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(Direttore: Prof. Plinio Richelmi)



Evaluation of the cosmetic effect of a pantyhose which helps to reduce imperfections caused by cellulite and local adiposities. The evaluation was carried out through a clinical test

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Customer: NILIT® Fibers LTD.

Introduction

The scope of this clinical test is to evaluate the cosmetic effectiveness of a pantyhose which helps to reduce the visibility of cellulite and local adiposities imperfections. The clinical study is a double-blind and placebo controlled test. Product's acceptance is evaluated too.

This test was performed by a dermatologist member of Bio Basic Europe staff: 40 female panellists, with an age between 18 and 60 years having cellulite and local adiposities, they were selected and divided into two groups of 20 women each.

The women used the products 8 hours daily for a period of 56 days: the first group wore the NILIT® INNERGY PANTYHOSE, whereas the second group used the PLACEBO (it has the same construction and appearance of the NILIT® INNERGY PANTYHOSE, but it is manufactured with normal fibers, such as nylon 6.6 fibers of same titration).

During this period specific instrumental and clinical parameters have been evaluated: skin elasticity, ECW (evaluation of extracellular water), FM (evaluation of body fat mass), skin compactness, skin smoothness, reduction of "orange peel" visibility and variation in the nodules visibility.

Panelists' self-evaluations have also been taken. The score they gave is according to the VNS scale (0-10 where 0 is the minimum value and 10 is the maximum value).

According to the obtained results we can state that the NILIT® INNERGY PANTYHOSE:

- has proved to help to reduce the visibility of cellulite and local adiposities imperfections;
- has proved to improve skin elasticity, skin smoothness and skin compactness;
- has also proved to have a fairly good acceptance of use.

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INTRODUCTION

The INNERGY PANTYHOSE is manufactured with Nilit® Innergy fibers.

EXPERIMENTAL PART

Scope

Scope of this test is to evaluate if the tested product has got cosmetic efficacy on cellulite and local adiposities imperfections. In particular, the test evaluates if daily use of the product can significantly change some of the clinical and instrumental parameters: skin elasticity, ECW (evaluation of extracellular water), FM (evaluation of body fat mass), skin compactness, skin smoothness, variation in the nodules and “orange-peel” visibility.

This test also evaluates the product’s acceptance.

CLINICAL TEST FEATURES

Panel

40 female subjects, with an age between 18 and 60 years having cellulite and local adiposities, according to specific inclusion and exclusion criteria.

Procedure of test management

This test has been performed with a double blind procedure :

- the experimenter didn’t know which panellist used NILIT® INNERGY PANTYHOSE or placebo.
- the panellists didn’t know that one of the 2 products is a placebo and they didn’t know which product they are using. The placebo has the same construction and appearance of the NILIT® INNERGY PANTYHOSE, but it is manufactured with normal fibers, such as nylon 6.6 fibers of same titration.

Use

Samples of the tested product have been worn by the panelists for 8 hours daily for 56 consecutive days.

EXECUTION OF THE TEST

The product has been used by the panelists for 8 hours daily for a period of 56 days.

In the medical studio, the experimenter evaluated the follow parameters before the treatment beginning, after 28 and 56 days of product use:



Instrumental parameters

We measured the instrumental parameters through appropriate and specific instruments.

- The **elasticity** measurement are taken with the elastometer CUTOMETER® – MPA 580. During the releasing phase, the quantity of deformation remaining in the skin can be observed.



- The **fat mass (FM)** and **extracellular water (ECW)** measurements are taken with INBODY 230 for the analysis of **Impedance**, or BIA (Body Impedance Analysis).



The **FM (Fat Mass)** represents the body total lipid mass (triglycerides). The body fat compartment, which is anhydrous, it doesn't contain potassium and it has a relatively constant density of 0.9kg/L. We defined it in kg and in reference people constitutes about 15% of body weight.

The **ECW (Extra Cellular Water)** represents about 40% of total body water (TBW). The ECW includes interstitial (14% of body weight), plasma (4%), lymphatic (1%) and transcellular (1%) water.

Anthropometric parameters

Measurement of circumferences through a metric methodology. Each anthropometric value is the average of 3 measurements.

