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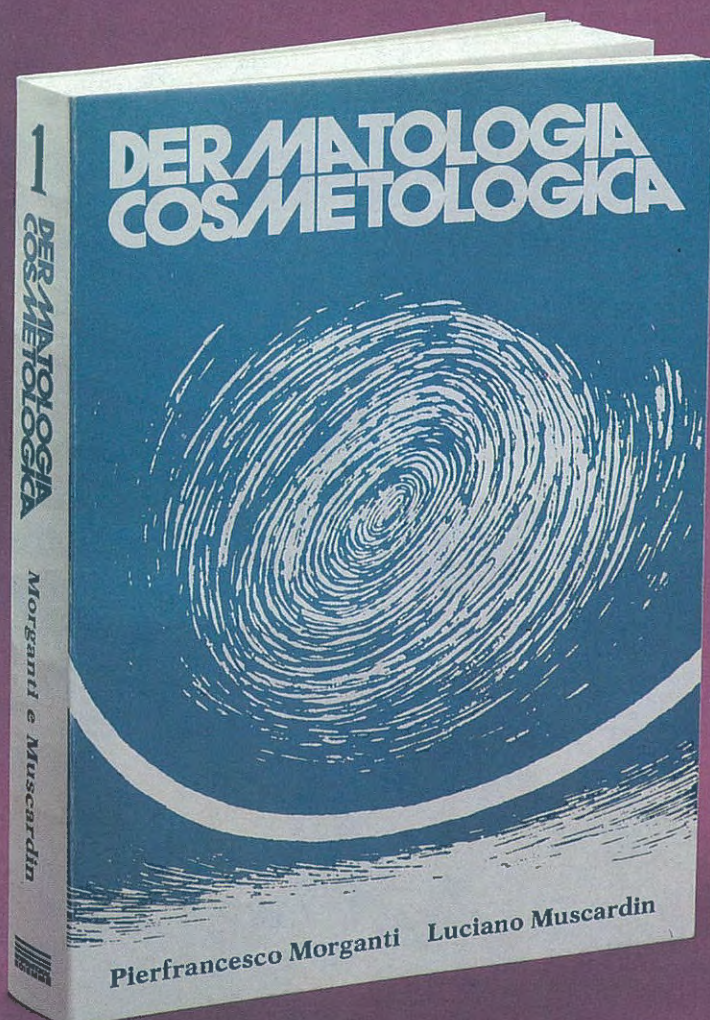


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DERMATOLOGIA COSMETOLOGICA

A cura di P. Morganti e L. Muscardin
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XIX Announcement

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ALPHA HYDROXY ACIDS IN THE COSMETIC TREATMENT OF PHOTO-INDUCED SKIN AGEING

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Key words: AHAs; Glycolic Acid; Photo-aging; Actinic Keratosis; Wrinkling; Age-spots.

Synopsis

The continuous adverse effects of light of over the years add to normal ageing processes. This increases the number and severity of wrinkles, reduces the efficiency of cell mechanisms responsible for the reparation of damaged genes due to UV rays in photo-exposed areas, causes actinic keratosis, slows down epidermic cell turnover and reduces surface lipids, the moisture level and, as a result, the suppleness of the skin.

The noticeable adverse effects generally decrease with the use of retinoic acid-based drugs or cosmetic-based products including various active components, from collagen to sodium lactate and aminoacids, from gelatine-glycine to Pyrrolidone Carboxylic Acid (PCA) and the newly-used Alpha hydroxy acids (AHAs), such as, for example, glycolic acid.

This double-blind study aims to control the activity of 8% AHAs and gelatin-glycine-based cosmetic emulsions over 90 days clinically evaluating the number of thin wrinkles.

Furthermore, the surface lipid film, the pH value and the skin moisture level were tested with the computerized methodology 3C System[®]. Finally, the cell turnover was tested with the "Scrub technique".

Riassunto

La continua attività negativa svolta dalla luce durante gli anni si sovrappone ai normali processi di invecchiamento, - aumentando il numero e la profondità delle rughe, - riducendo l'efficienza dei meccanismi cellulari preposti alle riparazioni dei geni danneggiati dalle radiazioni UV a livello delle zone fotoesposte, - provocando la comparsa di cheratosi attiniche, - rallentando il turnover delle cellule epidermiche e riducendo i lipidi di superficie, l'idratazione e conseguentemente l'elasticità della pelle.

Per ridurre questi danni cutanei evidenti si utilizzano generalmente prodotti cosmetici nella cui composizione sono presenti i più svariati principi attivi, dal collagene, al lattato di sodio, agli aminoacidi; dalla gelatina-glicina, all'acido Pirrolidon Carbossilico (PCA) e ai più recenti Alfaidrossiacidi (AHAs) quale, ad esempio, l'acido glicolico. Con questo studio a doppio cieco si è voluto controllare in un periodo di 90 giorni, l'attività svolta da emulsioni cosmetiche contenenti alfa-idrossiacidi all'8% e gelatina-glicina, valutandone il numero di rughe sottili.

È stato, inoltre, controllato il film lipidico di superficie, il pH e l'idratazione cutanea utilizzando una nuova metodica computerizzata denominata 3C System[®]. Il turnover cellulare è stato controllato con la tecnica cosiddetta "Scrub".

FOREWORD

The skin gradual ageing is known to depend on two main factors: intrinsic ageing due to genetic factors, which, as such, is relentless, and extrinsic ageing, which is basically linked to the amount of environmental pollutants, UV rays and IR rays we are exposed to throughout our life. These agents act by speeding up changes in the skins biological characteristics (1-4).

The continuous adverse effects of light over the years add to normal ageing processes. This increases the number and severity of wrinkles, reduces the efficiency of cell mechanisms responsible for the reparation of damaged genes due to UV rays in photo-exposed areas, causes actinic keratosis, slows down epidermic cell turnover and reduces surface lipids, the moisture level and, as a result, the suppleness of the skin (5-9). This noticeable adverse effects generally decrease with the use of retinoic acid-based drugs or cosmetic products including various active components, from collagen to sodium lactate and aminoacids, from gelatin-glycine to Pyrrolidone Carboxylic Acid (PCA) and the newly-used Alpha hydroxy acids (AHAs), such as, for example, glycolic acid (10-17).

PURPOSE

This double-blind study aims to control the activity of 8% glycolic acid and gelatin-glycine-based cosmetic emulsions over 90 days in a group of 60 volunteer women aged 45 to 60, who showed clear sun-induced skin changes.

After assessing the major role of the vehicle, the pH value and the concentration necessary for AHAs optimum performance (17-18), a visual analogic scale (19) was used to clinically evaluate the number of thin wrinkles on the face and back of the hands, actinic keratosis and the cheek telangiectasis before and after treatment as compared to the placebo group.

Furthermore, the surface lipid film, the pH value and the skin moisture level were tested with

the computerized methodology 3C SYSTEM® (20).

Finally, the cell turnover was tested with the Scrub technique (21-23).

MATERIALS AND METHODS

Materials

CLEANSING LOTION QM

Distilled water, Ceteareth-6, Isopropyl myristate, Octyl stearate, Sorbitol, Glycerin, Propylene glycol, Glycolic acid, Gelatin-glycine, Tocopheril acetate, Rethynil palmitate, Imidazolidyn urea, Linoleic acid, Methyl paraben, Hydrolized collagen, Sodium EDTA.

QM 5 H BASE (A1M control)

Distilled water, Decyl oleate, Propylene glycol, Glycerin, Cethyl Phosphate, DEA-cethyl phosphate, Hydrolyzed collagen, Sodium PCA, Micronized titanium dioxide, Gelatin-glycine, Carbomer, Imidazolidynil urea, Tocopheryl acetate, Butyl methoxy dibenzoilmethane, Methyl paraben, Propyl paraben.

QM 5 H/AHAs (A2M active)

QM 5 H BASE + 8% AHAs (glycolic and lactic acid)

QM 5 N BASE (A3S control)

Distilled water, Ceteareth-6, Isopropyl miristate, Sodium PCA, Octyl stearate, Propylene glycol, Glycerin, Tocopheryl acetate, Hydrolized collagen, Gelatin-glycine, Linoleic acid, Retinyl palmitate, Disodium EDTA, Imidazolidynil urea, Methyl paraben.

QM 5 N/AHAs (A4S active)

QM 5 N BASE + 8% AHAs (glycolic and lactic acid)

Methods

Previous tests (17, 18, 22) showed the major role of the cosmetic vehicle used and the pH va-

lue of the finished product, which are essential for clear positive results at skin level.

For example, it was possible to show that an acid environment seems to promote the AHAs activity whereas the concurrent presence of gelatin-glycine seems to enhance AHAs action.

