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A NEW INSTRUMENTAL METHOD FOR THE TREATMENT OF CELLULITE

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Introduction

An innovative massage device - CELLU M6 - has been developed by LPG Systems in Valence, France, based on original techniques for which the Company holds patents.

Initially, LPG Systems decided to automate the classical knead-and-roll massage method so well known to physical therapists, designing a device to reproduce this technique more effectively and avoiding the more painful and traumatic aspects of manual knead-and-roll massage techniques.

The technical solutions used in this device usher in a new concept in body-care : endermology, whose results have very little in common with more traditional knead-and-roll manual message techniques.

Material and methodologies

1 - The material

The CM6 device

The CM6 device is made up of two elements :

- A technical console containing the system's main parts.

- A main massage head used to perform the aspired " finger rolling " massage.

The space between the rolls of the massaging head self regulates and adapts itself to the subject's skin thickeness.

The Casing

Fitted with a 0.75 kW/220V/50 Hz standard suction pump, the safety of this device is guaranteed by magneto-thermic circuit-breakers and a 40.3 l/sec heat extractor.

With a filtered air flow-rate of 25 m^3/hour, this pump produces a low air pressure of up to 500 mbars. The suction is regulated by electronically-controlled electric exhaust fans automatically adjusted to usage requirements. Overriding manual commands allow the device to be regulated according to tissue quality and patient sensitivity.

- The Principal Knead-and-Roll Suction Head.

Fitted with a grip, this head consists of an air-tight suction chamber sealed by lateral and longitudinal valves. Low air pressure sucks the patient's skin up between two motorized rollers whose gap is determined by the actual thickness of this skin fold : the thicker the fold, the larger the gap. The device is designed to ensure that, no matter how wide the gap between the rollers, the lateral pressure on the skin fold remains constant, regardless of the skin thickness and subcutaneous adipose tissue. Light-up scales on the massage head constantly indicate :

- air-pressure in the chamber
- gap between rollers
- sensitivity reaction caused by tissue resistance to kneading skin fold.

The low air pressure produced by the vacuum pump sucks the skin up between the two rollers into a skin fold or pleat. This is then kneaded by the two rollers, powered by a small motor set in the massage head. The suction level is electronically controlled and constantly adjusted, maintaining the necessary equilibrium among the gap, the rollers, their turning speed, the air-valves, and the vacuum pump.

These technical characteristics endow this device with a unique operation that can no longer be compared with existing manual or mechanical massage methods. In fact, this is a totally new technique. Experiments carried out by the manufacturer of this device, as well as the experience built up by its many enthusiastic users over the years, show that its applications are virtually countless, in a wide variety of fields including :

- functional rehabilitation
- sporting activities
- beauty-care and body-shaping
- medical purposes prevention of bed sores, for example).

2 - Methodology

1) The principle used was the following : objectivize the reduction of the subcutaneous adipose masses on the thighs at the beginning and the end of the research.

Photogrammetry was used to make dimensional measurements.

a - Photogrammetry

Consists of using photography to determine spacial dimensions and shapes of a given object.

The shot

The subject is put in a referential system made up of a rigid frame; cameras and the subject itself.

The two cameras were gauged compared to stationary reference marks on the frame and the subject before the shot was taken ; measurements could in turn be perfectly reproduced. All the structures involved in the camera range were materialized by small targets.When the data was processed and analized, such targets allowed the

replacement of a subject compared to the frame ; it also allowed the replacement of the structure compared to the cameras. When the shot was made, the two photographs that were simultaneously taken gave a stereoscopic view of the area studied.

Whenever areas are studied, " make up " must be used to enhance contrasts in the area, such as marks made with a fat pen.

This technique is based on measurement reproductibility ; that is why the subject must keep stationary reference marks on several spots between the hip and knee all throughout the experiment.

A tridimensional model was also built using the various stereoscopic views ; each givenpoint was characterized by X, Y and Z coordinates.

The objective, when studying the development of adipose masses, is to determin the spacial coordinates of a series of points that were selected (before and after the left and right thighs were treated).

b) Selecting subjects

** Inclusion criteria*

20 healthy, non obese women subjects, averaging 36.3 + 2.4 years of age volonteered to partake in cellulite tests on the thighs and hips.

