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A new paradigm for reversal of skin aging

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The effectiveness of a novel treatment paradigm to reverse/prevent the signs and symptoms of extrinsic aging process has been documented in three prospective controlled, double-blind clinical trials. Two of the tested regimens (ER, EIC) have a dual mechanism of action: optimization of stratum corneum permeability barrier function coupled with safely reversing/preventing chronic inflammation. The test cosmeceutical formulations are based on highly purified extracts of date, flax, meadowfoam, avocado and safflower in emollient bases. These products do not contain retinols, alpha hydroxy acids, soy, or tea. EIC also contains two peptides, one from hydrolyzed yeast and the other from potato. ER was compared to a mass marketed moisturizer and a prescription moisturizer. EIC was compared to nonprescription Idebenone 1%. The test cosmeceuticals produced statistically significant results in all epidermal, histologic and dermal parameters of extrinsic aging evaluated. All clinical trials were conducted by a nationally prominent clinical contract research organization with trained investigators grading each clinical parameter. ER was highly statistically superior ($P < .001$) in all epidermal parameters (fine lines, wrinkles, mottled hyperpigmentation, laxity, and tactile roughness) that were clinically graded in a 16-week and a 12-week trial against two commercial moisturizers. The numerical results of ER in both clinicals were superior to those published results of products containing glycolic acids, polyhydroxy acids and kinetin. In the 12-week study against idebenone 1% the test cosmeceutical (EIC) was statistically superior in all epidermal parameters. EIC did produce significant dermal thickening while idebenone 1% had no measurable impact on the dermis. With regards to safety, EIC induced no contact irritation, while idebenone 1% induced a mild to moderate reaction in 30% of the panelists. A total of 53 patients were evaluated in these prospective controlled, double-blind clinical trials conducted by contract research organizations using the final marketed product. These profound clinical results support the validity of this new paradigm for reversing/preventing signs and symptoms of extrinsic aging using a novel botanical based cosmeceutical to safely reverse/prevent chronic inflammation and optimize barrier function.

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Evaluation of a cosmetic balm to reduce nipple pain and improve nipple skin condition in breastfeeding women

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Introduction: Sore nipples and cracked nipples are a frequent problem during for breastfeeding women. They seem to be related to inadequate positioning and suction of the newborn. The first symptom is pain. It may be followed by erythema, fissures, and desquamation, sometimes leading to surinfection and cessation of lactation. Women seek for a quick solution to continue breastfeeding and to avoid complications (mastitis). The present study was designed to evaluate the effectiveness of a new nursing comfort balm with soothing and dermorepairing properties. This balm has been formulated to reduce nipple pain and cracked nipples. It contains Lupeol, patented active ingredient, soya peptides, marine salts, soothing and nourishing ingredients (chlorophycea extract, candelilla wax, etc). Unlike many other products, this balm is free of lanolin.

Materials and methods: Fifty breastfeeding women with nipple pain or cracked nipple have been enrolled by gynecologists and midwives in an open trial. Tested balm was applied to the nipple area after each feeding. It did not need to be rinsed off before each feeding. Women with fungal or bacterial cutaneous infections were excluded. Following criteria were evaluated at days 0 and 7: pain, skin irritation, dryness, edema, fissures (cotation, 0-9) and quality of life.

Results: Included women (mean, 32.2 yrs old) were lactating for the first time in 67% of cases, 82% exclusively. Pain appeared after a mean delay of 14.7 days, with a mean number of 6.1 feedings per day, during 20.7 minutes each. Pain disappeared for 56% of the patients with a mean delay of 2.4 days (0.5-6). Superficial and deep fissures also disappeared in 58% and 69% of cases. If not, improvement was collected in 78% and no change in 22%, with no aggravations. Irritation and dryness were reduced by 78% and 92%; fissures and edema by 81% and 92%. Quality of life improved by 51%.

Conclusion: A new breastfeeding balm improved lactating conditions and nursing comfort for 88% of tested women (global satisfaction rate of both investigators and patients). It has a very rapid onset of action with a mean pain relief inferior to 3 days.