Selection of volunteer patients

This study was performed in 60 volunteer women aged 45 to 60, who had chronic skin damage due to a continuous exposure to sun rays and the so-called high-pressure lamps.

All selected women showed various signs of photoageing on their face, such as telangiectasis on the cheeks, thin wrinkles around the eyes and lips, actinic keratosis, wrinkles and hyperpigmented spots on the back of the hands. All suffered from dryness and clear dehydration of the skin of the face.

Cosmetic treatment

A double-blind cosmetic treatment was performed after teaching patients how to apply the A1M and A2M creams in the morning to the right or left half of the face (including the eye area) and to the right or left back of the hand respectively. The A3S and A4S creams were used always on the right or on the left, but in the evening. The creams marked with odd numbers had to be always applied to the same skin area.

Thirty minutes before applying the creams, the areas concerned were cleaned only with QM Cleansing Lotion that we supplied.

Fifteen women applied the 3AS product and 15 other women the 4AS product also to the inner part of the right forearm, whereas the left forearm was used as a control.

The cosmetic treatment lasted 12 weeks between January and March 1994, and tests were made always by the same researcher at 0, 4, 8 and 12 weeks, with a further test a month later, during which no cream was applied. The researcher

also checked that the creams be regularly applied according to instructions. During the treatment, no other cosmetic product was used. Thirty days before starting the study both topical and systemic treatments were discontinued.

Methods for skin mark detection

All photoageing-induced skin marks, which were separately detected in the various face areas, were examined before, during and after the cosmetic treatment using an analogic scale with 0 to 10 points, according to the Lever at all method (19). Results are shown in tables I - III.

Measurement of the moisture level, pH value and surface lipid film

These factors were measured before (0 weeks) and after 4, 8 and 12 weeks of treatment, always in the morning from 10.00 to 12.00 on skin cleansed the night before. According to instructions, no cream was applied the night before the measurement. A measurement was performed also on the 16th week. Values were obtained using the 3C SYSTEM® a new computerized equipment which automatically compares values always read at 22° C with 50% RH (20) (Fig. 1). Results are reported in figures 2 and 3.

Cell turnover

The cell turnover was tested by the Scrub technique on the forearms according to the Nicholls and Marks method (23), which had been already used by our research group in a previous study (24).

This method uses of a haemocytometer to count the number of desquamating horny cells taken from the skin with a 0.06 M phosphate solution of X-100 Triton by cutaneous scarification of a known surface and for a given time.

Results are reported in figure 4.

Table I

**THIN WRINKLES DETECTED ON THE SKIN IN EYE AREAS
WITH PHOTO-INDUCED AGEING**

Following treatment with 8% AHAs creams (as compared to the cream vehicles).

WEEKS	QM-8% (ACTIVE)	QM BASE (VEHICLE)	% REDUCTION	p
0	390	392	----	n.s.
4	298	335	11	< 0.001
8	273	307	11	< 0.001
12	250	283	11.7	< 0.001
16	246	280	12.1	< 0.001

Thin wrinkles detected around the eyes in 60 women treated with two AHAs-based creams on one side of the face (morning and night) and with the cream vehicles on the other.
Analogic scale (0-10) x 100.

Table II

**WRINKLES DETECTED ON THE SKIN IN BACK HAND AREAS
WITH PHOTO-INDUCED AGEING**

Following treatment with 8% AHAs creams (as compared to the cream vehicles).

WEEKS	QM-8% (ACTIVE)	QM BASE (VEHICLE)	% REDUCTION	p
0	344	349	----	n.s.
4	315	322	2	n.s.
8	303	313	3.2	n.s.
12	281	304	7.6	< 0.05
16	274	296	7.4	< 0.05

Thin wrinkles detected on the back of the hands in 60 women treated with two AHAs-based creams on one hand (morning and night) and with the cream vehicles on the other.
Analogic scale (0-10) x 100.

Table III

THIN WRINKLES AROUND THE MOUTH AND ON THE CHEEKS
 Following treatment with 8% AHAs creams (as compared to the cream vehicles).

WEEKS	QM-8% (ACTIVE)	QM BASE (VEHICLE)	% REDUCTION	p
0	424	430	----	ns.
4	402	411	2.2	ns.
8	385	403	4.5	< 0.05
12	366	386	5.2	< 0.05
16	354	378	6.3	< 0.05

Thin wrinkles detected around the mouth and on the cheeks in 60 women treated with two AHAs-based creams on one side of the face (morning and night) and with the cream vehicles on the other.

Analogic scale (0-10) x 100.

**Fig. 1**

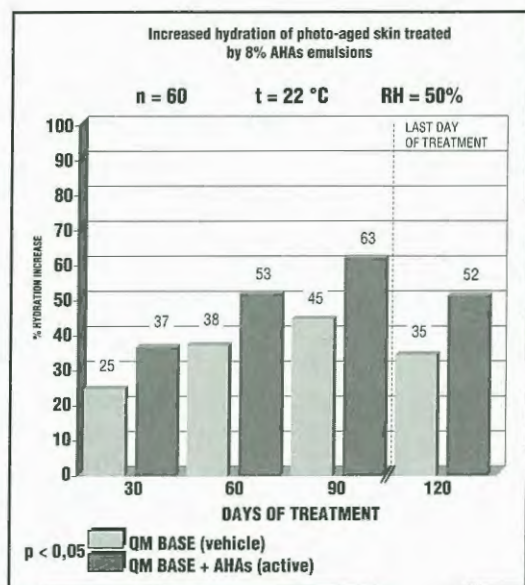


Figure 2

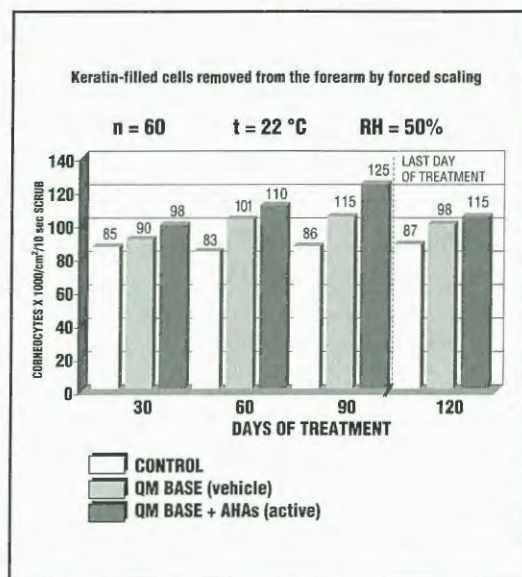


Figure 4

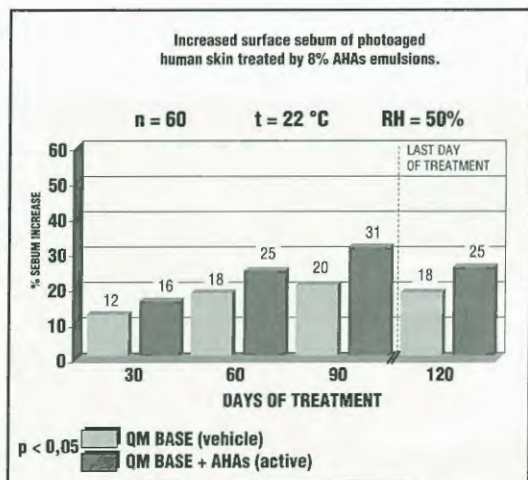


Figure 3

RESULTS AND REMARKS

As clearly reported in Tables I to III and as already shown by our research group (18), the vehicle by itself reduced the number of thin wrinkles which were detected on the face and hands between the 4th and 8th week of treatment. During the whole 12-week treatment, a significant decrease in thin wrinkles was detected,

which ranged from 16% (mouth and cheeks) to 20% (back of the hands) and 40% (eye area).

Adding AHAs to the vehicle reduced the number of thin wrinkles by a further 12%, 20% and 30% respectively. However, it should be underlined that the vehicle we used was added with Gelatin-glycine, which itself is active as an anti-ageing agent, almost like AHAs (18).

Only a slight depigmentation of actinic keratosis and hyperpigmentations on the back of the hands occurred, while the number of these age-spots remained nearly unchanged.

The same applies to telangectasis of the face.

The skin moisture level increased by 45% after 3 months of treatment and by a further 40% when the vehicle was added with AHAs.

The same applies to the surface sebum, which increased by 20% with the vehicle alone and by 30% approx. with the active cream (Figures 2 and 3).

Interestingly, at the 16th week, that is 4 weeks after discontinuance of the cosmetic treatment, the tested values were still markedly better than the baseline values.

Thus, the effectiveness of the cosmetic treat-

ment tends to be steady over time at least of extra 30 days approx.