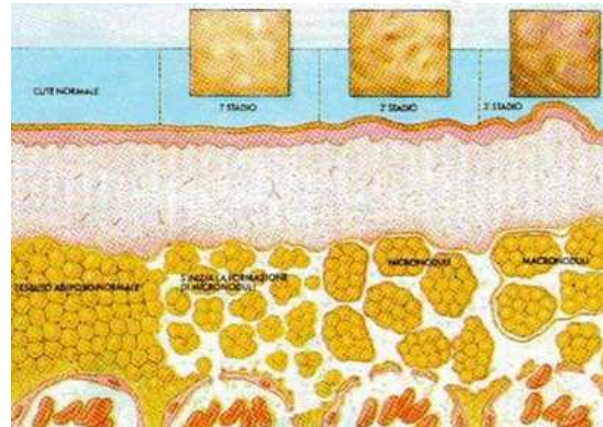
- Thigh circumference (cm)
- Buttocks circumference (cm)

Clinical parameters

The experimenter performed the clinical evaluation by the palpation of the interested area.

- Skin compactness
The skin compactness is the passive skin behavior following application of negative pressure
- Skin smoothness
The smoothness indicates how smooth is the skin
- Improvement in the "orange peel" skin visibility
The skin texture seems to orange peel, it is a characteristic cutaneous imperfection of cellulite

- Improvement in the nodules visibility
Visible micro and macro nodular formations, sometimes palpable and painful that characterize cellulite tissue



Self-evaluations

At [t28] and [t56] days, panelists' opinions are also taken.

This self-evaluation was performed according to VNS scale where 0 is the minimum value and 10 is the maximum value.

STATISTICAL METHODOLOGY

The instrumental, anthropometric parameters and the self-evaluations are evaluated through the **Paired t-test** and the **Student «t» test for independent samples**.

For the evaluation of the clinical parameters, the intra and infra-group comparison we applied the **Wilcoxon rank-sum test**.

Statistical significance

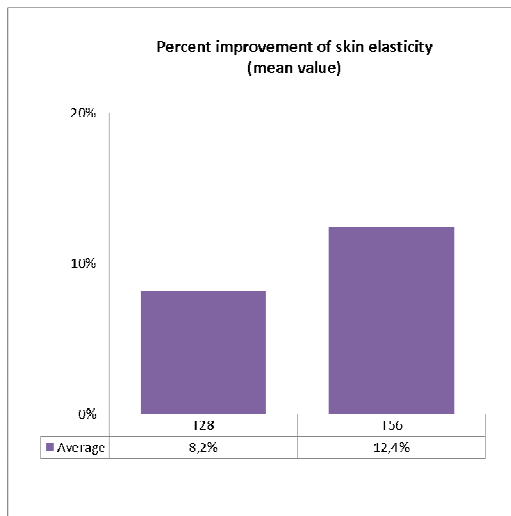
The statistical significance indicates that what it has been observed is barely due to chance, it also can provide an indication of the force with which the data contrast the **zero hypothesis** (or **null hypothesis**).

RESULTS

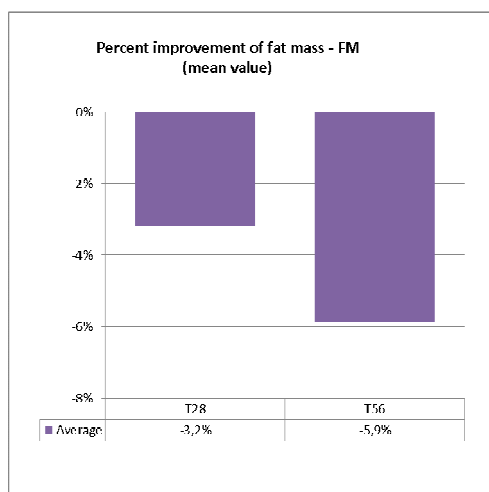
We summarize the results obtained after 56 days of product use.

Instrumental parameter

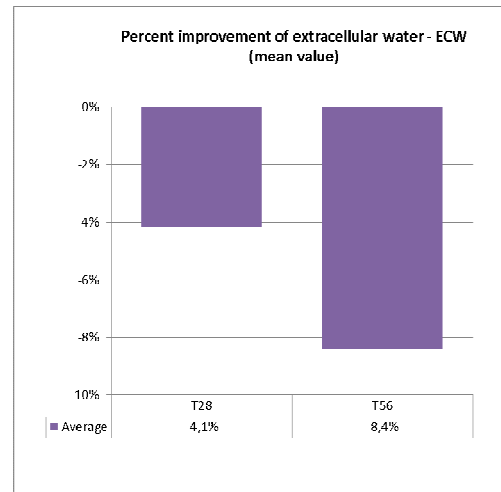
SKIN ELASTICITY (THIGH)			
	T0	T28	T56
Average	0.650	0.703	0.731
Percent improvement		8%	12%
Statistical significance		yes (t<0.01)	yes (t<0.01)



