OF AN ANTI-CELLULITE DEVICE
(i-LIPO^{TM})

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I. Introduction

The orange peel syndrome, cottage cheese skin, and the mattress phenomenon are all terms used to describe cellulite, the lumpy deposits of dimpled fat that plagues the thighs and buttocks of millions of individuals around the world. It is believed to affect more than 80% of women in Europe and America. Cellulite is not a medical or scientific term but it is commonly used term to describe the pitting, bulging and deformation of the skin usually affecting the thighs, buttocks, hips, breasts and the abdomen. Over the years there has been extensive debate concerning what actually constitutes cellulite and whether it differs from other fat cells in the body. Chemical analysis has shown that cellulite is the same as ordinary fat cells and that it is not a unique substance.

Fat cells make up adipose tissue, which is held together by a network of fibers that are nourished and cleansed by body fluids. Fat lobules are cut off by fibrosis divisions perpendicular to the surface of the skin. These lobules protrude in the dermis and attract the epidermis. Adipose cells fatten and proliferate, modifying vessels, leading to oedema. Poor circulation can result in a slowing down of the cleansing process with an accumulation of waste materials that thicken and harden into immovable pockets of fat causing a dimple effect. The lipolytic process occurs when adipocytes' triglycerides are transformed into glycerol by triglycerid lipase enzymes. Lipogenesis in the adipocytes has to be combated against or lipids destroyed in order to obtain smoother and firmer skin.

Many publications have described the effects of photo-biology using low level lasers operating in the red spectrum and near infrared wavelengths. Among these effects are those specific to adipose tissue. Recent experiments have shown that exposure to low-level red laser light induces the release of fat cells' content into interstitial space by increasing the size of cell membranes' pores. Red light also stimulates the synthesis of cells in the dermis and therefore may help in skin restructurization after the reduction of fatty tissue. Relapse of cellulitis may also be prevented with the use of such treatment.

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The objective of the study was to evaluate the anti cellulite effect of a device, i-Lipo™, which emits low-level laser energy through the skin at a wavelength of 650 nm. The system is composed of a command interface with a digital screen, 3 command buttons, light weight laser units that are attached to the body with Velcro straps, and lymphatic stimulators. The system emits predetermined wavelengths of visible red laser light that empties the membrane contents of adipose cells on targeting areas of the body. The triglycerides that are released from the disintegrated membranes of the cells move into interstitial spaces were they are slowly evacuated by the natural metabolic functions of the body.

A clinical study comprising 15 volunteers evaluated the improvement of cellulite following 8 sessions of the device lasting 20 minutes each.

II. Materials and Methods

15 patients with phototypes beween II and V and between the ages of 20 and 63 were selected and included in the study. The study comprised 12 women and 3 men who had expressly made the decision to improve their overall diet and exercise regime with the goal of weight loss depicted by a loss of 1-2 dress sizes in an anatomical zone. The anatomical area of focus was chosen according to « resistant » areas that were not improving despite regular gym exercise. The thighs were the target zone for 7 of the participants, while the abdomens of the 8 remaining participants were treated (**Table I**).

Patients were excluded from the study if they were not of appropriate age or if medical precedents hindered their ability to participate. Contraindications included pregnancy, epilepsy, thyroid dysfunction, diabetes, cardiac arrhythmias, heart disease or hypertension, pacemakers, history of cancer (5 years of remission), liver or kidney disease, photosensitivity to 650-660 nm light, and immuno-suppressed disorders.

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The Tefal BodySignal2 digital weight scale was used to determine both the overall weight of the subjects (kg) and also the weight of their fat tissue (kg).

The i-Lipo[TM] device, emitting low-level laser energy, was the device used to administer cellulite reduction treatment. As previously noted, the system is composed of a command interface with a digital screen, 3 command buttons, light weight laser units that are attached to the body with Velcro straps, and lymphatic stimulators.

Statistical analyses were completed using the paired student t-test.

