

# A NEW TRANSDERMAL DELIVERY COSMETIC SYSTEM TO CONTROL THE SKIN LOCALIZED LIPODYSTROPHY.

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## Synopsis

Transdermal Delivery Cosmetic System (TDCS) is a combination of an occlusive adhesive and special active cosmetic compounds (ACC) on suitable cosmetic vehicle. Following the application, the ACC starts to migrate from the system through the skin, furnishing a constant active compounds concentration in the interested skin area for a prolonged period of time. The influence of the TDCS on skin pH and hydratation was recorded by the 3C System Computerized Methodology. The effects of natural extracts on localized skin lipodystrophy was controlled by an echographic methodology. The obtained results show a good transmigration efficacy of the ACC used from the TDCS to the underlying cutaneous layer (85%) after 6 hours of treatment, together with an aspected increase of skin pH and hydratation. The effect obtained on the localized skin lipodystrophy seems to suggest a high efficacy of this TDCS for the treatment of the "cellulitis" and its validity as new concept to treat such skin problems.

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## Riassunto

Questo nuovo mezzo per l'applicazione di principi attivi cosmetici denominato TDCS, è rappresentato dalla combinazione di uno speciale cerotto occlusivo sul quale viene spalmato un adeguato adesivo-veicolo cosmetico in grado di incorporare adatti principi attivi.

I principi attivi cosmetici applicati sulla cute mediante il TDCS trasmigrano nei diversi strati cutanei, ivi permanendo, per un prolungato periodo di tempo. Con questo studio si sono controllate sia le variazioni del pH che dell'idratazione cutanea, utilizzando la nuova metodica computerizzata 3C System. Gli effetti esplicati da estratti naturali sulla cellulite, sono stati verificati mediante l'utilizzazione di una metodica ecografia. I risultati ottenuti dimostrano una trasmigrazione molto elevata dei principi attivi dal veicolo ai sottostanti strati cutanei (85%), dopo le prime 6 ore di trattamento, assieme ad un incremento previsto sia del pH che dell'idratazione cutanea. Gli effetti ottenuti sulla lipodistrofia cutanea localizzata sembrano dimostrare una alta efficacia di questo TDSC se usato per il trattamento della cellulite.

## INTRODUCTION

Transdermal Delivery Cosmetic System (TDCS) is a combination of an occlusive adhesive and special active cosmetic compounds (ACC) on suitable cosmetic vehicle. This new device may be topically and directly applied to the skin or to the mucous membranes providing a continuous infusion of the ACC used. Upon this topical application the ACC seems to migrate from the system through the skin, giving a constant active compounds concentration in the interested area for a prolonged period of time (1,2,3). The cosmetic activity can be stopped easily by just ending the skin contact. The aim of this study was to control the variations in thickness of hypodermis strata induced by local application of this new TDCS based on the activity of natural cosmetic compounds, having good skin uptake and minimal penetration into the capillaries.

## MATERIALS AND METHODS

### MATERIALS

The special acrylic base used for our devices

was enriched with *centella asiatica* and *fucus vesiculosus* extracts so that each plaster contained a total of 10 mg active compounds, 0,2 mg/cm<sup>2</sup> of which were *centella triterpenes* (4).