FM (Kg) – FAT MASS			
	T0	T28	T56
Average	19.565	18.945	18.420
Δ (mean value)		-0.62 Kg	-1.15 Kg
Statistical significance		yes (t<0.01)	yes (t<0.01)

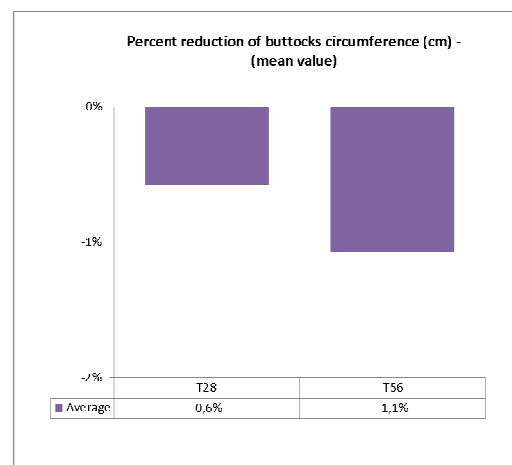


ECW (litri) – EXTRACELLULAR WATER			
	T0	T28	T56
Average	12.655	12.130	11.595
Δ (mean value)		-0.53 liters	-1.06 liters
Statistical significance		Yes (t<0.01)	yes (t<0.01)

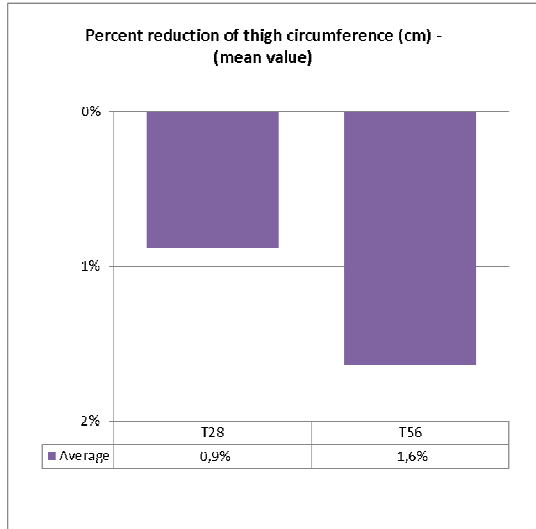


Anthropometric parameters

BUTTOCKS CIRCUMFERENCE (cm)			
	T0	T28	T56
Average	100.03	99.45	98.95
Δ (mean value)		-0.58 cm	-1.08 cm
Statistical significance		yes (t<0.01)	yes (t<0.01)

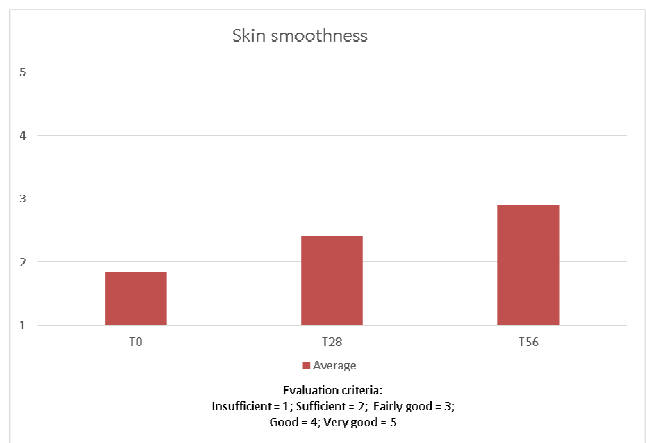


THIGH CIRCUMFERENCE (cm)			
	T0	T28	T56
Average	59.63	59.10	58.65
Δ (mean value)		-0.53 cm	-0.98 cm
Statistical significance		Yes (t<0.01)	yes (t<0.01)



SKIN SMOOTHNESS			
	T0	T28	T56
Opinion average	Sufficient	Sufficient	Fairly good
Mean Value	1.85	2.40	2.90
Percent of volunteers with an improvement		45%	85%
Statistical significance		yes (T<T-crit)	yes (T<T-crit)