Similar improvements were obtained by forced scaling. By treating the skin with both the gelatin-glycine base and the active component (addition of AHAs), a marked increase in the cell turnover was shown (Fig. 4).

The aged skin behaves as the young skin.

In fact, through further tests still under way by the Dansil fluorescence method, fluorescence was shown to disappear by 22 days (25), and not by 34 days, as detected before the cosmetic treatment.

Again, both AHAs and the gelatin-glycine appear to be active substances stimulating and speeding up the cell turnover which photo-induced ageing usually reduces. As a result, the appearance of the skin is improved.

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EXAMINATION OF FINGERNAIL PLATES BY MEANS OF POLARIZED LIGHT VIDEOMICROSCOPY

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Key words: *nail, videomicroscopy, polarized light.*

Synopsis

Examination of fingernail ridges or plates by means of polarized light has been performed using metallographic microscopes, stereomicroscopes and microscopes specifically designed for firearm and toolmark studies. All of these techniques require the drawing of nail specimens and their adequate preparation. To the best of our knowledge a polarized light videomicroscope has never been employed.

Material and methods.

The apparatus (Moritex Video Microscope System Scopeman, MS-S04, Meisei Bldg., Japan) is composed of a processing unit and a color monitor (14" TTL CVS); light from the light source (a 100W mercury vapour lamp) of the processing unit is guided with the optic fiber to the probe end. Objectives are equipped with non contact lens (from 1x to up 400x) and with contact lens (from 50x to up 1000x). The application of a light polarized objective x50 allows us to obtain perfect images of the surfaces. Fragile and brittle nails were evaluated. Furthermore some pathologies such as psoriasis, lichen planus, and rheumatoid arthritis were included in the study. Observations were made by polarized light and, for comparison, by videomicroscope with a normal objective

Results.

This technique has allowed early detection some of changes in nail plates such as onychoschizia, longitudinal and transverse lines, pits, nail beading when they were scarcely evident to the naked eye and to a normal objective. We believe that also in the field of cosmetic dermatology this technique will be very useful for example in the study and therapy of brittle and fragile nails and in the evaluation of new hair cosmetics.

Riassunto

Una delle tecniche impiegate per lo studio delle lamine ungueali e dei capelli è rappresentata dall'osservazione a luce polarizzata che sfrutta la birifrangenza della cheratina. All'uopo sono stati impiegati stereomicroscopi e microscopi metallografici. A quanto ci consta, non è mai stato utilizzato un videomicroscopio a sonda ottica dotato di obiettivo a luce polarizzata.

Materiali e metodi.

L'apparecchio è un Video-microscopio a sonda ottica, (Moritex Video Microscope System Scopeman, MS-S04, Meisei Bldg., Japan); si tratta di un sistema di "Video-imaging" microscopico costituito da una telecamera, da una sonda ottica e da un monitor a colori ad alta definizione (14" TTL CVS). È dotato di obiettivi intercambiabili, con lenti a contatto (da 50x a 1000x) e non a contatto

(da 1x a 400x). È collegabile ad un videoregistratore, a una stampante e a un computer. L'obiettivo a luce polarizzata utilizzato consente ingrandimenti di 50x. Sono stati studiati soggetti con unghie fragili e friabili e individui affetti da psoriasi, lichen e artrite reumatoide. Per confronto, le lamine sono state osservate anche con un obiettivo a luce non polarizzata.

Risultati

A luce non polarizzata la superficie delle lamine appare virtualmente trasparente. L'obiettivo a luce polarizzata ha consentito di ben evidenziare:

- la presenza di solchi verticali e trasversali;
- il "pitting" psoriasico, anche quando le lesioni non erano evidenti clinicamente,
- le alterazioni "a goccia di pioggia" (nail beading) in corso di artrite reumatoide

Questa tecnica, non invasiva e di facile esecuzione, può rivelarsi utile nella dimostrazione di alterazioni ungueali ancora clinicamente poco evidenti e, in campo cosmetologico, nella valutazione dell'effetto di cosmetici per unghie e per capelli.

Introduction

Diagnostic techniques to evaluate nail disorders include KOH examination for fungal hyphae, cultures for bacteria and fungi and nail unit biopsy. Onychology research has also resulted in technological advances such as x-ray microanalysis to determine nail plate composition and ultrasonography to evaluate thickness (1). More recently, optical profilometry after nail shadowing has been introduced as a new technique to quantify nail surface alterations (2). Examination of fingernail ridges or plates by means of polarized light has also been performed using metallographic microscopes, stereomicroscopes and microscopes specifically designed for firearm and toolmark studies (3). All of these techniques require the drawing of nail specimens and their adequate preparation. We have employed a non invasive method to investigate fingernail plates: the polarized light videomicroscopy (PLVM) (4).

Material and methods

Material

Video-microscopy is an extension of traditional epiluminescence microscopy. Using a fiber optic camera, magnifications from 1 up to 1000x may be obtained so that the possibilities of study are greatly enhanced. In our Clinic we employ a video-imaging system, "Hand-Held Video Microscope Imaging System" by which both cutaneous pigmented lesions and superficial microvasculature may be investigated. The apparatus (Moritex Video Microscope System Scopeman, MS-504, Meisei Bldg., Japan) is composed of a processing unit and a color monitor (14" TTL CVS~, light from the light source (a 100W mercury vapour lamp) of the processing unit is guided with the optic fiber to the probe end. Objectives are equipped with non contact lens (from 1x to up 400x) and with contact lens (from 50x to up 1000x). A still video recorder and a colour printer may be attached.

The quality of the recorded images is, however, lower than those seen on the screen. The instrument is usually employed in the metal industry for the evaluation of corrosion and in the artistic field for the study of the deterioration of works of art. It is also used in mechanics, electronics and aviation. The application of a light polarized objective x50 allows us to obtain perfect images of the surfaces with an optical effect very similar to scanning electron microscopy (SEM). Furthermore, crossed polarizing filters of the objective display bands of interference colors as a consequence of the birifringence of keratin.

Methods

Fingernail plates of housewives and aged people were evaluated. Furthermore some pathologies such as psoriasis, lichen planus, and rheumatoid arthritis were included in the study (Table I). Observations were made by PLVM and, for comparison, by videomicroscope with a normal objective.

Table 1:

CLINICAL FEATURES OF THE PATIENTS

PZ. AGE PATHOLOGY

	75	vertical lines
2	50	onycoschizia
3	48	fragile and brittle nails
4	29	psoriasis
5	25	psoriasis
6	64	psoriasis
7	59	artropatic psoriasis
8	47	lichen
9	59	rheumatoid arthritis
10	60	rheumatoid arthritis

Results

PLVM has allowed early detection some of changes of nail plates such as onychoschizia, longitudinal and transverse lines, pits, nail beading when they were scarcely evident to the naked eye and to a normal objective (Figg. 1a,1b; 2a,2b; 3a,3b). We have obtained "tridimensional" images very similar to those of SEM. In colour photographs, the birifrangence of keratin is also evident. The bands of different colours indicate regions of different thickness in the nail.

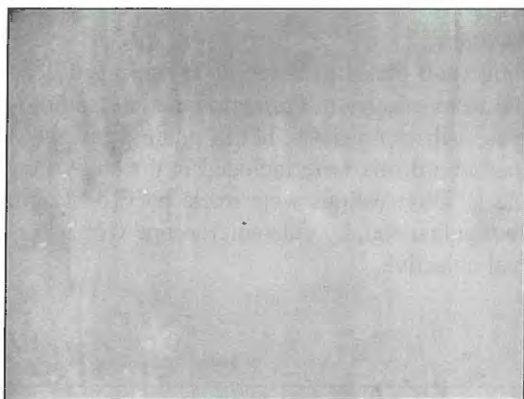


Fig. 1a - Pitting in psoriasis (Videomicroscopy, normal light, x50)



Fig. 1b - Pitting in psoriasis (Videomicroscopy, polarized light, x50)

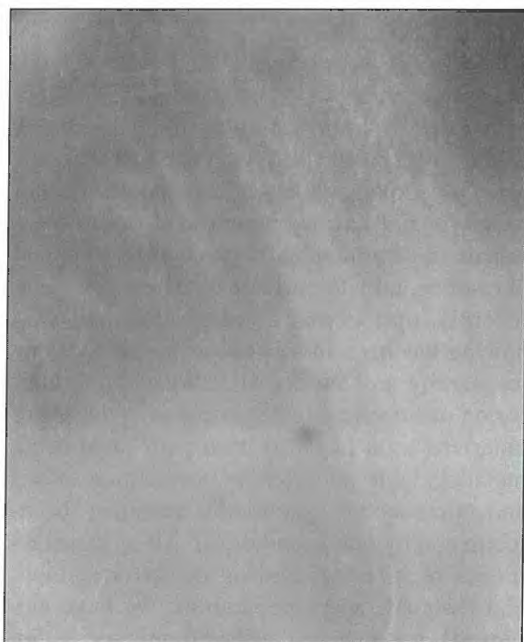


Fig. 2a - Nail beading in rheumatoid arthritis (Videomicroscopy, normal light, x50)