HPLC Varian Modello VLC 9010 Star System Work Station

### METHOD

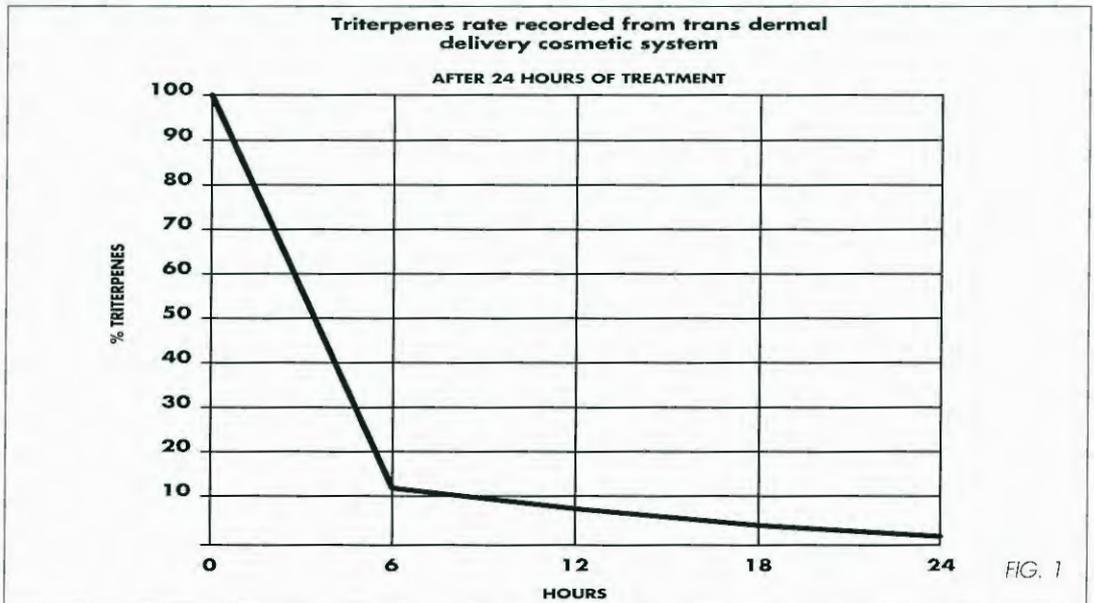
20 volunteers women ranged 27/42 years with visible sign of localized cellulitis applied the 44x57 or 50x72 cm<sup>2</sup> TDCS on the affected area for 30 days

### ACTIVE COSMETIC COMPOUNDS CONTROL

Plasters devices were taken at 6,12,18 and 24 hours and analyzed by HPLC according to Morganti et al. (4) before and after the topical applications, to precisely verify any *centella triterpenes* content after their use. (Fig 1)

