A Compensating Skin Care Complex Containing Pro-xylane in Menopausal Women: Results from a Multicentre, Evaluator-blinded, Randomized Study

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In addition to the natural process of skin aging, the skin of women is significantly impacted during and after menopause (1–3). In post-menopausal women, the effect of oestrogen deprivation results in decreased collagen synthesis leading to skin atrophy (4, 5), in reduced skin elasticity (6) and in increased skin dryness (7).

The aim of the present study was to assess the benefit of a fixed compensating skin care topical serum complex, containing the C-xylopyranoside derivative pro-xylane at 3%, hedione 1%, hydrovance and hepes 5% each (Laboratoires Vichy, Asnières sur Seine, France) and a moisturising cream (containing water, glycerin, cyclohexasiloxane, stearic acid, butylene glycol) versus the moisturizing cream alone during 60 days of daily application in post-menopausal women.

METHODS

A prospective, randomized, investigator-blind, multicentre study was conducted with 34 dermatologists in Spain and Poland in compliance with local regulatory and ethical requirements. A total of 240 healthy, post-menopausal Caucasian women aged between 55 and 65 years with a history of at least 3 years after the last menstruation and not taking any hormonal replacement therapy were suitable for the study. Inclusion criteria included a dry skin score between 2 and 6 on an analogic scale ranging from 0 = no sign to 9 = extreme signs, a skin aging grade of at least "3" for facial ptosis and neck folds as well as for naso-labial folds according to the photonumeric scales (8). Women having had cosmetic procedures on the face and neck within the year prior to recruitment or with evolving dermatoses on the face were to be excluded.

Women were randomized in a 1 to 1 way to receive for 60 days a combination containing the compensating skin care complex and a moisturizer cream (group A) or the moisturizer cream alone (group B). All subjects were instructed to apply in the morning and in the evening the provided products conditioned in neutral packs, after having gently cleansed their face and neck.

Clinical evaluations at Day 0, Day 30 and Day 60 comprised facial ptosis, neck and nasolabial folds using the photonumeric charts and the 10-score analogic scale for skin radiance, firmness, dryness and complexion evenness. Global investigator and subject perception assessments were rated at the end of the study using a 5-point questionnaire.

The quantitative lipid profile of the stratum corneum of the forehead of selected subjects (37 in group A, 39 in group B) was assessed at Day 0, Day 30 and Day 60 throughout specific lipid markers – squalene, sterols, free fatty acids, waxes, glycerides and total neutral lipids using a non-invasive, solvent-free method (Synelvia, Labège, France).

The "R" software (Foundation for Statistical Computing, Vienna, Austria 2012) was used for statistical analysis. The Student *t*-test was used to compare the mean difference between Day 30 and Day 0 and Day 60 and Day 0 of clinical criteria and between Day 0 and Day 60 of the lipid profile. The χ^2 test was used to compare percentages of responses of the overall dermatological and subject self-assessment. The Kruskal and Wallis test was used to compare the distribution of lipid variables. Probability limits were set at 5% using a two-tailed approach.

RESULTS

From the 240 post-menopausal women included in this study, 237 subjects – 118 in group A and 119 in Group B – accounted for the efficacy analysis. Two subjects were lost to follow-up one in group A withdrew after 20 days of application due to a product-related adverse event (erythematous plaques and papules that resolved spontaneously after discontinued application).

