

Facial anti-wrinkle cream: influence of product presentation on effectiveness: a randomized and controlled study

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Background/aims: The great interest in eternal youth has developed a large market for skin care products claiming anti-wrinkle effects. A high-priced luxurious anti-wrinkle cream dispensed in its original packaging and in a neutral jar, were compared with the effects from a regular moisturizing face cream in a luxurious jar.

Methods: Eighty Swedish women aged 35–64 years were randomly divided into three groups; group A treated their facial skin for 6 weeks with the expensive cream in its luxury jar, B used a regular moisturiser filled in the luxury jar, and C used the expensive cream filled in a neutral jar. Evaluation was made by the subjects, clinical evaluation by a trained observer, and measurement of skin surface relief by optical profilometry.

Results: Participants using jars A and B consumed more product than participants using jar C, and the luxury jar thus resulted in better compliance. There were no significant differences between the three groups relating to the effects

on wrinkles and smoothness, nor in subject assessment of their skin feeling younger or more beautiful. Facial appearance was the same. Profilometry showed reduced surface microrelief with all products.

Conclusions: The present study conducted as a formal trial could not verify a claim of anti-wrinkle effect of a known prestigious product. Surprisingly, there was no systematic effect on subjective and objective cosmetic parameters of the luxury packaging, except a better compliance. Product appreciation by consumers may, however, be different in spontaneous use not biased by study conditions.

Key words: anti-wrinkle – claims – cosmetics directive – placebo – skin replica – surface structure

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THE GREAT interest in eternal youth with minimum signs of ageing has developed a large market for skin care products claiming anti-wrinkle effects. Those products may have physiological actions in the skin, as well as generating pleasant emotions during their use. Anti-wrinkle products are regulated by the European Cosmetics Directive (1, 2). This directive mainly regulates safety issues, and little attention is given for efficacy substantiation.

Cosmetics may use strong marketing claims and elegant product presentation in a bid to move the frontiers of cosmetic consumption. It is common to refer to clinical tests and 'actives' in the advertisements for cosmetics rather than scientific documentation (3, 4). Substantiation of product effects ranges from *in vitro* tests via testimonials to randomized double-blind trials.

Principles for efficacy substantiation have been officially proposed by the Danish competent authority (5). In evidence-based medicine, results from double-blind trials gives more faith to the conclusions and subsequent recommendations than open trials (6), as open label studies makes it relatively simple to secure whatever results desired by either intentionally or unintentionally suggesting to the volunteers what outcome is being anticipated (7). Marketing of cosmetics using an elegant presentation may enhance the perceived actions of the product similar to 'placebo' treatment.

The aim of the present study was to compare a high-priced anti-wrinkle cream and a regular moisturizing cream. The chosen prestigious cream claiming anti-wrinkle effect was a well-known brand with high reputation among

elderly women (Chanel Ultra Correction Restructuring Anti-Wrinkle Cream SPF 10, Chanel, France) (8). The cream claimed to increase the firmness of the skin, minimize the wrinkles and diminish dark spots (8). The cream contained 51 substances, including two UV filters, and extract of liquorice root, 'Adhesioderm' and 'Life Cycle Regenerator' mentioned as active principles in the cream (8). The cost was almost €100 for a 50 ml jar, which is comparable to, for example, the new innovative dermatological drug product Protopic[®] (Astellas Pharma GmbH, Munich, Germany). In this study, a conventional moisturizer (ACO facial cream, ACO Hud AB, Uppsala, Sweden) marketed as a facial cream not claiming anti-wrinkle effect was used as a comparator product.

Materials and Methods

Volunteers and treatment

Eighty healthy women, recruited from the Stockholm region in Sweden (35–64 years, mean age 50.4 ± 6.8 years), were included in the study. Twenty-six subjects were randomly allocated to group A (mean age 50.8 ± 5.9 years), 27 to B (mean age 51.1 ± 6.6 years), and additional 27 subjects received treatment C (mean age 49.4 ± 7.8 years). The noninclusion criteria were known allergies to ingredients in the test products. The volunteers were allowed to continue their normal use of make-up and cleanser, but were asked to avoid using any other facial creams.