Fig. 2b - Pitting in psoriasis (Videomicroscopy, polarized light, x50)

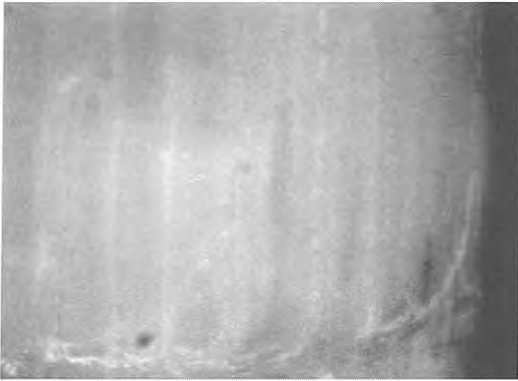


Fig. 3a - Vertical lines (Videomicroscopy, normal light, x50)

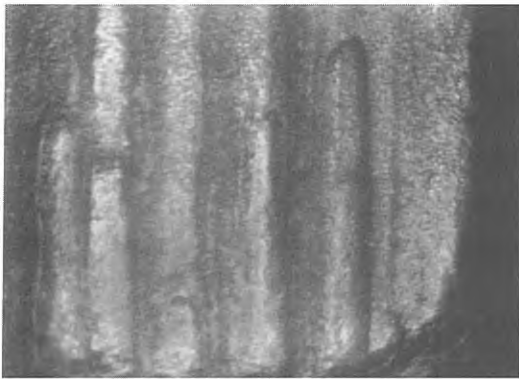


Fig. 3b - Vertical lines (Videomicroscopy, polarized light, x50)

Discussion

PLVM is a non invasive technique which allows us to investigate, in vivo, nail plates and hairs without drawing of specimens. This may be very useful when the effects of a prolonged therapy must be evaluated. The numerous magnifications are usefull in detecting very small lesions not yet visible to the naked eye. We believe that also in the field of cosmetic dermatology this technique will be very helpful, for example, in the study and therapy of brittle and fragile nails and in the evaluation of new hair cosmetics.

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USE OF VITAMIN-A GEL FOR THE PROPHYLAXIS OF POST-PARTUM VULVO-VAGINITIS: A PILOT STUDY - 1° note

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Key-words: Vitamin A; Vitamin E; Episiorrhaphy; Vulvo-vaginitis; Episiotomy-treatment; Sanitary pads.

Synopsis

This is our preliminary experience of the use of a vitamin gel (vit. A and vit. E) for the prophylaxis of the post-partum vulvo-vaginal pathology. 50 patients were treated and compared to a similar control group. All of them had undergone episiorrhaphy. Data show a considerable reduction of the disease in treated cases, and authorize further study on the subject.

Riassunto

E' qui riportata la nostra esperienza preliminare dell'uso di un gel vitaminico (vit. A e vit. E) per la profilassi della patologia vulvo vaginale post-partum. Sono state trattate 50 pazienti paragonate con un gruppo analogo di soggetti di controllo. Tutte le pazienti erano state sottoposte a episiorrafia. I dati mostrano una sensibile diminuzione della sintomatologia nei casi trattati e autorizzano ulteriori studi al riguardo.

INTRODUCTION

The vulvar epidermis is a biologically non-homogeneous entity with considerable anatomic-physiological differences according to the various areas (1,2). It is a chemical-physical barrier to various kinds of irritating agents. However, it is more sensitive than other epidermic areas to occlusions, sweat, urethrovaginal secretions and mechanic traumas deriving from sexual activity. For this reason, the vulvar epidermis is particularly exposed to dermatites of an allergic-irritating type. Delivery is, thus, a moment of particular tissutal miopragia. In fact, manipulations, traumas, the physiological execution of episiorrhaphy are moments in which the allergic-irritating pathology is easily started (3-9).

AIMS AND MATERIALS

Assuming that the small vulvo-vaginal pathology correlated to irritating-allergic-reactive phenomena affects 30% of the puerperas, assu-

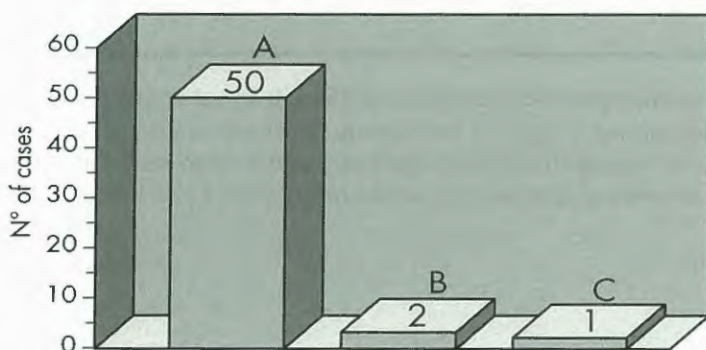
ming that can be also correlated to lochia and to the contemporary use of sanitary pads, we deemed that the local use (3-4 times a day) of A,E vitamin-gel activate by collagen (Elageno®A gel) could have optimum trophic and protecting effects, and thus drastically reduce the rate of this extremely disturbing small vulvar pathology.

50 patients were treated by 30 days use of the A-E vitamin gel cosmetic (Tab. 1) for the prophylaxis of the post partum vulvo-vaginal pathology and compared to a similar control group (Tab. 2)

RESULTS AND DISCUSSION

All selected patients have undergone a vaginal bacteriologic test before delivery. Patients with positive results were excluded. All patients were treated with amoxycillin and clavulanic acid.

TAB 1 - TREATED CASES



A= Episiotomy-Treatment with gel 4 times a day for 30 days.

B= Control after 20 days - Symptoms and objectionness: itching (1), burning sensation, oedema (1), redness (1), other.

C= Control after 40 days - Symptoms and objectionness: mild redness.

Results are shown in table 1 and 2.

In the light of these results, we thought to extend the treatment to all hospitalized patients undergoing greater pelvic and vaginal abdominal surgery and to all patients surgically treated for small vulvo-vaginal pathology.

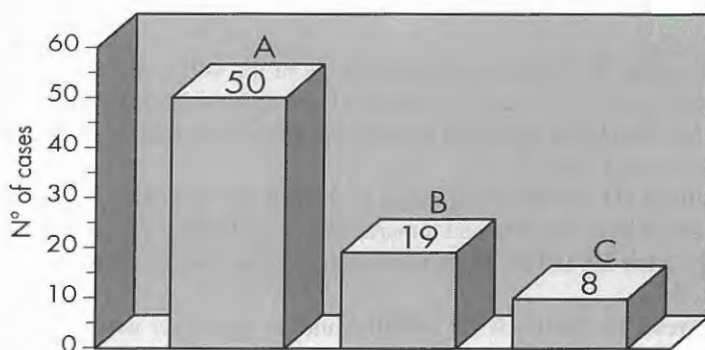
In the out-patient service, the use of this special A-E vitamin gel was deemed to be extended to teenagers making wide and indiscriminate use of sanitary pads, as well as to all patients taking low-dosage oestro-progestinic, who are quite frequently subject to intermenstrual spotting periods when they make extensive use of sanitary pads. Finally, the use of this gel is also interesting in the period following specific treatments for vulvo-vaginitis (bacterial, mycotic or from protozoans), since it definitely improves vulvo-vaginal trophism.

CONCLUSIONS

Results obtained so far are encouraging and lead us to continue on this way, widening the experience to a more vast population. Double-blind clinical trials will be needed for the exact evaluation of the effectiveness of this A-E vitamin gel.

In any case, the tolerability and acceptance by the patients and their motivation can easily anticipate the programming of multi-centred studies on the subject.

TAB 2 - NON TREATED CASES - CONTROL GROUP



A= Episiotomy of non treated.

B= Control after 20 days - Symptoms and objectiveness: itching (8), burning sensation (15), oedema (12), redness (14), other (3).

C= Control after 40 days - Symptoms and objectiveness: itching (4), burning sensation (2), oedema (1), redness (7), non perfect healing of the epis. wound (3).

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ENHANCED ANTIINFLAMMATORY ACTIVITY OF DICLOFENAC IN JOJOBA OIL SUBMICRON EMULSION CREAM

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Keywords: Submicron emulsion, oil-in-water emulsions, jojoba oil, jojoba wax, carrageenan paw edema model, diclofenac.