The volonteers that were selected had beforehand been acquainted with the experiment and were freely willing to carry it out complying with the Helsinki convention (1964), revised in Tokyo (1975) and Venice (1983).

** Exclusion criteria*

All subjects dieting and likely to slim down during the research, those beeing treated for cellulite or hormonally treated (except for the pill) were excluded from the experiment.

The subjects who became seriously ill during the experiment those who no longer complied with the experiment protocol or wished to give it up and those who gained more than 5% weight during the research were also excluded.

c) Application mode

** Treatment*

The treatment was carried out with the CM6 device once a day and the massages lasted 30 min ; a massage was also manually performed on some selected subjects 5 days a week during one month (totalling 20 massages).

The side wich was treated was not randomly selected.

The treatment was performed from the waist to the knee on one same thigh ; the side wich was not treated served as reference.

** Measures*

Each subject was treated during one month.

- A first measurement was carried out J0 days before the first treatment
- A second measurement series was carried out after the 12th massage (T1)
- A last measurement series was carried out J30 days after 20 massages (T12)

** Photogrammetry*

Assessing treatment efficiency means that a treated area must be compared with a non treated or reference area bearing the same characteristics and not influenced by the treatment.

The treatment efficiency can then be shown depending on wether the treated area slimmed down or not and by how

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much ; also if the area that was not treated did not vary or varied slightly.

For instance, for one measurement implied, the skin thickness slimmed down 4.62 mm on the thigh that was treated compared to 1.07 mm on the other non treated thigh, which means a difference of 3.55 mm :

- 3.55 mm : skin thickness reduced due to treatment.

- 1.07 mm : reduction due to factors that are not linked to treatment (nutrition, exercising...).

- 4.62 mm : total skin thickness reduction (treatment + other factors).

Measurement of E max

The research relied on the measurement of E max. which is the maximum difference between the positions of one same given point before and after treatment T0 and T1 and treatment T0 and T2 (it is measured in mm and compared to the body median axis). It is the measurement of the ultimate point on the axis perpendicular to the skin. Such measurement gives the depth result on the axis perpendicular to the skin which is different than the circumferential measurements and far more accurate.

Vizualisation

Modifications in the size of a thigh are vizualized on a computerized graph (appendix 1) ; the morphological variations of each subject is tridimensionaly represented on a computer screen and can be photographed (appendix 2).

Additional tests

In addition to photogrammetrical measurements, weight is also controlled before and after treatment (accuracy : 100 grams).

d - Résults

After 12 massages : comparisons between T0 and T1.

The measurements taken show a major cellulite tissue reduction on the thigh that was treated compared to the other. The reduction amounts to 1.85 + 0.59 mm (the measurement was made perpendicular to the skin axis and taken after 12 massages).

The student test shows that this improvement is statistically significant ($p < 0.5$). The results show that the thigh which was not treated did not change (variation 0.01 mm).

Results after 20 massages : comparisons between T0 and T2.

The cellulite tissue thickness slimmed down *on the average 4.98 mm* on the thigh wich was treated. On the other hand, the tissue thickness only slimmed down 0.58 mm on the thigh that was not treated. The difference between the two averages is statistically significant on the student test series ($p < 0.5$). The results are shown in chart number 1.

Weight measurements.

Only patients whose weight did not increase more than 5% were kept for the research when it was carried out. No particular dieting instructions were given before the tests to prove the efficiency of CM6.

Discussion

The results that were obtained are very important since they infact pertain to the measurement and slimming down of the theoretical thigh radius circumference.

In such conditions and assuming that the area that was treated homogeneously slimmed down, one can consider that a reduction of 0.1 cm on the perpendicular axis of the skin practically corresponds to a 0.6 cm reduction around the thigh (RC = 2 MR) (tacking in account irregularies in the thigh circumference).

Chart 1

Photogrammetry results variation between T0 and T2

Subject - Number	Subject - name	Untreated	Treated
1	Car.	-2,5	-5,5
4	Heu.	-1	-5
5	Ric.	-2	-2
6	Bat.	-1	-6,5
7	Pen.	-1,5	-3,5
10	De So.	-1	-2,5
12	Mal.	-5	-16
13	Lec.	3	-3
14	Fau.	0	-2,7
17	Par.	2	-1
18	Abb.	0	-6
19	Tri.	0	-6
Moy		-0,58	-4,98
Sm		0,61	1,13

Chart 1 - remarks

On the 20 subjects that had been preselected, only 12 were used from the previous chart at the end of the research.