III. Analyses

A) Pre-Treatment Protocol

The 15 subjects' treatment schedule consisted of a total of 8 twenty-minute sessions of i-Lipo[TM], at a rate of two twenty-minute sessions per week. The treatment zones were treated in accordance with the protocol established by Chromogenex[TM].

Before the first treatment an echography precisely measured compressible and non-compressible fat layer thickness. The difference between the two represented the total amount of adipose tissue identified by echography. The examination was completed within the 48 H preceding the first measurements and treatment session. The echography was conducted 5cm under the umbilicus in the case of abdominal treatment and 10cm under the greater trochanter in the case of saddle bag (thigh) treatment.

The subjects took a Liposcure Test consisting of 20 questions before starting their treatment to determine their type of cellulite and the corresponding diet that should be embraced in order to reduce the presence of cellulite. Depending on their responses, subjects were diagnosed with cellulite with water retention, adipose cellulite, fibrous cellulite or a combination of adipose with retention of water or adipose-fibrous cellulite. A detailed list of recommended foods, as well as foods to reduce or eliminate was given to each subject.

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B) Session Protocol

The precise circumferential measurements of the treatment area were taken on a standing patient immediately before and after the session. For subjects undergoing treatment of the abdomen, a measurement of the circumference of the waist was effectuated aimed at a point in the center of the zone of treatment for each subject. For those undergoing treatment of the thighs, measurement was taken around each circumference of each thigh. The weight, including measurement of fat in kilograms (BMI/BFI) was taken before and after each session. Jewelry and clothing except for undergarments were removed for the weight measurements. Photographs were taken in standardized conditions before each treatment session in order to document the pre-treatment appearance of each subject.

Subjects were bound to prescribed conditions related to their eating habits 2 hours before and after treatment and were specifically invited to avoid heavy meals, fasting, fizzy drinks, coffee or tea. Treatment around menstruation was also discouraged due to hormonal fluctuations in the body. Subjects were urged to practice a cardio-vascular activity as soon as possible following the treatment to encourage the body to drain a maximum of adipose fat from targeted cells in the treatment zone.

C) Post-Treatment Protocol

A post treatment echography was completed within the 48H following the last session of treatment in order to measure compressible and non-compressible fat layer thickness. Photographs were taken in standardized conditions to document the changes undergone by each subject.

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IV. Results

12 women and 3 men with an average age of 42.6 ± 9.87 years were included in the study. Pre-treatment the subjects weighed an average of 73.38 kg, with an average fat tissue total of 24.7 kg.

7 subjects underwent treatment for the thighs and 8 subjects for the abdomen (**Table I**).

 The Liposcore test permitted to determine each subject's cellulite type. 5 had cellulite with water retention, 5 had adipose cellulite, 3 had fibrous cellulite and 2 had mixed adipose cellulite with water retention.

There was no reported discomfort or unwanted post treatment effects.

A) Circumferential Measurement of the Treatment Area

Results for the circumference of each subject's right thigh or abdomen in centimeters (cm) are expressed in **Table II** and are represented in **Figures of subjects 1-14**.

The average circumference of subjects (n=8) treated on the abdominal zone by I-lipo^{TM} significantly decreased to 105.25 cm from 109.41 cm pre-treatment (p=0.0012).   This represents an equivalent average of 4.16 cm lost in abdominal circumference.

The average circumference of subjects (n=7) treated on the right thigh by I-lipo^{TM} significantly decreased to 60.04 cm from 61.57 cm pre-treatment (p=0.0302).   This represents a 1.5 cm average reduction in circumference.

B) Echography

Results for the milimeters (mm) of fat in each subject's target zone measured by echography, are expressed in **Table IIIa and IIIb** and are represented in **Figures of subjects 1 and 3**.

For the measurement of fat thickness without compression (**Table IIIa**) there was a statistically significant reduction from 47.14 mm to 41.57 mm (p=0.0026) for the thighs,

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corresponding to a reduction of 11.8%. For the measurement of fat thickness without compression there was a statistically significant reduction from 44.6 mm to 39.5 mm (p=0.01) for the abdomen, corresponding to a reduction of 11.5%.