All subjects were asked to use the test product twice daily for 6 weeks. They were advised to apply as much cream as necessary over the entire face and to be especially careful to apply cream on the periorbital region.

Test products

Group A used Chanel Ultra Correction Restructuring Anti-Wrinkle Cream SPF 10 (Chanel) in its original jar, while group B used a moisturizing cream (ACO Facial cream, ACO Hud AB) color matched to A and provided in the same packaging as the Chanel cream (Fig. 1). Groups A and B were also given leaflets about the Chanel Anti-Wrinkle Cream copied from the Chanel web page (8). Group C was given Chanel Ultra Correction Restructuring Anti-Wrinkle Cream SPF 10 in a neutral white jar (Fig. 1). Ingredients in the Chanel cream and the moisturizing cream are listed in Table 1.



Fig. 1. The luxury jar and neutral jar.

Evaluation

The evaluation consisted of subjects' assessment, clinical evaluation and profilometric measurement from skin surface replicas. Furthermore, the usages of the creams were determined by weighing the jars before and after use.

The subjects assessed the cosmetic properties of the cream (texture, scent, and absorption) and the influence of the cream on the skin, including potential adverse effects. The overall scoring of cosmetic properties of the cream was: 'bad,' 'somewhat bad,' 'neither good nor bad,' 'good,' and 'very good.' Questions concerning luxury, pleasantness, smoothing, less wrinkles, younger skin, and improved appearance were scored: 'not at all,' 'slightly,' 'moderately,' and 'very much.' The subjects answered the questionnaire before the visit week 6. Furthermore, the subjects were asked about potential adverse effects from the treatments.

The clinical evaluation by a trained observer of the degree of fine lines/wrinkles, skin surface roughness and hyperpigmentation was performed after 6 weeks. The signs were graded on a scale from 0 to 4, with 0 being none and 4 being the most advanced using published reference photos (9).

The skin surface silicone replicas were obtained from the 'crow's feet' area in the periorbital region at baseline and after 6 weeks. Surface debris and cream residues in the face were removed by a mild fat-free cleansing mousse (Cliniderm cleansing mousse, ACO Hud AB) approximately 1 h before the evaluation. The skin was also gently and rapidly cleansed with alcohol some minutes before application of adhesive rings defining the test area. (REPLIKA[™] locating rings, Cuderm Corporation, TX, USA). The orientation of the ringtap was facing outwards, towards the ear (10). 1.5 g of silicone rubber material was mixed thoroughly with a

TABLE 1. Ingredients of test creams

| Chanel Ultra Correction Restructuring Anti-Wrinkle Cream SPF 10 | ACO Facial cream |
|---|---|
| Aqua, glycerin, ethylhexyl methoxycinnamate, butylene glycol, methyl gluceth-20, cetyl ethylhexanoate, faex (yeast extract), canola oil, biosaccharide gum-1, butyrospermum parkii (shea butter) extract, caprylic/capric triglyceride, butyl methoxydibenzoylmethane, phenyl trimethicone, jojoba esters, prunus amygdalus dulcis (sweet almond) fruit extract, PEG-6, cyclopentasiloxane, steareth-21, cetyl alcohol, glyceryl stearate, polyacrylamide, phenoxyethanol, cyclohexasiloxane, mannitol, tocopheryl acetate, hydrogenated polyisobutene, methylparaben, sodium acrylates/C10–30 alkyl acrylates crosspolymer, hydrolyzed wheat protein, chlorphenesin, laureth-7, tetrasodium EDTA, parfum (fragrance), glycogen, propylene glycol, sodium citrate, sodium phosphate, potassium phosphate, sodium hyaluronate, ethylparaben, BHT, disodium succinate, glycyrrhiza glabra (licorice) root extract, butylparaben, tocopherol, propylparaben, isobutylparaben, CI 14700 (red 4), CI 19140 (yellow 5), CI 77891(titanium dioxide) and mica | Aqua, canola, cetearyl alcohol, glycerin, steareth-2, isopropyl myristate, sodium PCA, myristyl myristate, steareth-21, citric acid, phenoxyethanol, methylparaben, propylparaben, parfum |

few drops of a catalyst (Silflo[®] Impression Material and Catalyst, Cuderm Corporation). The silica imprint was taken with the subject supine. The replicas were detached and allowed to cure in open air for 24 h and then stored until analysis (BioNet, TX, USA).

