EVALUATION OF THE EFFICACY OF A COSMETIC PRODUCT - ANTI-STRETCH MARKS

CHECKING ITS ACCEPTABILITY AFTER APPLICATION UNDER NORMAL CONDITIONS OF USE

OBJECTIVE ASSESSMENT OF ITS QUALITIES AND EFFICACY

In use test with clinical control by a dermatologist and with instrumental evaluation

Short Report

This report is a summary of the report 800613.A, and reflects all data concerning the study developed with the product.

I . OBJECTIVE

The aim of the present study is to assess the **anti-stretch efficacy** and **cutaneous recovery of elasticity,** as well as to check the **acceptability** and assess the **qualities and efficacy** of the cosmetic product **LEITE CORPORAL LEITE DE BURRA, BATCH 330126/A 657** after application under the normal conditions of use planned by the Sponsor.

The **anti- stretch efficacy** and **cutaneous recovery of elasticity** of the product was assessed:

- objectively and quantitatively, by instrumental measurements with a Fringe projection system (Primos 3D®), before and after treatment,
- objectively and quantitatively, by instrumental measurements of the skin firmness and elasticity with a Cutometer® (Dual-Cutometer MPA 580®), before and after treatment.
- semi-quantitatively, by score measurements by the dermatologist or technician, under his authority.

The **acceptability** was:

- controlled after visual examination of the experimental area, by the dermatologist or the technician, under his authority, and after questioning of the subjects.
- checked every day, by the subjects themselves at home,

The subjective **qualities and efficacy** of the products are assessed, at the end of the study, using a target questionnaire.

This study allows justifying the claim "Firming and smoothing the appearance of stretch marks".

II . DATES OF STUDY

Beginning: June 27th, 2013
End: July 24th, 2013

III . SUBJECTS

Fifteen (15) subjects were included in the study. There were neither withdrawals nor exclusion. The efficacy and compatibility of the test product was, therefor, assessed in fifteen (15) subjects, corresponding to these specific inclusion criteria:

a) Age: 18 to 45 years,
b) Gender: female,
c) Phototype (Fitzpatrick) : I to V,
d) Women who have been mother less than one year
e) Individual Clinical Stretch marks Score (ICSS) superior to 2,
f) Type of skin: all types of skin.

IV. METHODOLOGY

IV.1. Assessment of the skin elasticity recovery

IV.1.1 Principle and equipment

Skin biomechanical evaluation was performed by a Cutometer® dual MPA 580 (Courage & Khazaka, Germany) using a 2mm probe. This system was used to measure elasticity of the upper skin layers using negative pressure which deforms the skin mechanically. The measuring principle is based on the suction method. Negative pressure is created in the device (450 mbar) and the skin is drawn into the aperture of the probe (2s) and after a defined time released again (2s). Inside the probe, the penetration depth is determined by a non-contact optical measuring system which consists of a light source and a light receptor, as well as two prisms facing each other, which project the light from transmitter to receptor. The light intensity changes due to the penetration depth of the skin. The resistance of the skin to the negative pressure (firmness) and its ability to return into its original position (elasticity) are displayed as curves (penetration depth in mm/time) in real time during the measurement. This measurement principle allows getting information about the elastic and mechanical properties of skin surface.

IV.1.2 Frequency of measurements

The measurements were performed on **D0 and D28.**

IV.1.3 Expression and interpretation of the results

At each experimental time, the biomechanical properties of skin were represented by a curve of deformation according to time.