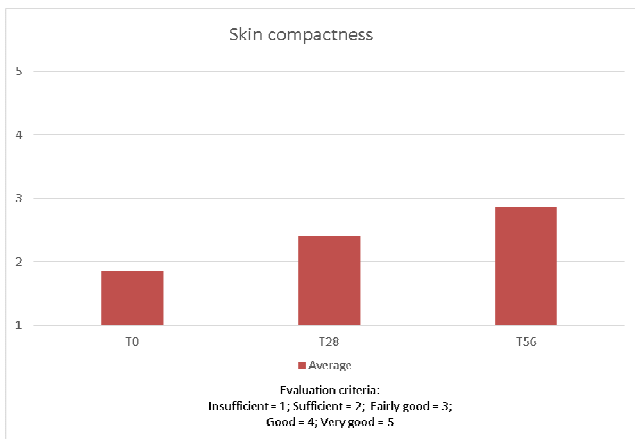
*Evaluation criteria:
1=Insufficient; 2=Sufficient; 3=Fairly good; 4=Good; 5=Very good*



Clinical parameters

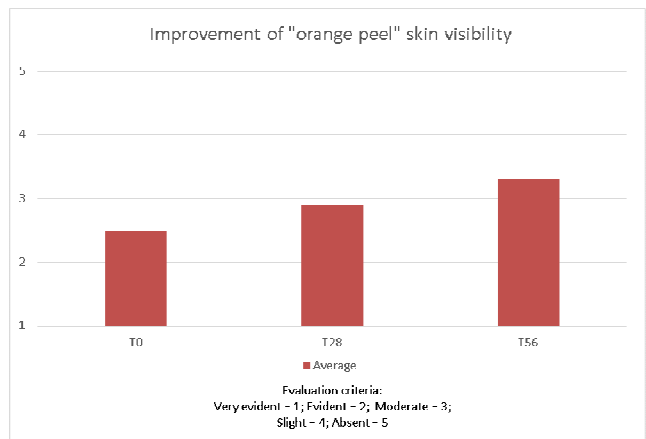
SKIN COMPACTNESS			
	T0	T28	T56
Opinion average	Sufficient	Sufficient	Fairly good
Mean Value	1.85	2.40	2.85
Percent of volunteers with an improvement		50%	85%
Statistical significance		yes (T<T-crit)	yes (T<T-crit)

*Evaluation criteria:
1=Insufficient; 2=Sufficient; 3=Fairly good; 4=Good; 5=Very good*

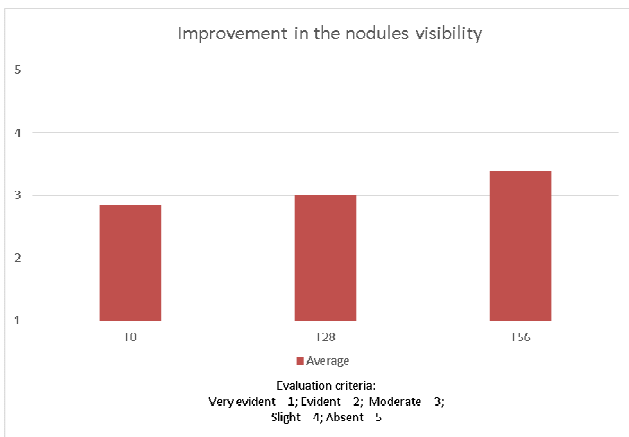


IMPROVEMENT OF "ORANGE PEEL" SKIN VISIBILITY			
	T0	T28	T56
Opinion average	Moderate	Moderate	Moderate
Mean Value	2.50	2.90	3.30
Percent of volunteers with an improvement		35%	75%
Statistical significance		Yes (T<T-crit)	yes (T<T-crit)

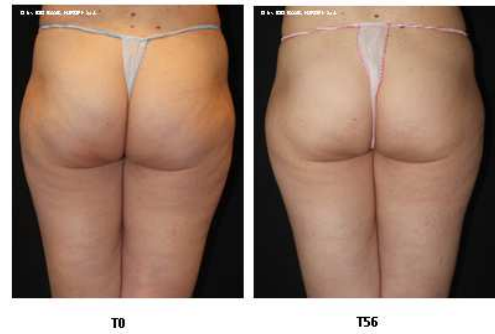
*Evaluation criteria:
1=Very evident; 2=Evident; 3=Moderate; 4=Slight; 5=Absent*