The replicas were analyzed by optical profilometry. A video camera (Cohu solid state B&W camera, 50 mm lens/30 mm extension, Corecto Ultra II frame grabber) with a computer containing image processing software (OPTIMAS v 6.2, Media Cybernetics, MD, USA). A light source directed at a 25° angle from the plane of the replica produced a brightness profile and the variation of luminance across the replica was indicative of skin roughness. The orientation of incident light relative to the major skin lines was both perpendicular (north or south) and parallel (east or west) (7).

The surface roughness variables R_z and R_a were considered primary end points (10, 11). R_z is the average maximum difference in luminance value in five sections of the scan and represents the wrinkle depth. R_a is the average deviation of the luminance curve from the mean luminance, representing the area above and below an average line through the center of the profile corresponding to surface roughness. R_z and R_a were reported in the units of brightness, gray levels, ranging from 0 to 255 (12). Rotation of the replicas is known to significantly change the values (7). North–south (NS) and east–west (EW) measures were taken.

Calculations and statistics

The variables on the categorical scales were summarized by bar charts with each bar divided

into segments corresponding to respectively category level. The area of each bar segment is proportional to the number of subjects in each category; thus each bar summarizes to the total of 100%. The replica data were evaluated for each subject by calculating the percentage change between baseline and week 6. Side-by-side box-and-whisker plots are used to display the results. The box is defined by the upper and lower quartiles and with the median marked by a subdivision of the box. The whiskers have a maximum length in the terms of the interquartile range, with display of outliers (Minitab Statistical Software, Minitab Inc., PA, USA).

Data on a categorical scale were analyzed by Mann–Whitney U -test. Changes of continuous data were tested for significance using the Wilcoxon test for paired data. The median percentage of the difference in each group was calculated and compared with the other group by using Mann–Whitney U -test. Minitab statistical software, release 13 (Minitab Inc.) was used for all statistical analyses. $P < 0.05$ was considered significant.

Results

Of the 80 subjects, 75 subjects (group A $n = 25$, B $n = 25$, C $n = 25$) completed the 6-week study according to the protocol with a complete set of data. Five subjects did not completely comply with the study regimen; three subjects applied the cream only once daily, one treated solely the periorbital region, and one subject developed irritation. These subjects only participated in the subjective evaluation of the cream.

Measurement of compliance showed differences in consumption between the groups

TABLE 2. Self-appraisal ratings of cosmetic properties of the creams A, B, C and the facial appearance of the treatments

| | Not at all | Slightly | Rather much | Very much |
|-----------------------------|------------|----------|-------------|-----------|
| Pleasant to use A/B/C | 4/0/7 | 15/11/11 | 46/37/52 | 35/52/30 |
| Luxurious feeling A/B*/C | 23/15/41 | 31/11/30 | 35/48/26 | 12/26/4 |
| Feeling of smoothness A/B/C | 38/33/44 | 39/30/26 | 15/26/18 | 8/11/11 |
| Less-wrinkled skin A/B/C | 64/52/64 | 36/36/32 | 0/12/4 | 0/0/0 |
| Younger skin A/B/C | 48/52/68 | 48/32/24 | 4/16/8 | 0/0/0 |
| More beautiful A/B/C | 80/64/76 | 20/28/24 | 0/8/0 | 0/0/0 |

*More luxurious feeling than C, $P < 0.01$.

Results are given in percent of subjects in each group.

($P = 0.012$), where groups A and B used significantly more cream than group C. The mean use was 34.7, 36.0 and 25.9 g for groups A, B, and C, respectively.