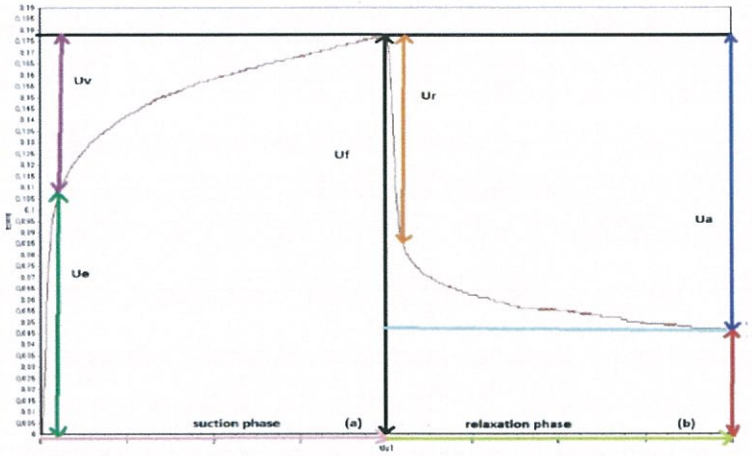

Figure 1 – Graphic representation of the Cutometer curves

From this recording, the following parameters are retained:

R0 (Uf) (in mm): Highest point of the first curve. This parameter represents the passive behavior of the skin to force and is a measurement of firmness. A lower result is related with a higher firming effect.

R2 (Ua/Uf) (in %): Ratio between the ability of returning to the original position and the maximum amplitude. It is a standard parameter of elasticity. The closer the value is to 1 (100 %) the more elastic the curve.

The means and standard deviations were calculated.

IV.2. Assessment of skin roughness and general topography

IV.2.1 Principle and equipment

3D images of the skin topography were obtained by a digital fringe projection using DLP® micro mirror displays. A Phase Shifting Rapid In-vivo Measurement of Skin system (PRIMOS 3D 40x30 mm evaluation area, Gfm, Germany) was used. A fringe pattern is projected on the skin and detected by the CCD camera of the optical system. The 3D effect is calculated by the deflection in the fringes which represent qualitative and quantitative the skin profile.

IV.2.2 Frequency of measurements

The measurements were performed on **D0 and D28.**

IV.2.3 Expression and interpretation of the results

At each experimental time, the standard roughness was calculated in the full aligned image.
The parameters defined were:
Ra = Arithmetic mean of the skin surface (roughness)
Rz = Average of the 5 highest peaks and 5 lowest valleys obtained in the field of measurement (Roughness)

IV.3. Assessment of *Anti-Stretch efficacy by clinical score*

All volunteers were subjected to a review of the stretches in clinical terms through the use of a semi-quantitative scale (Individual Clinical Stretch marks Score - ICSS).

- 0 = **ICSS** = no stretch marks
- 1 ≤ **ICSS** ≤ 2 = slight stretch marks
- 2 < **ICSS** ≤ 3 = moderate stretch marks
- 3 < **ICSS** ≤ 4 = important stretch marks
- 4 < **ICSS** ≤ 5 = severe stretch marks

determined according to the 3 following items:

- *Colour of the stretch marks* ***(P1)***

No stretch marks	0
Red stretch marks	1
Red to pinkish stretch marks	2
Pinkish stretch marks	3
Pinkish to white stretch marks	4
White stretch marks	5

- *Thickness of the stretch marks* ***(P2)***

No stretch marks	0
Very thin stretch marks	1
Thin stretch marks	2
Moderately thick stretch marks	3
Thick stretch marks	4
Very thick stretch marks	5

- *Depth of the stretch marks* ***(P3)***

No stretch marks	0
Not deep stretch marks	1
Light depth of the stretch marks	2
Light to moderate depth of the stretch marks	3
Moderate depth of the stretch marks	4
Important depth of the stretch marks	5

To calculate the ICSS, it was used the following formula:

Individual Clinical Stretch marks Score (ICSS) =∑ (P1 + P2 + P3) / 3

IV.4. Checking of the acceptability

The results were mainly expressed as descriptive data and do not require a statistical treatment. The test products been well accepted by the subjects, under these experimental conditions, by extrapolation it should be safe for human health when applied by a great panel of consumers.

