A RANDOMIZED, DOUBLE-BLIND STUDY TO EVALUATE IMPROVEMENT OF GYNOID LIPODYSTROPHY (CELLULITE) WITH WEARING INVEL® ACTIIVE SHORTS OF INVEL® TECHNOLOGY.

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Introduction

Gynoid Lipodystrophy (GLD) is a complex of changes in adipose tissue resulting in macronodes on skin surface. It features a major issue related to female esthetics and self-esteem, which makes the search for efficient and safe treatment methods relevant. It commits around 85 to 98% of post-pubertal women(1) and is characterized by changes in skin topography, which cause small skin depressions with appearance resembling that of orange peel.

Lipodystrophy is usually graded according to Curri's scale into four progression grades which are classified by their intensity.(2)

Grade I	Grade II	Grade III	Grade IV
			
Asymptomatic, no clinical changes are noted	Pallor, hypothermia, decreased elasticity, with no changes in relief at rest, which appear, however, when skin is compressed or muscle is contracted.	Upholstered skin and/or resembling orange peel at static examination; feeling of fine granulations on deep planes on touch; tenderness on touch, decreased elasticity, pallor and decreased skin temperature	Characteristics of Grade III and presence of visible and painful, palpable nodes; attachment of deep planes; large surface undulation.

Objective

Primary objective:

- To evaluate clinical improvement of areas committed with Gynoid Lipodystrophy (cellulite) through clinical (physical examination) and laboratorial (elasticity evaluation) parameters.

Secondary objective

- To evaluate the course of peripheral flow at the site committed with Gynoid Lipodystrophy with the aid of Infrared Thermography
- To evaluate safety of the product.

Methods

A national single-site, randomized, double-blind, placebo-controlled study has been performed that enrolled a sample of 151 female volunteers with grade III Gynoid Lipodystrophy (cellulite) on at least one of the evaluated areas from April to June 2009.

Investigational Product:

Invel® Actiive Shorts (anti-cellulite).

Method:

An Invel® Actiive Shorts (anti-cellulite), as well as a placebo shorts have been worn for a 60-day period for at least eight consecutive hours. Follow-up evaluations were carried out at days 30 (first visit) and 60 (second visit).

Evaluation means:

(a) Curri's scale : Visual classification of lipodystrophy;
(b) MPA580 Customer®: Skin elasticity;
(c) Infrared thermography, is an additional method in cosmetology and for the evaluation of esthetical medicine procedures, although not recent;
(d) Product safety has been measured by the rate of patients not developing adverse events, whether serious or not, related to the use of the product.

Results

Cellulite grade:

Significant differences in improvement rate of cellulite grades II and III of Curri's scale between Invel® Actiive Shorts (anti-cellulite) and Placebo on buttocks within 30 days for the difference (p=0.01623) and ratio (p=0.00644) tests.

Estimated relative risk of cellulite grade improvement at day 30 in buttocks was RR=2.107, which indicates that treatment with Biocerâmica® is 111% better than with placebo.

Elasticity:

There has been a significant time effect on elasticity in all sites and sides with a 5% significance level

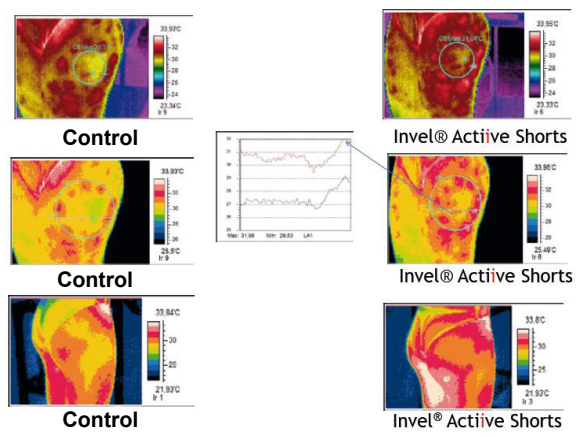
Thermography:

There have been significant time effects on all sites studied, i.e., mean temperatures at the three times differ in a significant way, with a 5% significance level

Safety:

No clinically significant events have been observed in the study population.

Higher tissue irrigation, decrease of least irrigated area, increased homogeneous perfusion:



Conclusion

An average improvement of 19% in grade-II and III cellulite (gynoid lipodystrophy) clinical appearance with wearing Invel® Actiive Shorts (anti-cellulite) for 8 hours daily, for 60 days, according to Curri's scale has been observed in this study.

Invel® Actiive Shorts (anti-cellulite) of Invel® technology has not caused irritation and/or sensitization in the trial subjects, which shows that the product is safe under the test conditions.

ANVISA, National Health Surveillance Agency, has acknowledge efficacy and safety of this product and granted registration ANVISA/MS **NK8O104760003** on 01/31/2011

References

1 .Avram AAM. Cellulite: a review of its physiology and treatment. J Cosmet Laser Ther 2004; 6:181-185.

2.Curri SB. Las paniculopatias de estrias venosas: diagnóstico clínico e instrumental. Barcelona: Hausmann, 1991.p.211.

Acknowledgement

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