The average reduction of adipose tissue thickness (**Table IIIb**) for the abdominal area was 15.62 mm from 17.37 mm (p=0.02), representing an average reduction of 1.75 mm. This is an average fat reduction of 8.8%.

Average thighs' adipose tissue thickness reduced after treatment by I-lipo^{TM} from 13.14 mm to 9.14 mm (p=0.0028), representing an average reduction of 4 mm. This is an average fat reduction of 30.4%.

For all subjects, the difference thickness of adipose tissue with and without compression reduced 2.8 mm, or 18%.

C) Weight

Results of the weight in kilograms (kg) of each subject are expressed in **Table IV**.

The average amount of weight lost during the course of the treatment was 1.37 kg (p= 0.0016). This represents 1.4% loss of the subjects' total weight following treatment by I-lipo^{TM}.

On average, those getting treatment for the thighs lost 1 kg (p=0.019) and those getting treatment for the abdomen lost 1.66 kg (p=0.018). One subject (n°3) lost 5.1 kg, or 4.1% of his weight during the course of the treatment.

D) Adipose Tissue

Results of each subject's overall adipose tissue in the body in kilograms (kg) are expressed in **Table V**.

On average the subjects lost 1.11 kg of fatty tissue, (p=0.0048) after treatment by I-lipo^{TM}. 2.41% was the average reduction of fatty tissue lost on the thighs, versus 4.8% on the abdomen. One subject (n°8) lost as much as 7.84% of her fatty tissue during the course of treatment.

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IV. Conclusion

This clinical study, incorporating 15 subjects, has permitted to visualize and quantify the statistically significant reduction of abdominal or thigh cellulite after the I-lipo^{TM} treatment. A good correlation was found between the clinical and echographic measurements of the cellulite. The double echographic measurements with and without compression permitted us to identify with more precision the effects of the I-lipo^{TM} treatment on adipose tissue.

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Paris, France

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Table I : Treatment Zones

Subjects (n=7)	Treatment Area		Subjects (n=8)	Treatment Area
N°1	Thighs		N°3	Abdomen
N°2	Thighs		N°4	Abdomen
N°5	Thighs		N°6	Abdomen
N°7	Thighs		N°8	Abdomen
N°10	Thighs		N°9	Abdomen
N°11	Thighs		N°13	Abdomen
N°12	Thighs		N°14	Abdomen
			N°15	Abdomen

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Table II : Circumferential Measurement of the Treatment Area (cm)

Abdomen	Day 0	End of Treatment	% Change
Subject 3	130	121	-6.9%
Subject 4	98	97.5	-0.5%
Subject 6	113.8	111.5	-2.0%
Subject 8	136	130.5	-4.0%
Subject 9	94.5	90.5	-4.2%
Subject13	98	94.5	-6.0%
Subject 14	97.5	94.5	-3.0%
Subject 15	107.5	102	-5.1%
Average ± Standard Deviation	**109.41** ± 14.91	**105.25** ± 13.44 $p = 0.0012$	

Right Thigh	Day 0	End of Treatment	% Change
Subject 1	61	60	-1.6%
Subject 2	55.5	55	-0.9%
Subject 5	59	58.8	-0.3%
Subject 7	58.5	57.5	-1.7%
Subject 10	68.5	64	-6.6%
Subject 11	55.5	55.5	0%
Subject 12	73	69.5	-4.8%
Average ± Standard Deviation	**61.57** ± 6.2	**60** ± 4.77 $p = 0.03$	

* statistical difference in comparison with Day 0 (paired t-Student test)

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Table IIIa : **Echography of fat tissue thickness** (mm): Measurement of fat thickness without compression

Abdomen	Day 0	End of Treatment	% Change
Subject 3	78	63	-19.23%
Subject 4	41	31	-24.39%
Subject 6	41	37	-9.76%
Subject 8	63	60	-4.76%
Subject 9	41	37	-9.76%
Subject13	30	30	0.00%
Subject 14	34	31	-8.82%
Subject 15	29	27	-6.90%
Average + Standard Deviation	**44.62** ± 16	**39.5** ± 13.11 p=0.01	