IV.4. Experimental conditions of use of the test product

The experimental conditions, defined by protocol, were the following ones:

Experimental area(s)	Product directions of use	Application(s) at the Institute	Application(s) at home Frequency/duration
Abdomen and hips	Application of LEITE CORPORAL LEITE DE BURRA, on clean skin by gentle digital massage until complete absorption, twice a day.	-	From D0 to D28 Application, twice a day (morning -after bath, evening – at bedtime) for 28 +/- 2 consecutive days

V . RESULTS

V.1. Results from the dermatological evaluation

Volunteers codification	Skin reaction	Number and % of subjects exhibiting skin reaction to the test product
/	None	0%

V.2. Results from the questionnaire asked to the volunteers and observation of the individual observation sheet

Volunteers codification	Sensations of discomfort noted by the volunteers at home	Number and % of subjects exhibiting sensations of discomfort ascribable to the test product
/	None	0%

No skin reaction was noted after the application of the products. No volunteer experienced any discomfort during the study. Therefore both products presented **very good** skin compatibility during the study.

V.3. Assessment of qualities and efficacy (self-assessment) of the product

Item	**Q1.** The product has a pleasant fragrance?					**Q2.** The product is easy to spread?					**Q3.** The product has a nice texture?				
Score	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Number of subjects	0	0	0	8	7	0	0	1	4	10	0	0	1	7	7
% of satisfied subjects	100%					93.3%					93.3%				

Item	**Q4.** The product is easily absorbed by the skin?					**Q5.** The product has a nice colour?					**Q6.** The product des not leave the skin greasy?				
Score	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Number of subjects	0	0	4	4	7	0	0	5	6	4	0	1	2	4	8
% of satisfied subjects	73.3%					66.7%					80.0%				

Item	**Q7.** The product is pleasant to touch?				
Score	**1**	**2**	**3**	**4**	**5**
Number of subjects	0	0	0	8	7
% of satisfied subjects	100%				

Figure 1: Self-assessment of qualities. % of total number of volunteers (n = 15), the favorable responses to the questionnaire cosmetic quality. It is also indicated that the responses were statistically significant (* p <0.05)

The product evaluation showed that, for a significant percentage of volunteers, the product:

- Has a pleasant fragrance,
- It is easy to spread,
- Has a nice texture,
- Leaves no greasy skin,
- Is pleasant to touch.

The following tables show in summary the results for each item, the number of volunteers, and score satisfied% of volunteers:

Item	**Q1.** The product is easily absorbed by the skin.					**Q2.** After using the product, I feel the skin softer and smoother					**Q3.** After using the product, I notice an improvement in the overall appearance of my skin				
Score	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Number of subjects	0	0	4	4	7	0	0	0	4	11	0	0	2	6	7
% of satisfied subjects	73.3%					100%					86.7%				

Item	**Q4.** The skin looks smoother, with a more uniform appearance					**Q5.** After using the product, I noticed reduced stretch marks				
Score	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Number of subjects	0	0	1	8	6	0	2	1	5	7
% of satisfied subjects	93.3%					80%				

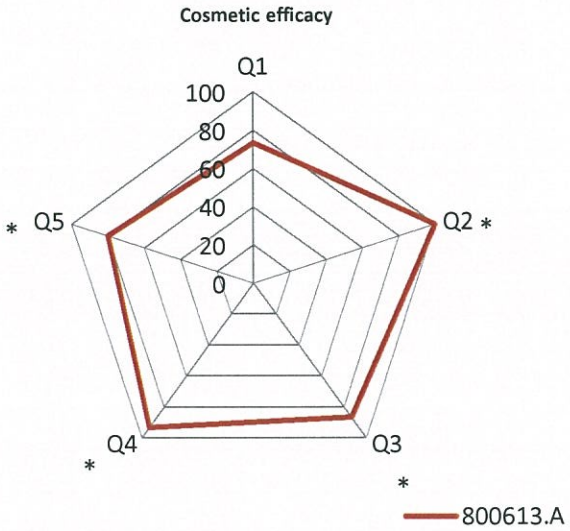

Figure 2: % of total number of volunteers (n = 15), the favorable responses to the cosmetic efficacy questionnaire. It is also indicated that the responses were statistically significant (* p <0.05).