Effectiveness

Group B rated the 'absorption' of cream B significantly better than the other two groups ($P = 0.0055$ compared with A and $P = 0.0004$ compared with C). The texture and scent of the creams were equally liked by the three groups.

The groups found the treatments equally pleasant, but group B considered the cream to be more luxurious than group C ($P = 0.0011$). There were no significant differences between the three groups in their judgement of the effect on wrinkles, smoothness, or if the treatment made the skin younger or more beautiful (see Table 2). 20% of group A and 28% of group C rated the anti-wrinkle effect good compared with 40% of group B. Between 50% and 70% of the subjects did not consider the treatment to improve the skin.

Safety

Seven subjects in group A recorded facial discomfort, two subjects reported rashes, one acne, one stinging, one dryness and two subjects considered the cream too oily. In group B, one subject felt some stinging and redness on application of the cream. Seven subjects from group C felt discomfort, i.e., one subject reported initial stinging and the other six subjects assessed the cream to be too oily.

Measurement of skin surface microrelief

No significant differences in the clinical signs of ageing symptoms, such as fine lines, roughness, and pigmentation were found between the groups after 6 weeks treatment (Fig. 2). Profilometry of the skin replicas before cream treatment,

TABLE 3. Roughness values (median and range) measured in east-west (EW) and north-south (NS) direction at the start of the study

| Parameter | A | B | C |
|-----------|--------------|--------------|--------------|
| R_z EW | 73 (49–156) | 78 (43–127) | 88 (44–135) |
| R_z NS | 149 (68–225) | 174 (82–222) | 145 (67–203) |
| R_a EW | 15 (10–31) | 16 (9–25) | 17 (10–29) |
| R_a NS | 29 (13–53) | 34 (16–59) | 28 (13–50) |

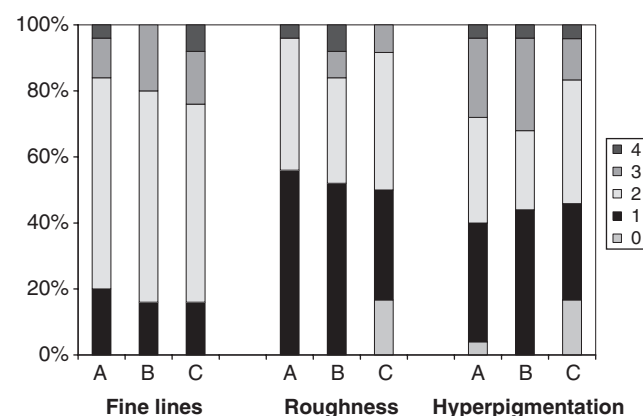


Fig. 2. Clinical evaluation of trained evaluator after 6 weeks of treatment with product A ($n = 25$), product B ($n = 25$), and product C ($n = 24$). Scoring from 0 = none to 4 = severe. There were no significant differences between treatments A (luxury cream in its original jar), B (regular moisturizer in luxury jar) and C (luxury cream in neutral jar) P -values > 0.05 .

metry of the skin replicas before cream treatment, showed that the roughness values measured in the NS direction were almost twice as high as the corresponding values measured in the EW direction (Table 3). After the treatment period, EW measurement of R_z showed significantly reduced values in all three groups, while groups B and C also showed lower values in R_a measured EW (Fig. 2). Only group B improved significantly in R_z and R_a , measured NS (Fig. 2). However, there were no significant differences in R_z and R_a