Synopsis

Jojoba liquid wax is a stable highly lipophilic, non-irritative and non-toxic "oil", obtained from desert plant Jojoba (*Simmondsia chinensis*). The potential use of Jojoba oil as excipient for the preparation of submicron emulsions (SME) for topical use was investigated. Submicron oil-in-water emulsion containing 20% Jojoba oil and the antiinflammatory drug Diclofenac Diethylammonium (1.16%) was prepared by a *proprietary* high pressure homogenization technique (mean droplet size about 150 nm). The effectiveness of the 1.16% Diclofenac Diethylammonium in the Jojoba SME topical cream was evaluated in carrageenan paw edema model. Diclofenac in Jojoba SME vehicle demonstrated significantly greater antiinflammatory activity than marketed Voltaren® Emulgel® cream (Ciba-Geigy). The unique penetrative properties of the SME delivery technology makes this novel topical vehicle attractive for development in cosmetic formulations. Water-insoluble substances used in personal care products as antioxidants and vitamins such as tocopherols (vitamin E), retinoids (vitamin A) have been successfully incorporated in SME formulations. The solvent-free SME technology can be also considered for use in cosmetic preparations to replace alcohols used as solvents and coolants (e.g. after-shaves and antiseptic solutions). Additional potential cosmetic uses of interest for SME lipoidal vehicle in the form of lotions, gels, or creams might include hair-lotions, sunscreens, after-sun gels, and encapsulation of fragrances and perfumes.

Riassunto

La cera liquida di jojoba è un olio altamente lipofilo, non irritante e non tossico, ottenuto dalla pianta desertica *Simmondsia chinensis*.

Si è voluto studiare il comportamento dell'olio di jojoba come eccipiente per la preparazione di sub-micro emulsioni (SME) di uso topico.

È stata perciò preparata una submicro emulsione O/W (con micelle di una grandezza media dell'ordine di 150 nm) contenente il 20% di olio di jojoba ed il farmaco antinfiammatorio Diclofenac dietilammonio (1,16%). L'efficacia dell'attività svolta dal Diclofenac all'1,16% nella jojoba SME è stata valutata sul modello dell'edema indotto dalla carragenina.

Il Diclofenac nel veicolo jojoba SME ha dimostrato una attività antinfiammatoria più marcata del

Voltaren® Emulgel® in crema (Ciba-Geigy). Le notevoli proprietà di penetrazione dimostrate da questa nuova tecnologia SME rendono tale veicolo interessante anche per l'uso cosmetico. I principi attivi idrosolubili usati nei prodotti di igiene personale come antiossidanti e le vitamine quali i tocoferoli (vit. E) ed i retinoidi (vit. A) sono stati incorporati con successo in questo nuovo veicolo.

Il veicolo SME privo di solventi può essere utilizzato in cosmetica per rimpiazzare l'uso dell'alcool come solvente e come agente rinfrescante (dopobarba e soluzioni antisettiche). Altri potenziali usi cosmetici del veicolo SME sotto forma di lozioni, geli o creme può essere nei prodotti solari nelle lozioni per capelli e nei profumi incapsulati.

Jojoba oil, also known as Jojoba liquid wax, is a non-toxic and non-irritative oil, which is now widely used in cosmetics (1). It is a highly lipophilic compound, consisting almost entirely of wax esters of high molecular weight monounsaturated acids and alcohols, mainly C_{18} - C_{22} (2,3). Jojoba oil is stable to oxidation and remains chemically unchanged for years (3, 4). The skin irritation potential of Jojoba oil in different preparations was evaluated by various methods and the material was classified as non-irritating (5). Acute and sub-chronic toxicity,

skin sensitization and mutagenicity assessments of jojoba oil also show lack of undesirable effects. Additionally, jojoba oil was found to be non-comedogenic in topical formulations even at high concentrations (5). The excellent safety profile of Jojoba oil makes it a promising component for topical preparations.

Emulsions play a critical role in the cosmetic field and they are of widespread importance in the cosmetic industry. They offer many advantages to the cosmetic chemist allowing compounding immiscible ingredients into single formula-

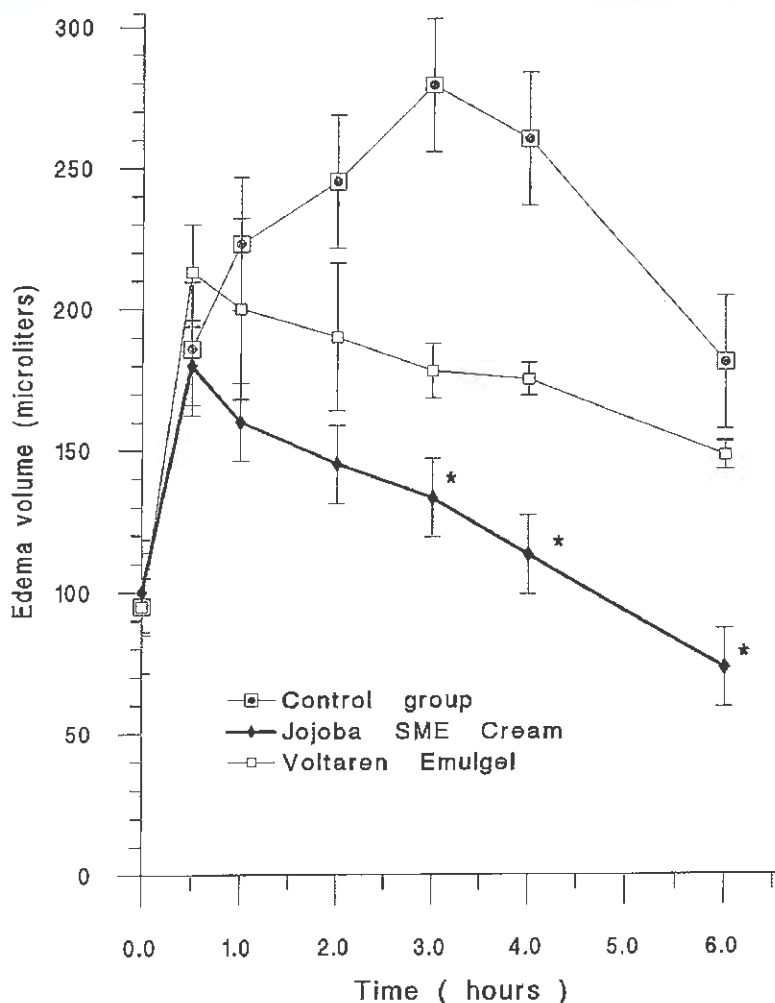


FIGURE 1

tions. We have developed a novel emulsion-based lipoidal vehicle consisting of stable, submicron particles of oil-in-water emulsions, termed Sub-Micron Emulsions or SME. SME droplets are characterized by a mean droplet size of less than one micron (generally in the range of 0.1-0.2 μm) uniformly dispersed in an aqueous phase. The droplet size reduction is essential to generate preparations with high stability. The uniqueness of the large internal hydrophobic oil core of the SME droplets provides high solubilization capacity for water insoluble compounds compared to other lipoidal vehicles such as liposomes (Figure 1).

Recently we demonstrated that submicron emulsions (SME) exhibit enhanced topical and transdermal delivery of several drugs, included into SME creams, prepared with different types of oil phase components, such as capric/caprylic triglycerides, soybean oil, isopropylmyristate and paraffin oil.. Drug activity increase up to 1.5 - 3 fold was demonstrated for antiinflammatory drugs (steroidal and non-steroidal), dialeipam, atropine and local anesthetics (6-10). The extended drug activity might be attributed to increased penetration of submicron oil droplets through the stratum corneum of the skin and improved association of the drug with increased surface of the SME particles (9).

SME cream comprised of 20% Jojoba oil phase and containing 1.16% Diclofenac (Diethyl ammonium salt) was prepared by a proprietary high pressure homogenization process. Diclofenac was dissolved in the oil phase, consisted of 85% Jojoba oil (Jojoba Israel Ltd., Israel) and 15% purified egg lecithin (Lipoid E-80, Lipoid AG, Germany). After drug dissolution, the oil phase was mixed with the water phase containing 2% Cremophor EL (Polyoxyl-35 castor oil, BASF, USA) as surfactant to obtain a 20% oil-in-water emulsion. The mixture was homogenized using a high shear homogenizer (Polytron K3000, Kinematica, Switzerland) at 20,000 rpm (1-2 min.) and then sized by a high pressure homogenizer (Micron Lab 70, APV Gaulin Inter-

national SA, Netherlands), 8 cycles at 800 bar. The resultant submicron emulsion was cooled and filtered through a 0.45 μm nylon filter (Schleicher and Shuell, Germany), and particle size distribution was determined by quasielastic light scattering, using a Coulter N4MD Particle Size Analyzer, (Coulter Electronics, USA). The Jojoba oil SME formulation containing Diclofenac showed a narrow size distribution (156 ± 56 nm), and 100% of the particles were below 215 nm. Diclofenac-Jojoba oil SME cream topical emulsion was prepared by thickening with Carbopol 940 (BF Goodrich, USA) to a 0.8% w/w final concentration and adjusting the pH to 6.0 - 6.5 with triethanolamine (Merck, Germany). Carbopol was added to the SME as preswollen gel (10% in water), by mixing with the help of a high shear homogenizer (Polytron K3000, 5,000 rpm, 2 min). The viscosity of the Jojoba oil SME cream with Diclofenac, determined by a Brookfield rotor viscometer DV II+ (spindle LV4, 6 rpm) was about 100,000 cP.