Demographic characteristics at Day 0 were similar in both groups. Clinical data at Day 0 showed no statistical significant difference between both groups. After 60 days

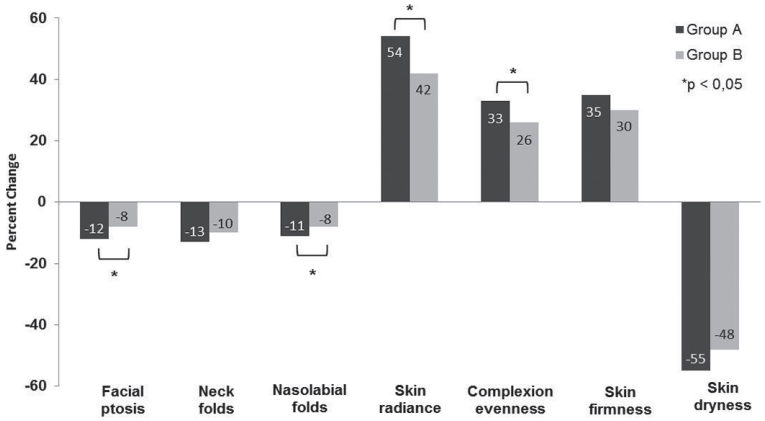

Fig. 1. Clinical assessment of skin aging signs at Day 60 vs Day 0. Clinical signs were assessed on the photonumeric Bazin 6-score scale (8) and on an 9-score analogic scale. Group A received the compensating skin care complex and a moisturizer, and Group B the moisturizer alone.

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of application, a statistically significant improvement in facial ptosis, nasolabial folds, radiance and complexion evenness in favour of group A compared to group B was observed ($p<0.05$). The improvement for neck folds, skin firmness, and skin dryness was similar in both groups. Detailed results are provided in **Fig. 1**.

Global investigator assessments after 60 days of daily use showed a statistically significant superiority of group A for firmness effect, even complexion, radiance, nourishing effect and overall global satisfaction ($p<0.05$). There was no statistical significant difference for the moisturizing effect (97% vs 93%). The subject perception of improvement after 60 days of application was significantly higher in group A for skin evenness, re-plumping of the skin, skin smoothness and skin tightness ($p<0.05$).

The lipid profile significantly improved in subjects from group A ($p<0.05$). After 60 days of daily application, a statistically significant difference for the total lipid weight (19%), for squalene (16%), sterols (27%), free fatty acids (34%), wax esters (56%), glycerides (98%) and neutral lipids (49%) was observed in favour of group A ($p<0.05$).

DISCUSSION AND CONCLUSION

Clinical evaluations demonstrated a significant improvement of the visible signs of menopausal skin in subjects who applied the combination product compared to subjects who only applied the moisturizer cream. Skin firmness, density, radiance and homogeneity improved while a replenishing and nourishing effect was reported by both the evaluators and subjects. The fact that no significant difference between both groups was observed for skin rehydration confirmed that a daily application of a moisturizer provides an, albeit limited, adjunctive skin care in the studied population.

One of the weakness of the study is the lack of objective criteria to confirm the clinical assessments. Indeed we did not include standardized pictures or skin biomechanical measures which could further support the investigators conclusions.

The quantitative lipid analysis showed that a serum containing pro-xylane significantly improves the quantitative composition of both sebum and epidermal lipids, since squalene and wax esters are specific to sebum and sterols are specific epidermal lipids. The increased sterols and free fatty acids may improve the skin barrier function. Furthermore, increasing the wax esters and glycerides may result in a better protection of the skin via a filmogen activity. During the aging process, sebum production in women decreases by about 40% during the 6th decade, declining additionally in the 7th and remaining constant thereafter (9, 10). As a result, a negative change of the quantitative and qualitative sebum composition may affect the skin barrier function by decreasing photoprotection, antimicrobial activity and the delivery of fat-soluble anti-oxidants to the skin surface (11). Therefore, restoring the initial quantitative composition of the sebum is important in the skin management of post-menopausal women.

In conclusion, the present study demonstrated that the regular daily use of a topical serum, containing pro-xylane 3% reduces visible signs of skin aging and improves the sebum composition of the skin in post-menopausal women.

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Conflict of interest: AB is an employee of Laboratoires Vichy. AM and BC have received fundings from Vichy Laboratoires. ER has received honoraria from Laboratoires Vichy as clinical investigator and speaker. CCZ has received honoraria from Laboratoires Vichy as a consultant and speaker.

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