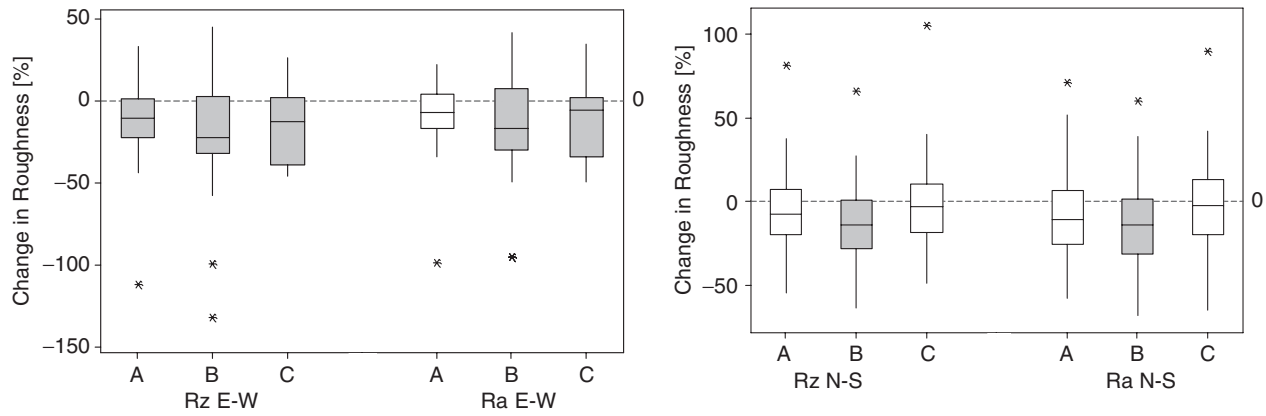


Fig. 3. Profilometry changes in skin roughness (%) from start to week 6, measured as R_z -EW and R_a -EW and as R_z -NS and R_a -NS. No significant differences between treatments A (luxury cream in its original jar), B (regular moisturizer in luxury jar), and C (luxury cream in neutral jar) were found. Boxes in gray denote significant changes compared with baseline.

(measured EW and NS) between the groups at the end of the treatment (Fig. 3).

Discussion

Almost all of the women considered the test creams to be pleasant to use. The cosmetic properties were considered to be 'good' or 'very good' by more than two-thirds of the women. The majority of the individuals also considered the test products to induce a luxurious feeling and smoothness of the skin. The moisturizer was perceived as being significantly more luxurious than the expensive cream in the neutral white jar.

No differences between the groups were found in the clinical and profilometric evaluation of ageing signs, including surface structure and wrinkles. Absence of significant differences in studied effects between the expensive creams in the two types of jars, suggests that the placebo effects of product presentation were below detection limits. It is possible that another test design would have produced another test result of the expensive cream. For example, if the test subjects had made much effort to acquire the cream and have had high expectations from the treatment, then a stronger placebo effect might have been induced (13). A consistent finding was the use of more cream if dispensed in luxury jars (A and B) as compared with a neutral jar (C). Thus, product presentation influenced application habits and improved compliance. The women in the present study were not selected as a random sample among identified loyal customers and they were also well aware of the fact that the anti-wrinkle effect was to be measured in other ways besides

their own perceptions. Being in a trial is likely to influence their treatment habits and product perception.

Profilometry of skin replicas is a sensitive method, which also can detect subclinical changes in the skin. In the present study treatment for 6 weeks induced significant improvement in the roughness parameter R_z in all three groups and in R_a in two of the groups. Improvement in roughness from the formulations is compatible with a moisturizing effect. It is not surprising that the differences between the creams and effects on ageing skin symptoms were scarce. Results from multicenter studies comprising several hundred subjects on the anti-wrinkle substance tretinoin, suggest rather modest differences between this active drug and placebo (10, 14, 15). True anti-wrinkle effect is difficult to produce with cosmetics. However, filling of surface irregularities with cream components will induce a smoother appearance. Therefore, cleansing of the skin before surface evaluation facilitates analyses of true changes of the skin properties.

The British Advertising Authority recently forced an international cosmetic company to withdraw a major advertisement campaign claiming 'visibly reduced expression lines' which was not scientifically substantiated (3). 'Visibly' truly means that the claimed effect can be expected and seen by the naked eye of the consumer or a clinical evaluation, documented in a randomized, controlled study. *In vitro* testing and laboratory studies, such as profilometry, may document subclinical changes and support clinical noticeable effects. The present study

conducted as a formal trial could not verify a claim of anti-wrinkle effect of a known prestigious product. We found to our surprise no systematic effects on the subjective and objective cosmetic effect of a luxury product. Product appreciation by consumers may, nevertheless, easily be different in spontaneous and unbiased daily use.

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