

# A NEW COSMECEUTICAL FOR THE "ORANGE PEEL" SKIN

**P. Morganti\***, **S.D. Randazzo\*\***, **G.Fabrizi\*\*\*** and **C. Bruno\*\*\*\***

\* President/Director, R & D Mavi Sud S.r.l., Viale dell'Industria 1, 04011 Aprilia (LT), Italy.

Department of Dermatology, Dermatologists Training School, II University of Naples, Italy.

\*\* Department of Dermatology, University of Catania, Italy.

\*\*\* Department of Dermatology, Catholic University of Rome, Italy.

\*\*\*\* Physiology Institute, University of Urbino, Italy.

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## Synopsis

"Cellulitis" represents an unaestheticism capable of modifying the harmony of the figure referring to modern rules. The skin opaque, arid, scabrous and painful to the touch is characterized by a rugged appearance known as "orange peel skin".

The present study was designed to evaluate the activity of a new Transdermal Cosmetic Delivery System (TCDS) on the anterior lateral surface of the thighs of 30 female volunteers (aged 18-30) presenting cutaneous signs of "cellulitis" of different degrees of intensity, treated each night for 21 days with this special patch in a double blind study.

Before and after the study the thickness of the cutaneous tissue was controlled by the Dermoscan C<sup>®</sup> (Denmark, version 3 at 20-MHz) and skin hydration and TEWL by 3C System<sup>®</sup> (Rome, Italy). The TCDS caused a both a decrease of skin thickness, and of the cellulitic layer thickness and a contemporary high increase of skin hydration and TEWL ( $p < 0.005$ ).

No adverse reactions were observed. The obtained results seem to prove the validity of this new cosmeceutical device for the treatment of the so called "cellulitis".

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## Riassunto

La "cellulite" rappresenta un inestetismo capace di modificare l'armonia della figura secondo i parametri moderni. La pelle opaca, arida, scabra e dolorante al tatto è caratterizzata da un aspetto ruvido noto come "pelle a buccia d'arancia".

Con il presente studio si è voluta valutare l'attività di un nuovo cerotto transdermico denominato Transdermal Cosmetic Delivery System (TCDS). La valutazione è stata effettuata sulla superficie antero-laterale delle cosce di 30 donne volontarie (di età compresa tra i 18 e i 30 anni), che presentavano segni cutanei di una cellulite con diversi gradi di intensità, trattate ogni notte per 21 giorni

con questo speciale cerotto in uno studio a doppio cieco.

Lo spessore della pelle è stato controllato prima e dopo lo studio tramite il Derscan C® (Denmark, versione 3 a 20 MHz), l'idratazione della pelle e la TEWL per mezzo del 3C System®. Il TCDS ha provocato una diminuzione dello spessore della pelle, una diminuzione dello spessore dello strato di cellulite ed un contemporaneo aumento sia dell'idratazione cutanea globale ( $p < 0.005$ ) da addebitarsi essenzialmente all'attività occlusiva esercitata dal cerotto, che del TEWL.

Non sono state rilevate reazioni collaterali.

I risultati ottenuti sembrano provare la validità di questo nuovo mezzo cosmetico per il trattamento della cosiddetta "cellulite".

## INTRODUCTION

"Cellulitis" represents an unaestheticism capable of modifying the harmony of the figure referring to modern rules. The skin opaque, arid, scabrous and painful to the touch is characterized by a rugged appearance known as "orange peel" skin (1-3).

## STUDY DESIGN

The present study was designed to evaluate the activity of a new Transdermal Cosmetic Delivery System (TCDS) on the anterior lateral surface of the thighs of 30 female volunteers (aged 18-30) presenting cutaneous signs of cellulitis at different degrees of intensity, localized on the anterior-lateral surface of thighs, treated each night for 21 days with this special patch (4x4 cm) in a double blind study.