Some subjects did not complete the experiment due to therapeutic restrictions : either because they had to drop out before the end or because the observations made were incomplete, lastly because their weight had signicantly increased during the research (+5%) (appendix : chart number 1).

Given the diversity of patients participating in the research and selected solely on the presence of cellulite when the clinical test was made as well as their willingness to accept the 30 mn test every day, 5 days a week, during 4 weeks, these results prove the efficiency of the CM6 device. In fact, out of 12 patients, not one shown the same clinical type of " cellulite " depending on their age and physiological state.

Two patients (number 14 and 18) Who were over 40 years old (41 and 45) were obese, wich is completely different than the patient who was young (19), slim and clinically showed mild traces of cellulite.

Case number 5 (RIO) intrigued us since the results were identical on both thighs. We noticed, upon further investigation, that during the second part of the treatment between T1 and T2, the masseurs broadned their therapeutic field to the stomach and hips to satidfy the patients urgent needs and that was done in a particular psychological surrounding.

Case number 12 (MAL) is the most spectacular one : the skin thickness slimmed down 166 mm on the axis perpendicular to the cutaneous surface, wich approximately represents a 10 cm reduction in the size of the thigh. This observation proves that the results are more spectacular when the patient is young and has non-hormonal type of cellulite.

A subjective result assessment made by the patients (charts 2 and 3).

Chart 2

Overall assessment

Opinion	Number of subjects
very nice	6
nice	4
good	1
average	0
poorly appreciated	1

Chart 3

Individual treatment assessment (treatment using CM6)

Assessment	Response Number of subjects		
	yes	no	no opinion
difference between treated and non-treated thigh	10	2	0
more relaxed	10	1	1
firmer	8	2	2
less blood flow problems	8	3	1
smoother skin	11	1	0
less tired	6	0	6

Subjectively, the results were globally assessed as good.

Among the 12 patients volunteering in the experiment, 10 clearly noticed a difference between the thigh that was treated and the other that was not. 10 patients appreciated the relaxing effect, 8 noticed that their blood circulation improved and that the massages relieved fatigue.

Lastly, 11 subjects out of 12 globally qualified the massages as being " nice " or " very nice ".

CM6 is a device which proved to be efficient in the treatment of cellulite using objective methods that were favourably appreciated by the patients, whatever type of cellulite was involved, wether etiological or clinical.

Conclusion

The study was carried out among 12 patients showing a clinical type of cellulite ; its purpose was to demonstrate the efficiency of CM6 device, which is a French invention based on a completely new concept.

The results obtained prove the efficiency of CM6 studied on clinical cellulite cases in the Dermatology Department of the Hotel Dieu Hospital in Marseille. " Photogrammetry " was the method used and proves to be responsive enough to validate the study.

After 12 massages the treatment shows

an average improvement of *1.86 mm + 0.54* on the perpendicular axis to the skin (cutaneous thickness) compared to the thigh that was not treated.

After 20 massages, the improvement is even better, showing an average improvement of *4.98 mm* on the thigh that was treated compared to the other one, wich represents *an average thigh reduction of 3.1 cm.*

This rigorous study, through its accurate method, showed that CM6 was an efficient device to treat cellulite.