Right Thigh	Day 0	End of Treatment	% Change
Subject 1	51	40	-21.57%
Subject 2	39	35	-10.26%
Subject 5	70	61	-12.86%
Subject 7	27	24	-11.11%
Subject 10	55	53	-3.64%
Subject 11	41	38	-7.32%
Subject 12	47	40	-14.89%
Average + Standard Deviation	**47.14** ± 12.59	**41.57** ± 11.20 p=0.0026	

* statistical difference in comparison with Day 0 (paired t-Student test)

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Table IIIb : **Echography of fat tissue**: Difference of measurement of fat thickness with and without compression (mm)

Abdomen	Day 0	End of Treatment	% Change
Subject 3	31	25	-19.4%
Subject 4	13	13	0%
Subject 6	16	14	-12.5%
Subject 8	26	25	-3.8%
Subject 9	18	15	-16.7%
Subject13	12	12	0%
Subject 14	14	13	-7.1%
Subject 15	9	8	-9.9%
Average *± Standard Deviation*	**17.37** ± 7.00	**15.62** ± 5.74 p = 0.0206	

Right Thigh	Day 0	End of Treatment	% Change
Subject 1	19	12	-36.8%
Subject 2	8	5	-37.5%
Subject 5	15	8	-46.7%
Subject 7	7	6	-14.3%
Subject 10	23	18	-21.7%
Subject 11	13	12	-7.7%
Subject 12	7	3	-57.1%
Average *± Standard Deviation*	**13.14** ± 5.82	**9.14** ± 4.79 p = 0.0028	

* statistical difference in comparison with Day 0 (paired t-Student test)

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Table IV : **Weight** (kg)

Abdomen	Day 0	End of Treatment	% Change
Subject 3	124.6	119.5	-4.1%
Subject 4	60	60	0%
Subject 6	82.2	82	-0.25%
Subject 8	110	106.1	-3.5%
Subject 9	64.3	63.1	-1.8%
Subject13	60.7	60	-1.2%
Subject 14	80.9	79.8	-1.4%
Subject 15	90.2	89.1	-1.2%
Average *± Standard Deviation*	**84.11** ± 22.03	**82.45** ± 20.51 p = 0.0186	

Right Thigh	Day 0	End of Treatment	% Change
Subject 1	62.9	61.7	-1.9%
Subject 2	48.6	48.2	-0.8%
Subject 5	73.3	71	-3.1%
Subject 7	58	57.4	-1%
Subject 10	71.1	68.5	-3.7%
Subject 11	46.4	46.6	+0.4%
Subject 12	67.5	67.1	-0.6%
Average *± Standard Deviation*	**61.1** ± 9.82	**60.1** ± 9.04 p = 0.019	

* statistical difference in comparison with Day 0 (paired t-Student test)

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Table V : Adipose Tissue (kg)

Abdomen	Day 0	End of Treatment	% Change
Subject 3	41.9	38.9	-7.2%
Subject 4	20.7	20.7	0.0%
Subject 6	32	30.2	-5.6%
Subject 8	52.3	48.2	-7.8%
Subject 9	23	21.9	-4.8%
Subject13	19.8	19.7	-0.5%
Subject 14	20.4	19.8	-2.9%
Subject 15	19.3	18.9	-2.1%
Average ± Standard Deviation	**28.68** ± 11.6	**27.3** ± 10.23 p = 0.016	

Right Thigh	Day 0	End of Treatment	% Change
Subject 1	20.8	20.5	-1.4%
Subject 2	11.4	11.9	+4.4%
Subject 5	30.5	29.3	-3.9%
Subject 7	16.4	16	-2.4%
Subject 10	28.1	27.1	-3.6%
Subject 11	13	13.4	+3.1%
Subject 12	21	19.6	-6.7%
Average ± Standard Deviation	**20.17** ± 6.69	**19.69** ± 6.12 p = 0.07	

* statistical difference in comparison with Day 0 (paired t-Student test)