The product evaluation showed that for a significant percentage of volunteers, the product:

- Leaves skin softer and smoother.
- Shows an improvement in overall skin appearance,
- Leaves skin with a smoother, more uniform appearance,
- Reduces stretch marks

The overall product evaluation showed that for a significant percentage of volunteers, the product:

- Was very highly rated by the volunteers,
- Would be purchased by the volunteers,
- Would be recommended by the volunteers,
- Preferably be available in plastic packaging.

V.4. Assessment of the firming effect and skin elasticity recovery

The results of skin elasticity and firmness before and after use of the product expressed in % change relative to D0 and are summarized in the following charts:

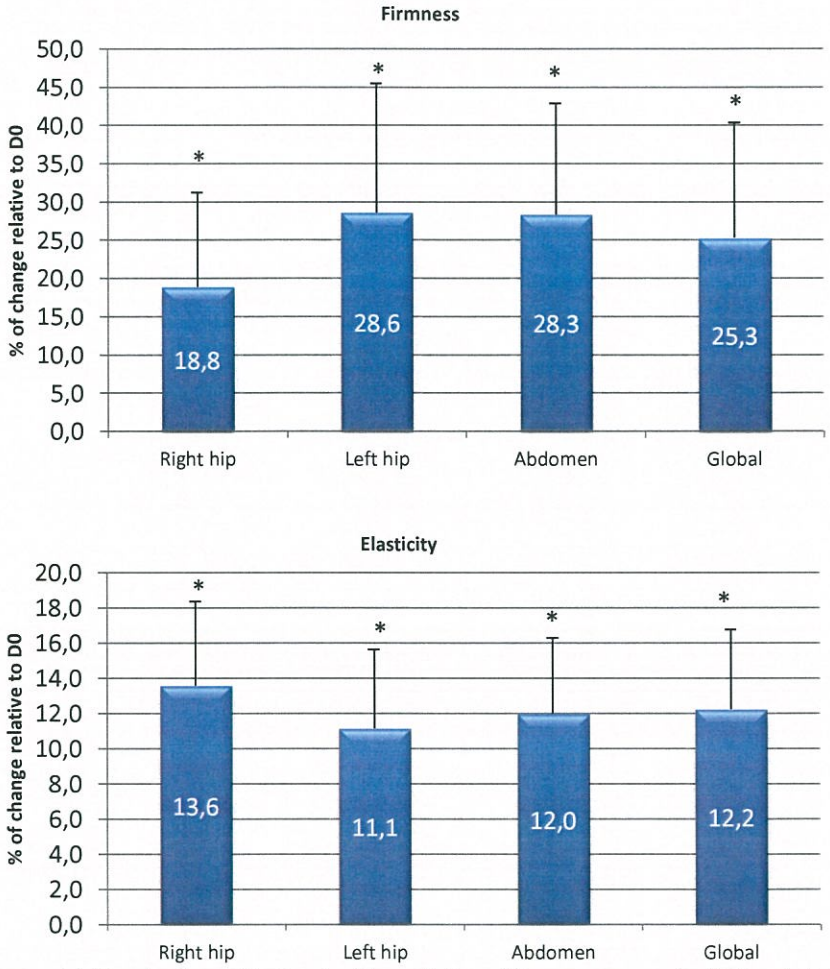

Figure 3 and 4: (Mean + std. Standard) graphic showing the variation of firmness parameter (R0) and of elasticity parameter (R2) relative to D0. It is also indicated statistically significant (* p <0.05).

