

ABSTRACT

Changes in the regulatory guidelines for cosmetics as well as consumer interest have led to increased efforts in assessment of product efficacy and claim substantiation. Within the framework of the development of modern emulsion systems with improved percutaneous absorption, it is important to be able to detect even slight alterations in skin conditions. This requires a selection of suitable measurement procedures with high reproducibility. This dissertation focuses on the evaluation of methods for the noninvasive measurement of biomechanical skin parameters, particularly in conjunction with application of cosmetic skin care products.

In the first series of studies a new device for in vivo measurement of torsion (MEdyS) was evaluated by assessing the reproducibility, validity and measurement range. In a study with 3 volunteers (1 male, 1 female, 1 patient with systemic sclerosis) intra- and interindividual differences were assessed by making repeated measurements (5-10) on various regions of the body. In a second study interindividual differences were evaluated on healthy skin in 116 volunteers with constitutional skin alterations (seborrhoea, seborrhoea, normal and aged skin; group 1) and lesional skin in 63 patients with skin diseases (psoriasis, atopic dermatitis, acne vulgaris, polymorphic light eruption; group 2). In group 1 test fields were located on the forehead and the right volar forearm. In group 2 multiple lesions on various body regions were assessed. In both groups three measurements were performed per test field. Due to the high variability of the results in both studies it was not possible to determine viscoelastic skin properties with sufficient accuracy. On the basis of the results the prototype MEdyS does not appear suitable for discrimination of skin characteristics associated with different skin conditions. Therefore this device was not included in the further testing of skin care products.

Important criterias for skin care products are their influence on skin hydration and viscoelastic properties. In the main study of this dissertation the influence of two skin care products (liposome cream vs. vehicle) on these properties and stratum corneum thickness were investigated. Validated devices for measurement of skin moisture (Corneometer CM 825[®]) and viscoelasticity (Cutometer SEM 575[®]) were tested as well as a prototype designed for measurement of skin moisture and stratum corneum thickness (IONTO HANA). In addition skin structure was assessed by using a new device for Photodocumentation (Beauty scope).

Topical application of liposomes has been shown to improve the water binding capacity and hydration of the stratum corneum. The therapeutic use of phospholipids by every form of dry skin, including aged skin, is based on this pharmacodynamic effect. The test product, an O/W emulsion containing loaded liposomes, was tested in a double-blind, placebo-controlled, randomized study with intraindividual comparison of treatment effects. Fourtyeight women aged 50 years and older with dry but otherwise healthy skin in the treatment areas (volar forearm) participated in the study. Treatment with the test product and vehicle was performed twice daily at home over a 3 week period. Measurements of skin moisture, stratum corneum thickness and viscoelasticity as well as photodocumentation were performed at baseline (day 1) and following a 3 weeks treatment. A significant increase in the hydration of the stratum corneum (approximately 20%; $p = 0,000$) was measured for both products using the validated corneometer for measurement of skin moisture. No statistical differences were observed between the test fields treated with liposomes and the

liposome-free vehicle ($p = 0,1392$). Even though the stratum corneum thickness values measured with the prototype IONTO HANA were plausible and were negatively correlated with the values measured with the corneometer ($r = -0,7282$; $p = 0,000$), plausible values were not obtained for skin moisture. However, since the values are recorded as arbitrary units the results are not useful for the determination of absolute thickness of stratum corneum.

No significant influence on elastic and viscoelastic parameters (UA/UF, UR/UF, UR/UE, UV/UE, $UV_{(5)}/UE_{(5)}$ / X/UF) were detected as a result of treatment. Only a significant reduction in the viscoelastic parameter ($X_{(5)}/UF_{(5)}$) was detected for both products (test product: $-6,4\%$, $p = 0,023$; vehicle: $-8,1\%$, $p = 0,047$). This corresponds with the internal softness of the skin, which is probably related to easier displacement of the corneocytes. Using a small diameter probe (2 mm) and a negative pressure of 200 mbar the suction method was not suitable for objective assessment of cosmetic efficacy. Minor alterations in skin conditions can not be sufficiently detected. In conclusion the present study shows that other biomechanical devices are needed for monitoring the effect of moisturizers on skin viscoelasticity.

An interpretation of in vivo tests can be difficult, as no analytical model has been developed that can relate measurements from these tests directly to basic skin properties. Subtle differences between methods make a comparison difficult. However, the alternative to bioengineering methods is the hand and eye, which provide subjective (and often biased) nonlinear, and notoriously variable data between individuals. Even experienced clinicians have difficulties with judging the severity of involvement, the changes due to treatment or progress of disease and the efficacy of competing treatments. Objective, numerical information on the effects of different active compounds and their formulations is essential if new preparations are to be optimized. Measurement of biomechanical properties is one aspect of this important field of endeavor.