The antiinflammatory activity of Diclofenac in Jojoba SME cream was investigated using the carrageenan induced paw edema model in rats (11, 12). Voltaren® Emulgel® (Ciba-Geigy, Switzerland), a marketed antiinflammatory cream with identical active component content (1.16% Diclofenac Diethylammonium) was used as a comparative formulation. Edema volume changes after topical application of the creams were tested using a plethysmometer (Ugo Basile, Italy).

Rats (Wistar, 230-250 g bodyweight, 6 animals in each group, Anjlab-Israel) were anesthetized during the experiment by sodium diethylbarbiturate (120 mg/kg S.C., Fluka, Switzerland) and Rompun® (10 mg/kg I.P.) injections. One hundred microliters of 1% iota- Carrageenan (Fluka, Switzerland) solution in saline was injected subplantar into the hind paw of the rat. Sixty μl of topical preparation (Diclofenac dose 2.5 mg/kg) was applied on the hind paw and gently rubbed into the skin, and edema volume changes were tested at 0, 0.5, 1, 2, 3, 4 and 6

Table I

**RELATIVE ANTIINFLAMMATORY ACTIVITY OF DICLOFENAC
IN JOJOBA SME CREAM AND IN VOLTAREN® EMULGEL®**
(Mean data $\pm$ S.D., AUC - area under curve for edema volume; for Control group - 100%)

GROUP	AUC, μ l . hr	RELATIVE ACTIVITY, %
Control	981 $\pm$ 154	100 $\pm$ 16
Voltaren® Emulgel®	774 $\pm$ 107	79 $\pm$ 14
Jojoba SME cream	456 $\pm$ 83	46 $\pm$ 18

hours time intervals. No signs of skin irritation were observed during the experiment in any group. A control group of animals did not receive any antiinflammatory treatment. The results obtained are presented in Fig. 1.

The onset of antiinflammatory activity for Diclofenac in Jojoba SME vehicle is about 1 hour, and at 3, 4 and 6 hour paw edema volumes were significantly ($p < 0.05$) lower than for Voltaren® Emulgel®. Antiinflammatory activities, presented in terms of area under the curve (AUC, μ l.hr), were calculated using the trapezoid method with the help of SigmaPlot® program, (see Table 1).

It is evident from the Table 1 and Fig. 1 that Diclofenac Diethylammonium in Jojoba SME topical vehicle demonstrates enhanced antiinflammatory activity compared to Voltaren® Emulgel® with identical drug content. In contrast to Voltaren® Emulgel® formulation, which contains propylene glycol and isopropyl alcohol, the Jojoba SME vehicle does not include any organic solvent or other irritative penetration enhancer.

In conclusion, Jojoba oil as a non-toxic and non-irritative lipophilic compound is very suitable for preparation of submicron emulsion for topical and transdermal drug delivery. Incorporation of Diclofenac into SME Jojoba oil cream provides a highly effective antiinflammatory topical preparation. The unique penetrative pro-

perties of the SME delivery technology makes this novel topical vehicle attractive for development in cosmetic formulations. Emollients and lubricants are used in cosmetics to improve consumer acceptance of the product by providing skin-care preparations with the appropriate slip, tactile feel, and rub-in properties to encourage the consumer to use the product more liberally and more frequently. Since emollients and lubricants can be easily incorporated in SME formulations, topical preparations of SME lipoidal vehicle in the form of lotions, gels, or creams may have potential applications in cosmetics to deliver moisturizing agents and lipids to skin.

The solvent-free SME technology can be also considered for use in cosmetic preparations to replace alcohols used as solvents and coolants (e.g. after-shaves and antiseptic solutions). Additional potential cosmetic uses of interest for SME might include hair-lotions, sunscreens, after-sun gels, and encapsulation of fragrances and perfumes. Water-insoluble substances used in personal care products as antioxidants and vitamins such as tocopherols (vitamin E), retinoids (vitamin A) have been successfully incorporated in SME formulations.

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COSMETIC PRODUCTS FOR THE BODY: AN ECONOMIC STUDY OF THEIR DISTRIBUTION AND CONSUMPTION

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Key-words: Cosmetic product; Consumption; Product's labelling

Synopsis

Everybody knows the increasing market diffusion of the cosmetic products; they are largely used both in Italy and in Europe. According to the economic situation of Italy, the cosmetics' market has confirmed the general course of the consumer goods.

Whereas the cosmetic industry must be analyzed in relation to the different typologies and nature of the products, in the present work the market's variations through the single distributive channels are reported in detail.

The Authors of this note have particularly studied the body's products. The Italy market of these cosmetics is in the third after hair and face products.

The aspects of the consumer's health on the basis of the recent law will be also examined with regard to the products' labelling.

Riassunto

È nota a tutti la crescente diffusione nel mercato dei prodotti cosmetici; questi infatti sono largamente utilizzati sia in Italia, sia in Europa. In Italia il mercato dei prodotti cosmetici ha seguito il generale andamento dei beni di consumo, in accordo con la situazione economica del paese.

Tenendo presente che l'industria cosmetica va analizzata in relazione alle diverse tipologie ed alla natura dei prodotti, nel presente lavoro vengono esaminate in dettaglio le variazioni di mercato dei prodotti cosmetici attraverso i singoli canali distributivi.

Agli autori della presente nota è inoltre sembrato opportuno soffermarsi sul mercato dei prodotti cosmetici per il corpo infatti, in Italia, essi costituiscono il terzo gruppo di riferimento dopo i prodotti per il viso ed i prodotti per i capelli.

Gli aspetti relativi alla sicurezza del consumatore, sulla base della recente legislazione, verranno analizzati in riferimento all'etichettatura dei prodotti.

INTRODUCTION

The international economic recovery, the rationalisation of markets and of distribution systems and contained prices are producing clear signs of growth related, in various economic sectors, to variations in exchange rates, to political factors and to international relations.

The high production capacity of the Italian cosmetics industry, largely made up of small and medium-sized enterprises which fill market niches such as professional products, herbalists and make-up, has found opportunities as a result of its price competitiveness in international markets, with exports up over 30% compared to 1993. This confirms the trend towards increased sales in the cosmetics sector, which now accounts for a not inconsiderable proportion of the Italian chemical industry, with over 1,300 companies, 25,000 employees and a turnover of over 72,000 billion lira.

In terms of the domestic market, it may be said that the economic situation in Italy has gradually reduced the confidence of Italian families, progressively diminishing sales of non-durable consumer goods. Nonetheless, sales of cosmetic products, which make up 2% of the consumer goods bought by Italian families, are progressively less tied to economic influences and fashions. Data on the current state of the cosmetics sector confirm decreasing demand elasticity for hygiene and beauty products, confirming that these are decreasingly influenced by economic factors or by other factors external to the perception of the consumer who evaluates cosmetic products in terms of quality-functionality-price terms, which vary with the type of product and the time and place of purchase.

Care for one's outward appearance has become a way of experiencing one's own identity, a way to be rather than a way to look, a duty to society and a pleasure for oneself. This leads to numerous body treatments which necessarily call for the help of cosmetics and of experienced beauticians.

Cosmetic products: definition and aspects of the market

THE NEW DEFINITION OF A COSMETIC PRODUCT

The relevant legislation in Italy is Law 713 of 39/10/1986, which, over the years, has been modified a number of times. The last change, the VI modification of EC directive 76/768/EC, introduced in Italy, as in the other European countries, on 30/6/1995, has a number of innovative elements.

One of these is the introduction of a new definition of "cosmetic product" which has changed from a product designed to protect and maintain the condition of the skin and related parts of the body, to a product intended to "modify the appearance and/or correct body odours and/or protect and maintain it in good condition". This new definition gives greater recognition to the functional properties of cosmetic products. Functions which have, until now, been considered of secondary importance, "maintaining good condition", "modifying the appearance", "correcting body odours", are now recognised as primary aims.

The current classification of cosmetics is also provided (see table 1) showing a diversified and elaborate range of products. Each of these, within its own segment, has a different economic significance for the cosmetics industry, for individual or seasonal motives.