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A new and innovative emollient with Cu-Zn-Mn triad for irritant and allergic dermatitis

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Introduction: Irritant, allergic contact dermatitis (ICD, ACD), and atopic dermatitis (AD), beside therapeutic prescriptions, need a specific cosmetic management with emollient, antiirritant, antimicrobial, and healing products. A new emulsion for ICD and ACD with no antiseptic, no common preservative, no perfume, and no colorant has been developed. It contains the first oligo-element triad (Cu-Zn-Mn), phytosphingosines, a glycerol/capryl glycol complex and dimethyl oxobenzo dioxasilane. First, we investigated the in vitro effect of [Cu-Zn-Mn] triad on the skin repair improvement. Then, the clinical efficacy and tolerance of the new emulsion have been performed.

Methods: After treatment of fibroblasts or keratinocytes with [Cu-Zn-Mn] triad, we examined cell migration and proliferation by the scratch-assay and we evaluated the markers of keratinocytes proliferation (b1-integrin), differentiation (involucrin) and dermal−epidermal junction (b4-integrin) using ELISA. Clinical efficacy of the emulsion has been tested on 139 patients with 67% of children. They were affected by various pathologies: irritation from external origin; AD and ACD and superficial cutaneous alterations. The tested product was applied twice daily for 10 days.

Results: In vitro, we have shown that the [Cu-Zn-Mn] triad acted at different levels of the skin in order to enhance wound healing by promoting re-epithelialisation, reinforcing dermal-epidermal junction and improving dermal wound recovery. Moreover, in clinical study, overall, the product was efficient on 81% of the patients and the following improvements were reported: pain 83%, irritancy 91%, discomfort 90%, pruritus 88%, erythema 88%, dryness 89%, acceleration of healing time 77%, and cicatricial aspect 78%. The comparison of the 3 groups revealed firstly that the Cu-Zn-Mn triad was efficient for all the dermatological conditions tested, and secondly that this product is totally adapted for children: irritant dermatitis (82%), eczemas (83%), and other cutaneous alterations (91%).

Conclusion: A new Cu-Zn-Mn emollient has been developed for various irritant, allergic and traumatic dermatitis and give excellent results for adults and children. It was the first time that we could demonstrate that the Mn addition to the Cu-Zn complex stimulates the epidermal regeneration and restores skin barrier function.

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Novel *Hamamelis virginiana* serum reduces post-filler bruising incidence and duration

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Hamamelis virginiana, better known as witch hazel, has been used since ancient times because of its antiinflammatory properties. The leaf extract is rich in polyphenols including the very potent antioxidants gallocatechins. Polyphenols as oral agents are recognized for their antioxidant and antiinflammatory properties but were also described to ameliorate endothelial cell function, which may in part explain their cardioprotective effect. For example, in vitro studies show that polyphenols such as epigallocatechin-3-gallate activate endothelial nitric oxide synthase and induce endothelium dependent vasodilation. We use a novel serum containing a proprietary, ethanol-free *H virginiana* extract to reduce the bruising and swelling associated with hyaluronic acid filler injection for periorbital hollows, a facial area known for its marked vascularity and therefore ubiquitous postprocedure ecchymosis. This *H virginiana* active ingredient was gently extracted after cryogrinding the witch hazel leaves, a process that best retains the integrity of the polyphenol moieties. An investigator-blinded study was conducted with 12 healthy female volunteers between 35 to 65 years of age undergoing symmetric filler injections for periorbital hollows. Subjects taking NSAIDS or other antiplatelet medications were excluded from the study. The subjects were asked to pretreat the randomly assigned half-face for 2 weeks twice daily, and posttreat for 1 week twice daily with the serum. The other half-face received Cetaphil cream as a control. Clinical digital photographs were taken before and immediately after, then two and four days after the treatment sessions. A 10-point bruising severity scale was used by investigator and patient to assess product efficacy. Treatment with the *H virginiana* serum significantly reduced bruising as compared to pretreatment with a simple moisturizer in all patients who bruised (score > 1). Swelling was also reduced on the serum site but did not reach significance. This study indicates that topical application of certain polyphenol mixtures before and immediately post filler injection is a valuable adjunctive treatment to efficiently prevent the bruising and swelling associated with these minimally-invasive procedures. The exact mechanism of action of *H virginiana* extract (strengthening of microvascular system?) in preventing bruising remains speculative and needs to be further investigated.

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