V.4.1 Evaluation of skin relief

The results of the skin relief, before and after using the product are summarized in the chart below:

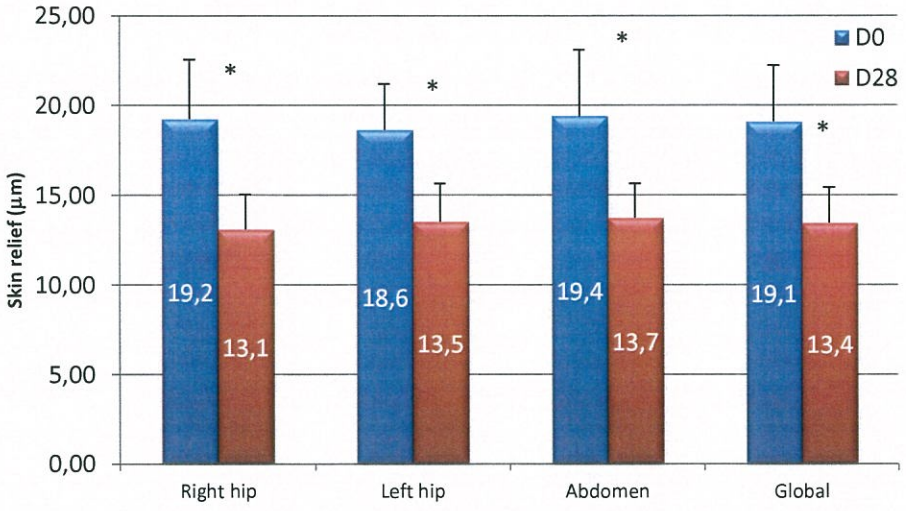

Figure 5: (Mean + std. Standard) graphic showing the evolution of roughness, Ra (µm) during the study. It is also indicated statistically significant (* p <0.05).

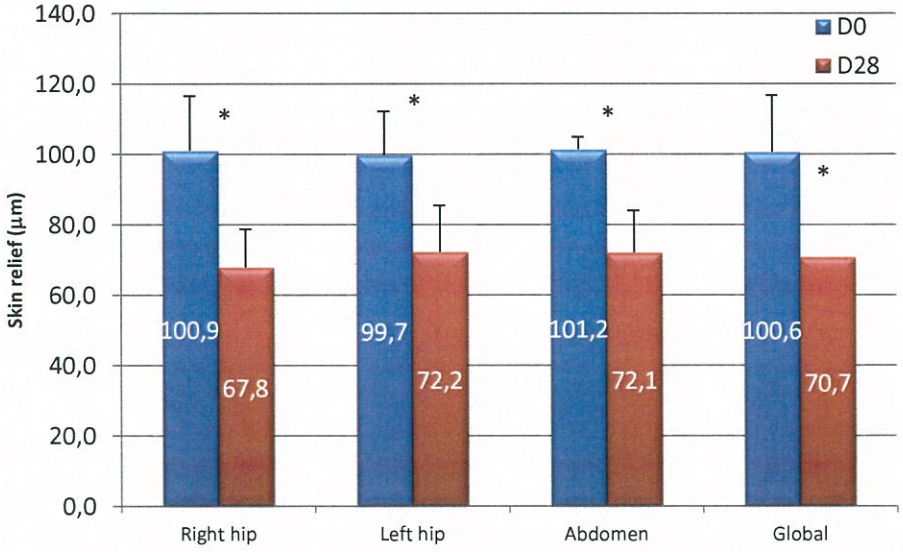

Figure 6: (Mean + std. Standard) graphic showing the evolution of skin roughness, Rz (µm) during the study. It is also indicated statistically significant (* p <0.05).