CONSUMPTION OF COSMETIC PRODUCTS

Consumption of cosmetic products in Italy follows the trend of family consumption. This shows the role of primary consumption, taken on by hygiene and beauty products, which for a number of years have made up around 2% of consumer spending on non-food products.

In 1994 there was a slight contraction in distri-

Table I
CLASSES OF COSMETIC PRODUCTS

Creams, emulsions, gels and oils for the skin (hands, feet, face etc.)
Beauty masks (excluding products for peeling)
Face colouring products (liquids, pastes, face powders)
Face powders for makeup, talcum powder for use after bathing or for bodily hygiene etc.
Toilet soaps and deodorant soaps
Perfumes, toilet water and Eau de Cologne
Bath and shower preparations (salts, foams, oils, gels etc.)
Depilatory products
Deodorants and anti-perspirants
Hair treatment products
- hair dyes and bleaches
- waving straightening and fixing products
- products for curling
- hair cleaning products (lotions, powders and shampoos)
Products for keeping the hair in place (lotions, lacquers, brillantine)
Shaving products (soaps, foams, lotions etc.)
Eye make up and products for removing eye make up
Products to be applied to the lips
Oral and dental hygiene products
Products for cleaning and polishing the nails
Personal hygiene products
Sun tanning and protection products
Self tanning products
Products to whiten the skin
Anti-wrinkle products

bution and consumption in the cosmetics sector, to varying degrees according to the distribution channel and type of the product. A quantitative variation in the market analysed in terms of single product types corresponds to quite different consumption changes in the different types of product making up the cosmetics market. Within each distribution channel, the general market trend shows those variations which are typical of the trade.

Overall demand for cosmetic products has been slightly reduced over the past year, with a 2.2% contraction in volume of sales and a 2% mean increase in prices to the public (lower than the rate of inflation).

Table 2 shows the trend for each distribution

channel.

5% mean price increases for sales via chemist's shops did not offset falling sales, which were 8% lower by value and 12.4% lower by quantity. This negative result stems from the repositioning crisis in this channel as a consequence of changes in pharmaceutical costs, specialities and over-the-counter products. In specialised perfume shops the slight contraction in sales by value (0.7%) was a result of price increases (6%) which largely compensated for the reduction in sales by volume (6.3%). This is justified by the general trend in this channel towards quantitative repositioning as a result of point of sale closures, and improved service to customers. The stability of sales by value through de-

partment stores is a result of increased volumes distributed through this channel (3%), sold at lower prices. This confirms, for a number of toiletries, the success of own brands. Door-to-door sales have performed well, with a 19.5% increase, and there has also been a large expansion in

mail order sales which have almost doubled in importance in the sector since last year. The value of the professional beautician market has remained stable, since price increases have compensated for quantity reductions. Hairdressing has declined, however, with a contraction in

Table II
COSMETICS SECTOR DISTRIBUTION CHANNEL TRENDS, 1994

CHANNELS	INCREASES		
	Consumption	Quantity	Price
Chemist's	-8,0%	-12,4%	5,0%
Perfume shops	-0,7%	-6,3%	6,0%
Other channels	-0,4%	3,0%	-2,5%
Total traditional channels	-1,2%	-2,6%	1,4%
Door-to-door sales	19,5%	15,5%	3,5%
Beauty salon sales	0,0%	-5,7%	6,0%
Women's Hairdr. salons	-4,8%	-9,3%	5,0%
Men's Hairdress. salons	-2,0%	-6,6%	5,0%
Overall total	-0,3%	-2,2%	2,0%

Sales distribution by channel - 1994

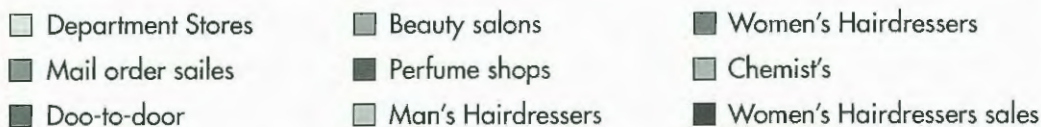
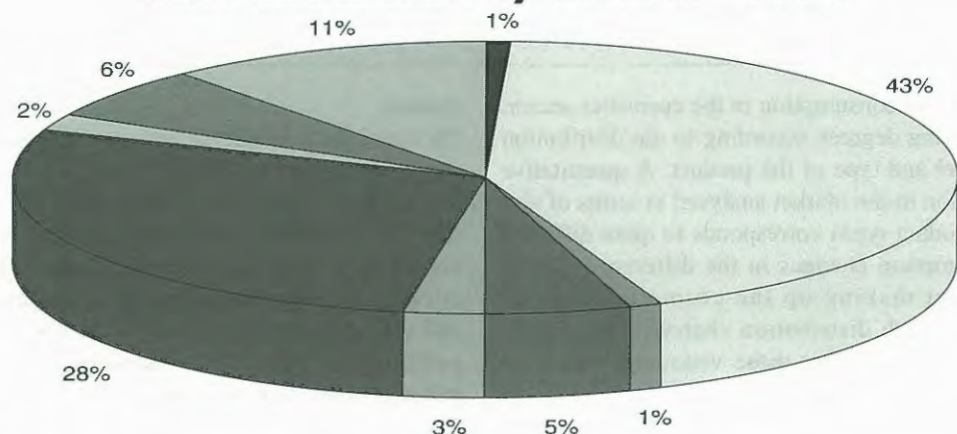


FIGURE 1

consumption by quantity, only partially offset by moderate price increases.

In conclusion we may note that department stores, which account for 43.6% of total consumption, were not able to monopolise the attention of consumers, who, though undoubtedly concerned with the price-functionality-quality relationship, remained faithful to the range of products and the additional services offered by specialised channels, with perfume shops in first position. The distribution of sales by channel for 1994 is shown in Figure 1.

Table 3 illustrates how, from 1983 to 1992, increasing cosmetics consumption developed differently, even within individual functional areas. Nutrition and protection increased by around 6%, to the detriment of hygiene-cleansing and perfuming, which lost 6% of increased consumption during the decade under consideration. It may, therefore, be concluded that, over the years the increase in consumption of hygiene and cleansing products was lower than that of products for facial and body skin nutrition and protection (including protection from the sun) which registered considerable increases. In so far as treatment products are concerned, a slight increase may be observed over recent years,

as a result of a circa 6% increase in facial and hair treatment product sales, which increased from 36.9% in 1983 to 43.9% in 1992 with the decrease in body treatment products from 40.2% in 1983 to 37.2% in 1992.

THE SUPPLY OF COSMETIC PRODUCTS: ADVERTISING INVESTMENTS

The competition scenario of the cosmetics sector involves a large number of products scattered over the market with a constant process of concentration on the part of the multi-nationals present in the sector or in other areas of consumer retailing. This concentration process goes hand in hand with the internationalisation of the sector, such that 75% of cosmetics, perfumes and toiletries turnover is accounted for by international companies. Italian industry survives on the basis of its niche in alcohol based perfumes, make up and products for professional beauticians. The diversity of the goods on offer in perfume shops has increased competition and reduced the life cycle of products. The 20 principal brands account for almost 60% of sales there and the first three brands have market shares between 5% and 6%, whereas all the remaining

Table III

COSMETIC CONSUMPTION BY FUNCTIONAL AREA, 1983-1992

	1992 value (in bln. lira)	%	1983 value (in bln. lira)	%
Hygiene/cleansing	2.441	31,1	1.082	35,1
Nutrition	1.411	18,0	425	13,8
Bleaching	1.244	15,8	475	15,4
Perfuming	872	11,1	422	13,7
Deodorants	485	6,1	200	6,5
Shaving	435	5,5	186	6,0
Protection	288	3,7	71	2,3
Treatment	225	2,9	78	2,5
Other	459	5,8	14	4,7
TOTAL	7.680	100,0	3.084	100,0

brands have less than 4%. The principal companies and brands for perfume shops are set out in table 4. Publicity is of crucial importance in building the image of the product and determining its market placement. Advertising investments retain their fundamental role in the presentation of a product and the development of its market. 1994 expenditure was over 840 billion lira, though growth in the industry's advertising investment was slower during the year as a result of the economic situation in Italy and the inability of the market to sustain further pressure on prices. The cosmetics sector's commitment to advertising shows, however, no signs of reduction, with a 2.8% increase in value. The sector's propensity to advertise is influenced by the importance of foreign markets and the consumers desire to choose between products on the basis of a selective analysis founded on qualitative and functional factors inherent in the product, with advertising playing a complementary role in informing the consumer. It is to be noted that the relationship between advertising investment and consumption is increasing. Inve-

stments in advertising for 1994 by type of product are shown in Figure 2.