In order to eliminate possible external influences 15 women were randomly treated on the right or on the left thigh with both the active-patches or with the vehicle-patches (control), the other side serving as untreated control. In this way both the active and the control patches were indifferently applied both on the right and the left thigh.

The selected subjects were not taking drugs for systemic administration or anti-cellulitis topic products and, moreover, had not undergone specific diets before and during the clinical trial's period.

## MATERIALS AND CHEMICALS

1. 4x4 cm patch with acrylic base (vehicle-control B);
2. 4x4 cm patch enriched with centella asiatica and fucus vesiculosus extracts so that each plaster contains a total of 10 mg active compounds, 0.2 mg/cm<sup>2</sup> of which are centella tri-terpens (4-9).

## INSTRUMENTAL MEASUREMENTS

### *Ultrasound-B-mode imaging*

This two-dimensional B-scan procedure gives ultrasounds single lines (A-Scan lines) corresponding to a cross-sectional image of the skin. In fact when a beam of ultrasounds passes through the different layers of the skin, different echoes are produced depending on the acoustic characteristics of the examined areas; those echoes are recorded by the instrument and visualized on the screen as peaks (A-Scan). By measuring the distance among the peaks, it is possible to determine the thickness of the different structural components of the skin (10).

Before and after the study the thickness of the subcutaneous tissue was controlled on 3 points of skin surface for both the thighs by the DermoScan C<sup>®</sup>, (Denmark) version 3, at 20-MHz. Skin hydration and TEWL were controlled by 3C System<sup>®</sup>, (Rome, Italy) which was previously used by our team (11).

### **3C System<sup>®</sup>**

This computerized system through the capacitive resistance permits a simple and quick control of surface lipids, skin hydration and TEWL. The 3C System<sup>®</sup> collects up to 10/15 measure-



3C System<sup>®</sup>

ments over 25 seconds sampling period and records the mean value automatically standardizing the environmental conditions (RH=50%, T=22°C). Measurements were performed on 1st day (baseline) and after 7, 14, 21, 28, 35 days. TEWL is expressed as the amount of water evaporated per unit of surface in 1 hour  $gr/m^2/h$  and the system collects up 10/15 measurements over 25 second sampling period and record the mean value automatically (11).

### Statistical analysis

Differences in TEWL, skin hydration and subcutaneous tissue thickness were examined for statistical significance using the non-parametric Friedman test. When the Friedman test revealed significant values between the treatments, multiple comparisons of all groups were conducted by the Wilcoxon-Wilcox tests.

## RESULTS

The obtained results are reported in Fig. 1, 2 and 3.

## COMMENTS

As already proven by our group and by other authors the scan-ultrasound technique seems to be the best methodology feasible for measuring the variations of the cellulitic layers during an anti-cellulitis treatment (12-18).

As it can be seen on Fig. 1 patch application on day 21 highlights a remarkable change in the thickness of the cutaneous layer ( $p < 0.005$ ) before and after the treatment. This change is surely due to the activity carried out by the used active ingredients, since the sole vehicle has proved to be ineffective.