	Right hip	Left hip	Abdomen	Global
% of change of roughness global means (Ra) after 28 days	-30.7	-26.6	-27.4	-28.3
% of change of roughness global means (Rz) after 28 days	-31.9	-27.0	-26.8	-26.8

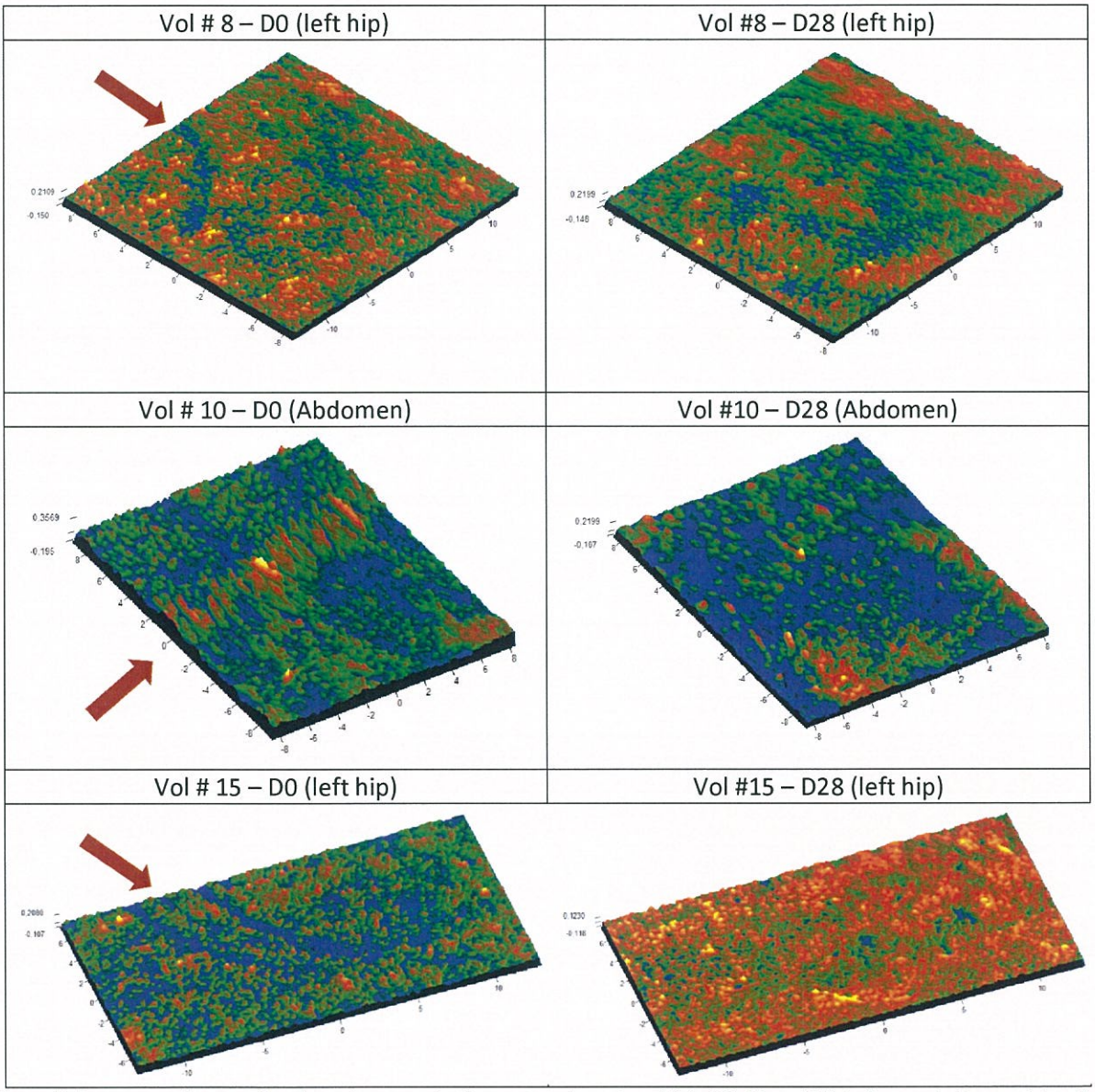

Figure 7: Representative graphic of roughness reduction – stretch marks – (Vols # 8, 10 and 15) before and after applying the product. Figure obtained after detection of the common area and standard automatic alignment.