PRODUCTS FOR THE BODY

The authors felt it particularly important to analyse body products market segment. In conformity with the importance of body care in Italy, this segment is highly dynamic both in terms of its market and in terms of scientific research into product innovation. Cosmetics research is particularly concerned with treatment. In order to meet the requirements of consumers, who demand immediately visible results, cosmetics producers have developed products which combine functionality and ease of use, pleasant tactile and visual characteristics and which require little skill in their application. In terms of innovation in basic formulae, new emulsifying agents have been developed for facial and body creams and new techniques for modulating the penetration of the active ingredients, which may be immediate or delayed. For cellulite treatment, in particular, there are a number of gel-creams which combine the fre-

Advertising investments by type of product, 1994

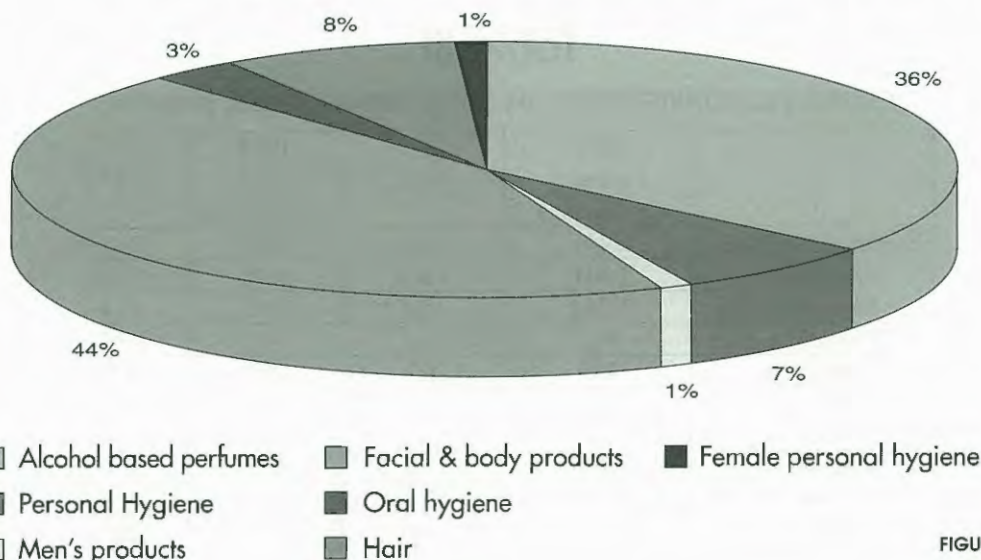


FIGURE 2

Table 4. Principal companies and brands distributed via specialist perfume shops

brands in perfume shops			others brands/channels		
FRANCE			ITALY		
L'Oreal	Lancome, Helena Rubinstein, Guy Laroche, Biotherm Cacharel, Paloma Picasso, Lanvin, Giorgio Armani, Jean Piaubert, Ralph Lauren	Farmacia: Vichy, Phas. Misti: Plenitude, L'Oreal, Corolle, Mennen, Gemey, Garnier	Euroitalia	Moschino, Charro, Reporter, Coveri, Naj Oleari, Dolce e. Gabbana	
Lvmh	Christian Dior Kenzo, Fahrenheit Givency	Farmacia: Roc	Diana de Silva	Hanorah, Woltz, Olga Tschecowa . Ferrè	
Chanel	Chanel		Giraudi	Orlane, OffShore Visconti Modrone	Kelémata, Venus Perlier
Guerlain	Guerlain		Schiapparelli	Lancetti, Pikenz	Benessere
Sanofi	Yves Saint Laurent Krizia, Fendi, Nina Ricci, Van Cleef Roger Gallet		Icr	Trussardi, Versace Marvin, Nazareno Gabrielli	
Clarins	Clarins		GERMANY		
UNITED STATES			Hoechst	Marbert	Testanera
Procter & Gamble	Ellen Betrix, Hugo Boss, Max Factor, Laura Biagiotti	Misti: Oil of Olaz Panten, Camay, Infasil, Clearasil	Benckiser	Lancaster, Monteil Davidoff, Jil Sander	
Revlon	Revlon, Ultima II	Misti: Charlie	GREAT BRITAIN - THE NETHERLANDS		
Estée Lauder	Estée Lauder Aramis, Clinique Prescriptives		Lever	Elisabeth Arden Nino Cerruti Rimmel	Atkinsons, Clear, Leocrema, Lux, Dove, Rexona
JAPAN			Manetti & Robert's	Collistar	Robert's
Shiseido	Shiseido, Carita				

shness of a gel with the functionality of and emulsion, which can act more deeply, as well as sophisticated liquid crystal emulsions with long-term rehydrating action and the gradual release of their active ingredients. In terms of health and the toxicological aspects of the active ingredients in cosmetic preparations based on natural products, particularly those of vegetable origin, efforts have been made to produce ingredients synthetically in the laboratory, to

make the preparations in which they are contained safer and more effective. Research and safety evaluation can make use of modern in vitro techniques instead of testing on animals, in line with legislation and consumer trends, with highly reliable results.

In terms of an analysis of the market, it must be said that cosmetic products for the body are distributed through both traditional and non-traditional channels. The former type includes perfu-

me shops, chemist's and the mass-market. Although, distribution through department stores has maintained its market share by selling greater quantities of goods at generally more economical prices. The trend towards increased competitiveness in this channel confirms the gradual introduction of forms of discount. Examining the composition of the cosmetics market, it may be seen that products for the body, with overall consumption exceeding 1,200 billion lira per annum, form the third group in order of importance, with 14.9% of the market, after hair products (17.4%) and facial products (15.0%).

An analysis of Table 5, which sets out the consumption of each individual type of product for the body by distribution channel, shows the positive performance of perfume shops, where sales have increased by 6.9% and the mass market (3.4%). Chemist's shops show, however a reduction of 9.2% over the year in question.

In terms of individual body product types, increases can be seen for softening creams (+5.4%) and for sun and skin colouring products (+3.6%). Reductions are to be found in anti-cellulite products (5.7%) and firmness creams and gels (4.3%). Deodorants have also done well, as have anti-perspirants, which make up over 40% of sales of products for the body.

CONSUMER PROTECTION

One of the innovative aspects of the VIth modification of directive 76/768/EC concerns the labelling of cosmetic products which, in order to better inform consumers, from 1.1.1997 will have to give a series of supplementary information, not currently provided for by legislation.

The new labelling procedure aims to guarantee two fundamental objectives: uniformity in the European market, to permit the free movement of goods, and more information for the consumer. The fundamental aspects of the new directive are therefore, the new definition of cosmetics, new provisions in terms of responsibility for providing product information to avoid incorrect use, identification of the person or company responsible for the documentation alongside the person or company responsible for the sale of the cosmetic, a description of the product's use in the language of the country in which it is sold, the formula of the product using the common European system.

In addition, therefore, to the five elements which must currently appear on cosmetics packaging or containers (the manufacturer, the nominal content of the product, minimum product life unless over 30 months, precautions for use of the product and the lot number), products will have to show their use and the formula in decreasing order of weight of the constituent at

Table V
PRODUCTS FOR THE BODY
CONSUMPTION IN BILLIONS OF LIRA BY DISTRIBUTION CHANNEL

	Total	Chemist	Perfume	Dept Stores	Var % Total	Var % Chemist	Var % Perfume	Var % Dept. St.
Products for the body	1.209,0	237,0	357,0	615,0	1,6%	-9,2%	6,9%	3,4%
Softening Creams	175,0	28,0	63,0	84,0	5,4%	-6,7%	12,5%	5,0%
Anti-cellulite	99,0	45,0	47,0	7,0	-5,7 %	-8,2%	-4,1%	0,0%
Firmness creams	45,0	18,0	23,0	4,0	-4,3%	-10,0%	0,0%	0,0%
Deodorants	487,0	68,0	114,0	305,0	1,7%	-13,9%	3,6%	5,2%
Hair removers	60,0	10,0	5,0	45,0	-2,9%	-15,3%	-16,7%	2,3%
Sun products	343,0	68,0	105,0	170,0	3,6%	-4,5%	16,7%	0,0%

time of manufacture using the common European system.

This is clearly important information for the consumer who, although having no scientific knowledge, may at any time ask for the opinion of qualified persons on the possible effects of the use of a product on health. The VIth modification also compels the manufacturer, or delegate, or the person on whose behalf a cosmetic is manufactured, to compile a dossier with information on the identification, quality, safety and effectiveness of a finished cosmetic product. Most of the provisions of this directive, therefore, concern consumer protection and the information available to the consumer. The cosmetics industry is, therefore, currently oriented towards fully supporting this regulation with the necessary scientific and technological techniques required by these new needs.

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