It is also interesting to point out that the patch-

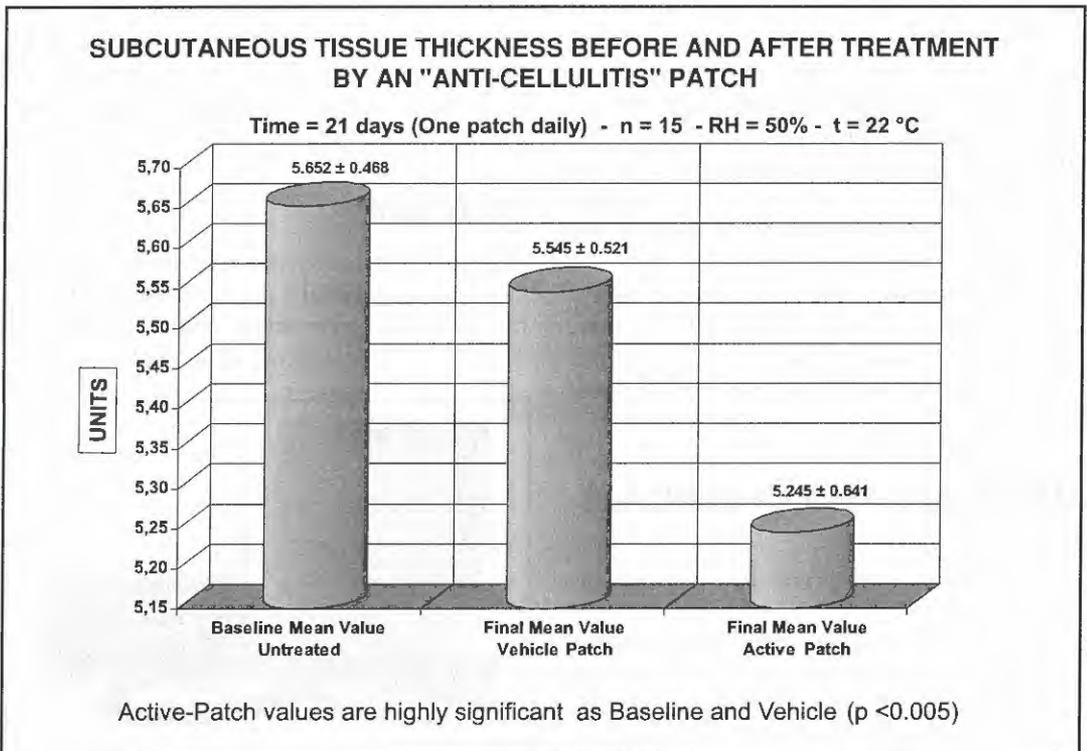


Fig. 1

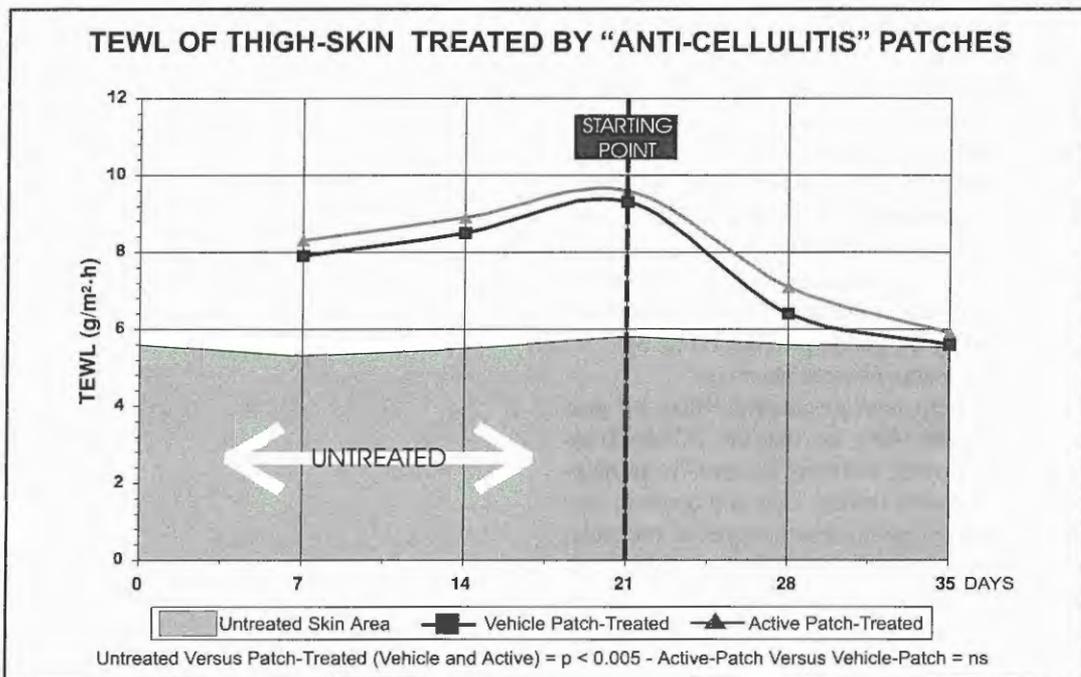


Fig. 2

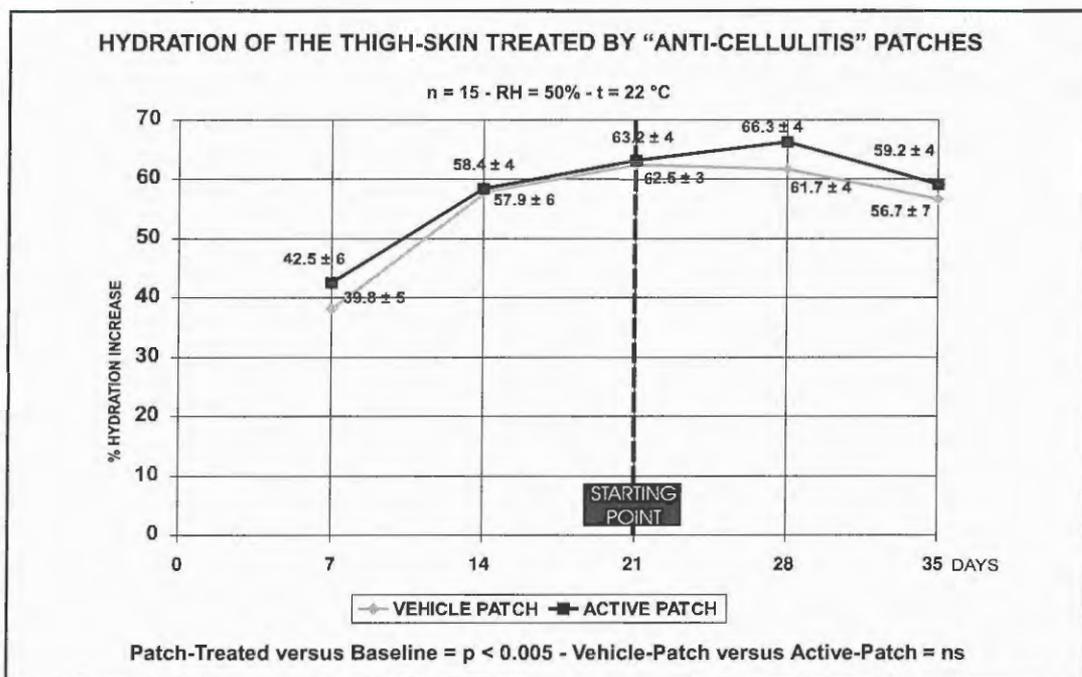


Fig. 3

treatment causes the TEWL to increase considerably ( $p < 0,005$ ), independently from the presence of the active ingredient. This means that it acts by changing the stratum corneum barrier. That should be the reason why the active ingredients seem to be able to easily reach the hypoderm. By interrupting the treatment TEWL gets back to normal values ( $p < 0,005$ ) (Fig. 2).

Also concerning the cutaneous hydration the increasing problem is due also to the occlusive effect caused by the patch ( $p < 0,005$ ) (Fig. 3).

No adverse reactions were observed.

Obtained data seem to confirm what we previously proved (4-8), i.e. that the TCDS (Transdermal Cosmetic Delivery System) is an helpful cosmeceutical device, easy and quick to use, and capable of giving good results in the treatment of the cutaneous unaesthetism called "cellulitis".