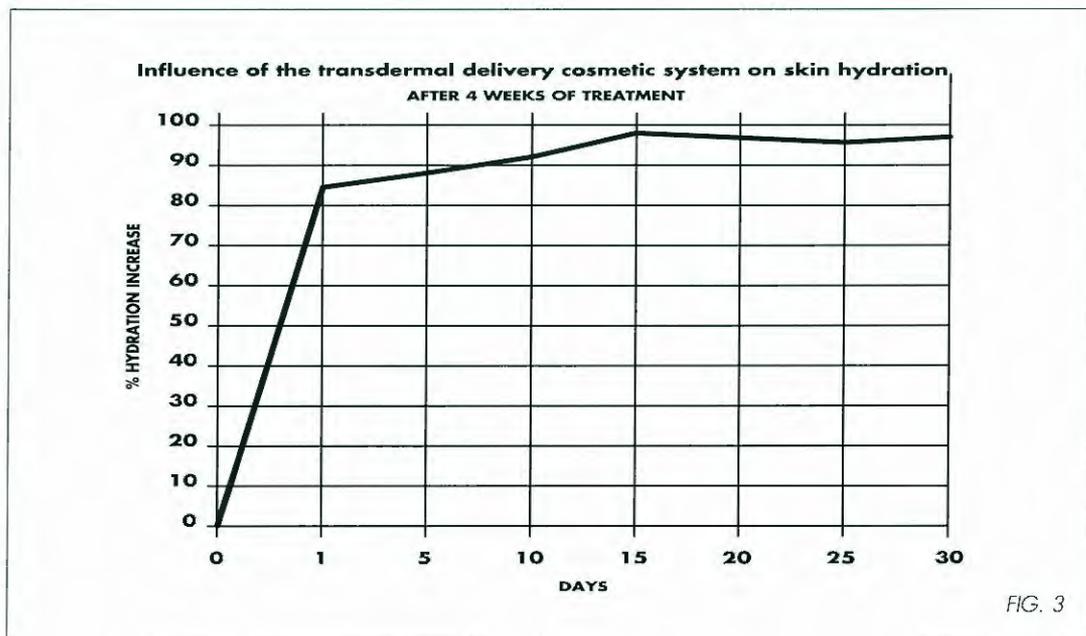
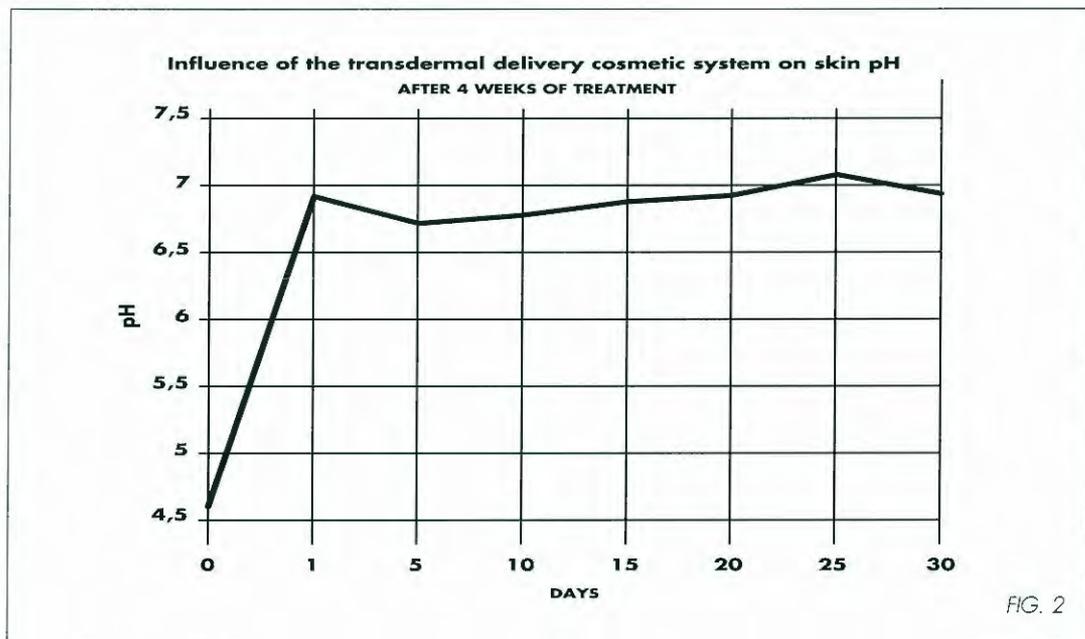
### pH AND SKIN HYDRATION

Skin hydration and pH were monitored through the



new 3C System Computerized equipment at day 0/1 and every 5 days. It records the values in direct redout, while environmental conditions are

automatically standardized (RH= 50% t=22°C) by the use of proper correction factors (5). Obtained results are reported in Figure 2-3.



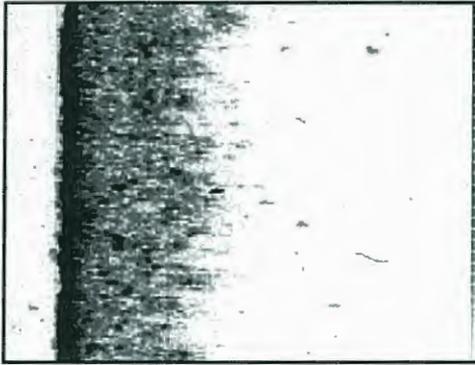
### HIGH-FREQUENCY SONOGRAPHY MEASUREMENTS

Because of the limited results of some technique such as xenoradiography (6) and A-mode sonography (7) in measuring skin thickness, and according to Fornage et al. (8-9), the effects of the daily 30 day topical application of the TDCS used were evaluated by a high- frequency (20-

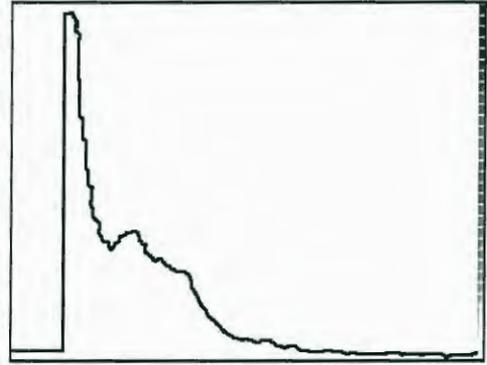
MHz) sonography equipment, providing us cross-sectional images of the skin with high resolution. With this device we were able to show the Dermal-hypodermal junctions and the modifications induced by treatment.