V.4.2 Clinical score

The results of the clinical score, before and after using the product are summarized in the chart below:

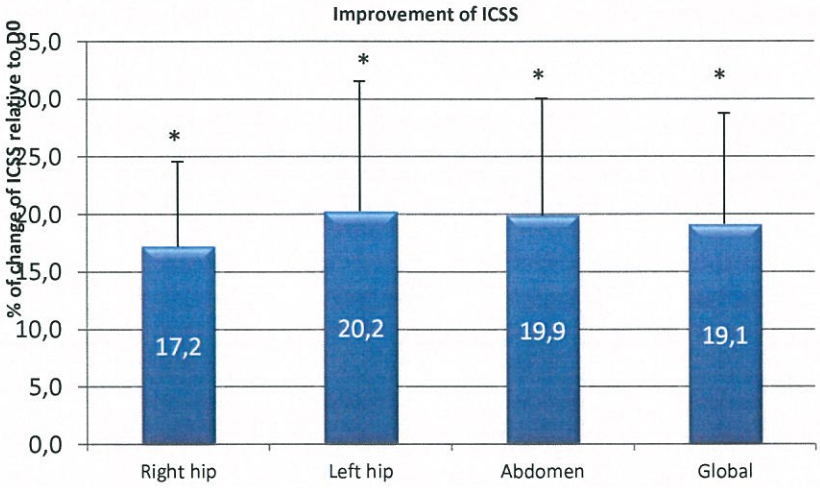

Figure 8: (Mean + std. Standard) graphic showing the change of ICSS relative to D0. It is also indicated statistically significant (* p <0.05).

V.5. Discussion

The results of instrumental evaluation demonstrate a significant increase of the overall skin firmness and skin elasticity by 25.3% and 12.2%. This result is consistent with the expectations for a product with firming and elasticity modeler characteristics.

After use of the product, the evaluation results of the skin relief suggested a statistically significant reduction in roughness by 28.3%. This change of roughness standard is particularly noticeable when some stretch marks have been significantly reduced, and may even be smoothed in full (see vols # 8, 10 and 15). These data are confirmed by semi-quantitative clinical evaluation which demonstrates an average 19% reduction in the appearance of stretch marks.

VI . CONCLUSION

Under the experimental conditions and taking into account the grading scale established by the researcher center, the product **LEITE CORPORAL LEITE DE BURRA, BATCH 330126/A 657** has a very good acceptability. A very good skin tolerance was thus confirmed.

Regarding other features , the product was well known for its cosmetic qualities, notably:
- Pleasant fragrance ,
- Ease of spreading,
- Nice texture ,
- Ability to not let oily skin
- Pleasantness to the touch

Likewise, the product was much appreciated for its cosmetic efficacy , including:
- Ability to leave softer and smoother skin
- Show an improvement in overall skin appearance ,

- Leave the skin with a smoother, more uniform appearance ,
- Ability to reduce stretch marks

In quantitative terms :

The application of the product increased significantly the skin firmness in 25.3 %.

The application of the product increased significantly the skin elasticity in 12.2 %.

The application of the product reduced significantly the overall roughness of the skin in 28.3 %.

The application of the product reduced significantly the roughness of the skin in 26.8 %.

The application of the product reduced significantly Stretch Marks in 19.1 %.

The results suggest that the product **LEITE CORPORAL LEITE DE BURRA, BATCH 330126/A 657,** after application on 15 volunteers for 28 days under the conditions described, has shown characteristics of "firming product" and of "reducing the appearance of stretch marks".

Pedro C+H. 2/8/2013

Scientific Manager : Pedro CONTREIRAS PINTO

I the undersigned, Pedro CONTREIRAS PINTO, declare that:
- the final report was examined on August 2nd, 2013,
- the results reported accurately and completely reflect the raw data of the study.

PharDevelopment Trials, Lda
NIF: 509753914
Rua do Centro, 23 2240-300 Chãos