

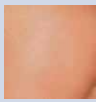



# A Randomized, Double-Blind Study to Evaluate Improvement of Gynoid Lipodystrophy (Cellulite) with Wearing Invel® Active Shorts of Invel® Technology

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## Introduction

Gynoid Lipodystrophy (GLD), commonly known as cellulite, refers to a condition involving alterations in adipose tissue, leading to the formation of macronodes on the surface of the skin. This condition primarily affects the aesthetic appearance and self-esteem of females, highlighting the importance of finding effective and safe treatment methods. GLD is prevalent in a significant majority, ranging from 85% to 98%, of post-pubertal women. It is characterized by changes in the texture of the skin, resulting in small depressions that resemble the appearance of an orange peel.

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 affected with Gynoid Lipodystrophy (cellulite) through clinical (physical examination) and laboratorial (elasticity evaluation) parameters.

### Secondary objective :

To assess the peripheral flow at the affected site in Gynoid Lipodystrophy using Infrared Thermography.

- To evaluate the safety of the product.

## Methodology

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® Active Shorts (anti-cellulite).

### Method :

An Invel® Active 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 :

- Curri's scale: Visual classification of lipodystrophy;
- MPA580 Customer®: Skin elasticity;
- Infrared thermography, is an additional method in cosmetology and for the evaluation of esthetical medicine procedures, although not recent;
- 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® Active 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 MIG3® Invel® Bioceramic is 111% better than with placebo.

### Elasticity :

A statistically significant time effect on elasticity was observed in all sites and sides, with a significance level of 5%.

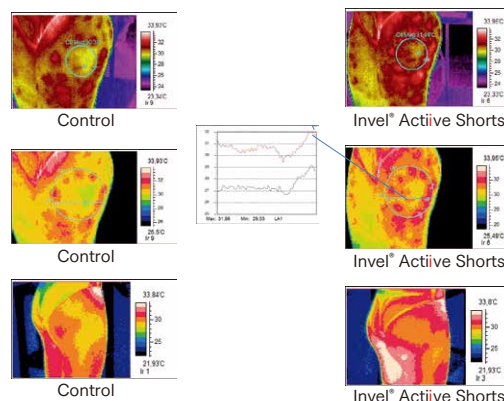
### Thermography :

Significant time effects were observed in all sites studied, indicating that the mean temperatures at the three time points differed significantly, with a significance level of 5%.

### Safety :

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

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



## Conclusion

In this study, it was observed that wearing Invel® Active Shorts (anti-cellulite) for 8 hours daily, over a period of 60 days, resulted in an average improvement of 19% in the clinical appearance of grade-II and III cellulite (gynoid lipodystrophy) based on Curri's scale.

Furthermore, the trial subjects did not experience any irritation or sensitization from using Invel® Active Shorts (anti-cellulite) with Invel® technology, indicating that the product is safe under the test conditions.

The efficacy and safety of this product have been acknowledged by ANVISA (National Health Surveillance Agency), which granted registration ANVISA/MS NK80104760003 on 01/31/2011.

## References

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

## Acknowledgments

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