The obtained results are reported in Figure 4 and 5.

#### ECHOGRAPHY TAKEN AT THE BEGINNING OF THE TREATMENT ON CELLULITIS SKIN AREA (n=20)



B- MODE

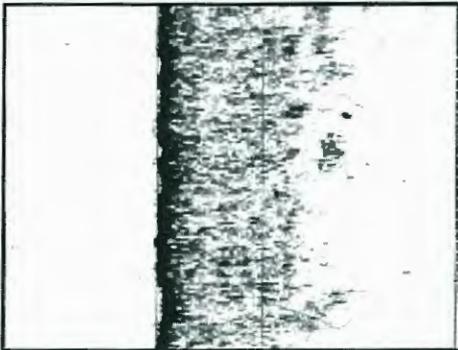


A- MODE

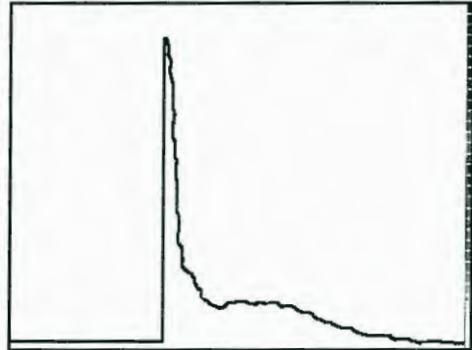
FIG. 4

#### ECHOGRAPHY TAKEN AT THE END OF THE TREATMENT ON THE CELLULITIS SKIN AREA

(n=20) (12 hours Daily Application x 30 Days)



B- MODE



A- MODE

FIG. 5

## RESULTS AND COMMENTS

As shown in Figure 1 the triterpenes rate recorded at 6,12,18 and 24 hours of application was reduced from 88 to 98% on the average ( $p < 0.001$ ).

On the basis of this result we may assume that there was an high trasmigration of our active compounds from the vehicle to the underlying cutaneous layers.

Obviously we don't know how much of our active compounds actually reached the hypodermis.

For this reason we are also carrying out further analitical survays on the various cutaneous layers in order to assess the indirect absorption indices of our active compounds. Local modifications in the configuration of the dermis and of dermal hypodermal junction can be seen by echography (Fig 4). Figure 4 shows the echography taken at the beginnig of the study. In the echography by B-mode it can be seen the treated area by normal ultrasound echography performed through a probe working at 20 MHz. In the A-mode it is shown the impedance obtained by the equipment in the same treated area.

The Figure 5 shows the same skin area at the end of the treatment.

The B-mode scanning demonstrates a reduction of the dermal oedema which results more omogeneous.

The A-mode shows very important modifications of the profile of the skin impedance, due in our opinion, to a reduction of the accumules of the subcutaneous fat and oedema phenomena. As shown from Figure 3 and in perfect agreement with the literature data, the skin hydration is increased by 85% to 97% due to the occlusiveness of the plaster used. pH reached mean value of 6.9 increasing by 1.4/1.5 units in 1 month treatment (Fig.2).

Furthermore to better investigate the effects of TDCS on cellulitis we undertaken a new study by normal echography which is able to reach the hypodermal tissue.

## CONCLUSION

This new TDCS seems to represent a new cosmetic device which enables to achieve a sub-stained and constant action through the skin. Even if further studies have to be conducted to better understand and confirme the echography results, within short time application TDCS seems to represent an efficacious cosmeceutical therapy for the treatment of localized skin lipodistrophy, improperly called "cellulitis"

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