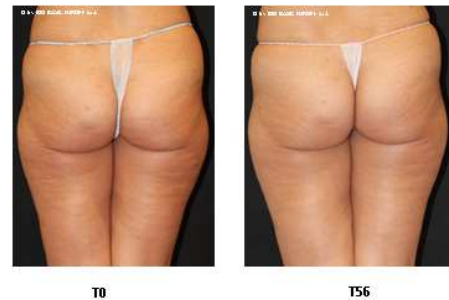
IMPROVEMENT IN THE NODULES VISIBILITY			
	T0	T28	T56
Opinion average	Moderate	Moderate	Moderate
Mean Value	2.85	3.00	3.40
Percent of volunteers with an improvement		15%	55%
Statistical significance		no (T>T-crit)	yes (T<T-crit)
<i>Evaluation criteria:</i> 1=Very evident; 2=Evident; 3=Moderate; 4=Slight; 5=Absent			



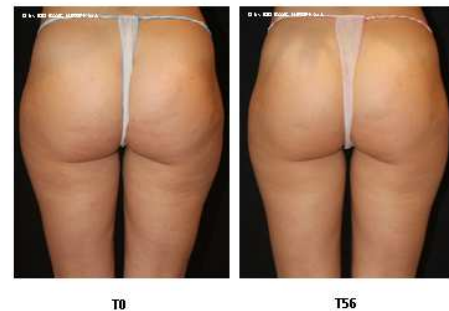
Protocollo n° / Report no. 1401N30F NILIT LTD. Vol. 15



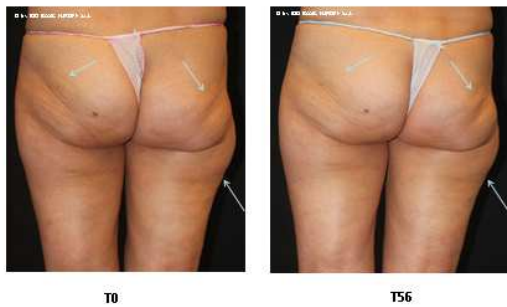
Protocollo n° / Report no. 1401N30F NILIT LTD. Vol. 17



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Protocollo n° / Report no. 1401N30F NILIT LTD. Vol. 06

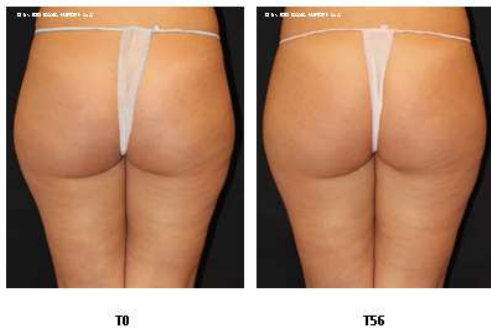


Fig. Improvement of "orange peel" skin visibility and local adiposities imperfections visibility (ref. report 1401N30F, Customer: NILIT®Fibers LTD.)

Self-evaluations

self-evaluations questions	T28 – mean value	T56 – mean value
1	6.55	7.00
2	6.70	7.05
3	6.80	7.00
4	6.65	7.30
5	6.15	6.55
6	6.00	6.45
7	6.70	7.00
8	6.90	7.20
9	7.50	7.85
10	7.60	7.85

Self-evaluations questions list:

- 1) *How much do you think this product increases skin compactness?*
- 2) *How much do you think this product increases skin smoothness?*
- 3) *How much do you think this product increases skin tonicity?*
- 4) *How much do you think this product increases skin elasticity?*
- 5) *How much do you think this product visibly reduces the appearance of orange peel?*
- 6) *How much do you think this product visibly reduces local adiposities?*
- 7) *After the product use how much do you feel your skin is firmer?*
- 8) *After the product use how much do you notice your silhouette has improved?*
- 9) *How much do you like the product?*
- 10) *Would you buy this product? Pls quantify.*

CONCLUSIONS

The product is able to change the instrumental, anthropometric and clinical parameters evaluated on the panelists who underwent the clinical test in the period of treatment. Therefore the product has proved to help to reduce local adiposities and cellulite imperfections visibility. It has proved to have cosmetic efficacy in improving skin elasticity, skin compactness and smoothness.

The product has also proved to have a fairly good acceptance of use.

BIBLIOGRAPHY

- **Regulation (EC) no1223/2009** of the European Parliament and of the council of 30 November 2009 on cosmetic products.
- **Declaration of Helsinki - ethical principles for medical research involving human subjects** adopted by the 18th wma general assembly, Helsinki, Finland, June 1964, and consecutive amendments (last amendment: 59th wma general assembly, Seoul, October 2008)
- **Guidelines for the evaluation of the efficacy of cosmetic products, revised version may 2008**
Cosmetics Europe – The personal care association

Controllo Qualità

Dott. Claudio Angelinetta