### **Author Address:**

*P. Morganti, PhD - Research and Development*

*MAVI Sud srl - Via dell'Industria 1,*

*04011 Aprilia (LT), ITALY*

*Phone: + 39 06 9286261*

*Fax: + 39 06 9281523*

*E-mail=mavi@colosseum.it*

*URL=<http://www.colosseum.it/st81/mavi>*

## REFERENCE

1. **Braun Falco O., Scherwitz C. (1972)**, Histopathologie der Sog. *Zellulitis. Hautartz*, **23**, 71-75
2. **Binazzi M., Papini M. (1983)**, Aspetti chimico-istomorfologici. In: (Ribuffo-Bartoletti eds) *La cellulite*, Ed. Salus Internazionale, Roma, Italy
3. **Scherwitz C., Braun Falco O. (1978)**, So-called cellulitis, *J.Dermatol.Surg.Oncol.* **4**, 230-234
4. **Morganti P., Celleno L. and Vasselli A. (1995)**, A new Transdermal Delivery Cosmetic System to control the skin localized lipodystrophy, *J.Appl.Cosmetol.* **13**, 15-20
5. **Morganti P. (1995)**, Nuove applicazioni di principi attivi vegetali: il cerotto cosmetico, *Cosm. News*, 107-109
6. **Morganti P., Tiberi L., Vasselli A., Tolaini M.V., Serafini G., Celleno L. (1995)**, Transdermal Cosmetic Delivery System: a new device for cosmetic use. Evaluation of its effects in the treatment of so called "cellulitis", Presented at IFSCC Congress, Montreux, Switzerland, 18-21 September 1995
7. **Morganti P. (1996)**, The cosmetic patch: a new frontier in Cosmetic Dermatology, *Soap, Cosm. Chem. Special.* (February), 48-50
8. **Morganti P, Fionda A., Tiberi L. (1996)**, The Transdermal Cosmetic Delivery System: A new cosmeceutical device, Presented at Active Ingredients Conference, Paris 13-14 November 1996, in print on *Cosmetics & Toiletries*.
9. **Morganti P., Fionda A., Tiberi L., Icare M., Rusch F., Elia U. (1996)**, Extraction, analysis by HPLC of cosmetic active ingredients from an anti-cellulitis transdermal delivery system, *Submitted for publication*.
10. **Seidenari S. (1995)**, Ultrasound B-mode imagine and in-vivo structure analysis. In: Non invasive methods and the skin (Serup and Jemec Edrs.), *CRC Press Inc.*, Bocaaton, Florida, p. 257
11. **Cardillo A., Morganti P. (1994)**, A fast non-invasive method for skin hydration control, *J. Appl.Cosmetol.* **5**, 105-120
12. **Webb S. (1990)**, "The Physics of medical imaging", Ed. Adam Hilger, Bristol.
13. **Edwards C. (1988)**, Non invasive in vivo measurement of dimensions and properties of stratum corneum and epidermis by A-Scan ultrasound, *15th IFCC International Congress* **4**, 263-4
14. **Pugliese P.T. (1989)**, Use of ultrasound in evaluation of skin care products, *Cosm. Toil.* **104**, 61-76
15. **Armengol R., Girones E., Belles A. et al. (1992)**, Quantitative evaluation of the anti-cellulitis efficacy by scan-ultrasound and its relation with clinic studies, *17th IFCC Int. Congr.* Vol. 3, 1218-1240
16. **Fornage B.D. and Anderson M.D. (1995)**, Ultrasound examination of the skin and subcutaneous tissues at 7.5 to 10 MHz. In: Non-invasive methods and the skin (Serup and Jemec Eds.), *CRC Press Inc.*, Bocaaton, Florida, p. 279
17. **Agner T. (1995)**, Ultrasound A-mode measurement of skin thickness. In: Non-invasive methods and the skin (Serup and Jemec Eds.), *CRC Press Inc.*, Bocaaton, Florida, p. 289
18. **Morganti P. (1997)**, A new peloid mask of Etruscan origin. Presented at IN-COSMETICS Conference, Düsseldorf, May 6. Published on the Conference Proceedings "Modern challenges to the Cosmetic Formulations", p.451-456, *J. Appl.Cosmetol.* **15**, 109