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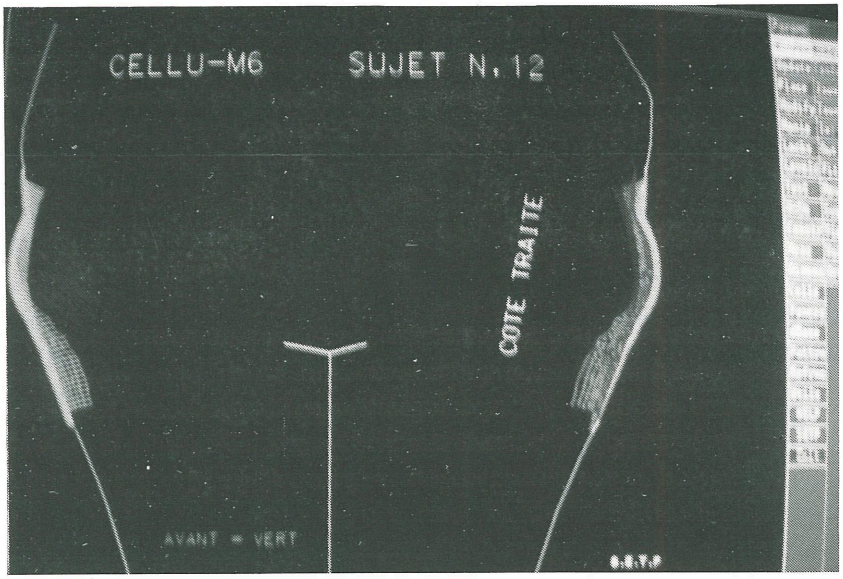
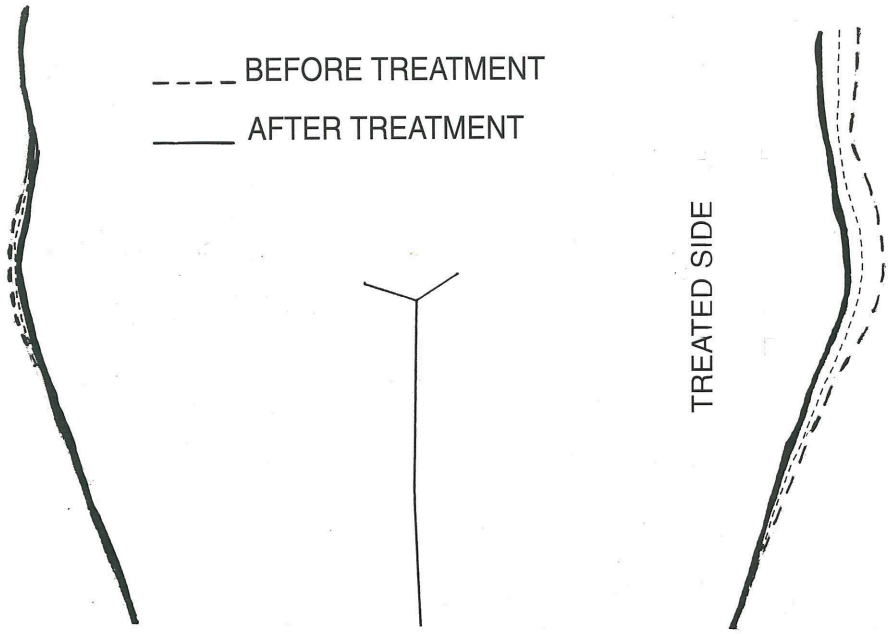
APPENDIXES



Frame of patient 12 (Evolution of adipose tissue under treatment)



APPENDIX 2

Computer-Reconstituted Silhouette, before and after treatment

APPENDIX 3

Consent Form - Healthy Volunteers

VOLUNTEER DATA AND FREE AND INFORMED CONSENT FORM

Surname : First Name :

By signing this Declaration, I herewith volunteer to participate in a clinical and paraclinical study of the effectiveness of the CELLU M6 massage device.

The nature and purpose of this study, and problems that it might cause me have been clearly explained by the Researcher : Professor J.P. Marchand.

These treatments will take place on pre-determined body zones five days a week for four weeks. I will present myself at the Cutaneous Functions Experimental Laboratory Professor Privat's Dermatology Unit, " Hotel Dieu " Hospital, Marseille, at the times and dates stipulated, prior to the treatment.

I hereby agree to respect all instructions given me by the Researcher, and I understand that any failure to comply with restrictions or attempts to hide the truth may adversely affect the proper progress of the experiment.

In am fully aware of the research nature and purpose of this project and of the fact that it has no therapeutic purpose, and that this means that all possibilities of skin irritation cannot be formally excluded.

I hereby freely agree to take part in this study, under no constraints, whatsoever, and am also aware that I may drop out at any time. In this case, I will receive pro-rata compensation for my participation, and will be asked to submit to an examination on the day I cease to participate.

I have received satisfactory replies to all questions that I could freely ask regarding this study.

The information collected by the Researcher will be handled on a confidential basis.

Marseille, ... (date) .....

Read and approved :

Signature of Volunteer Signature of Researcher