



AN OPEN LABEL PILOT STUDY TO EVALUATE THE EFFECTIVENESS OF A PROPRIETARY NUTRACEUTICAL FORMULATION ON ELEMENTS OF SKIN FUNCTION ASSOCIATED WITH AGING.

Medical Science

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ABSTRACT

This open label pilot study evaluated the effect of a proprietary nutraceutical formulation-Skin Within™-on objective measures of skin function associated with aging over 3 months. The supplement containing collagen, citrus and rosemary extract, maritime pine bark extract, vitamin C, Coenzyme Q10, astaxanthin and biotin was taken twice daily. After 84 days compared to baseline, highly statistically significant effects were observed in the 30 individuals who completed the study regarding reduction in trans-epidermal water loss and skin roughness, along with increases in hydration, elasticity, and smoothness of the skin. 29 participants also reported subjective improvements in the condition of their hair and nails. This study demonstrates that Skin Within has the potential to deliver significant benefits in skin condition and reverses objective measures of skin function associated with skin aging. A larger placebo controlled trial is now proposed.

KEYWORDS

cosmeceutical, skin aging, collagen, Skin Within™

Methods and Materials

The primary objective was to assess the effect Skin Within™ administered twice daily had on non-invasive objective measures of skin function, namely; elasticity, hydration, trans-epidermal water loss, skin roughness and smoothness. This study was conducted in accordance with the guidelines set forth by the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), and the Declaration of Helsinki regarding the treatment of human subjects in a study. The study population consisted of 40 healthy male and female individuals aged 20–72 years recruited via social media. Inclusion criteria:- Healthy individuals aged 18 and above, able to give informed consent. Exclusion criteria:- use of anti-coagulant medication and/or anti-epileptic medications.

When participants arrived at the study site, written informed consent was taken. The environment was kept at 61%–65% relative humidity and 21°C–22°C for all assessments. An area of skin, just below the elbow on the inner side of the right forearm was assessed on day 0 and on day 84 using Corneometer, Tewameter, Cutometer, and Visioscan. Day 0 measurements were considered “baseline” scores. Final measurements were repeated on day 84. No visits to the test sites otherwise occurred. All equipment is CE marked and manufactured by Courage and Khazaka, Koln, Germany.

A Corneometer CM825 probe with a Multiprobe Adapter MPA5 was used to perform noninvasive assessments of the level of hydration of the participant's stratum corneum. It delivers validated and well-confirmed measurements of hydration levels of the skin (1). The corneometer scores are presented in arbitrary units. A Cutometer was used to evaluate parameters relating to skin elasticity (2). Transepidermal water loss (TEWL) assesses water evaporation through the skin and hence provides an insight into the integrity of the barrier of the skin (3). It is measured in g/m²/h. using a Tewameter MPA5. Visioscan VC98 uses special illumination and evaluation technology to provide a graphic image of the skin of skin roughness and skin smoothness. The device uses a camera and UV-A light video to capture high-resolution images (4).

The supplementation phase started on day 0 and continued today 84. Daily dosage was 2 capsules each day. Adherence was assessed by counting unused capsules in containers returned at the end of the study.

Skin Within™ contains collagen hydrolysate, a high polyphenolic mixture of rosemary and citrus extracts (Nutroxsun®), Cosmythic® maritime pine bark extract, co-enzyme Q 10, astaxanthin, vitamin C and biotin.

Collagen hydrolysate is a bioavailable form of collagen rapidly absorbed when taken orally. Collagen hydrolysate has been shown to significantly improved skin elasticity, especially in those over 50 years of age. Skin hydration improved by 11% and trans-epidermal water loss by 6%. (5) In a 12 week study of slightly older women, there was a significant reduction in eye wrinkle volume. (6)

Nutroxsun® has been shown to improve skin elasticity by 4.6% after 2 months and reduce wrinkle depth by 14%. (7)

Cosmythic® was shown to improve skin firmness by 7%, skin elasticity by 4%, with a decrease in the total wrinkled surface of 15% and a reduction in the number of medium wrinkles of 12%. (8)

Astaxanthin has been shown to reduce wrinkles, age spot size and trans-epidermal water loss and improve elasticity, skin texture, moisture content of the skin and crow's feet wrinkles. (9,10)

The content of endogenously synthesized Co-enzyme Q10 in skin decreases with aging. It is considered to be an effective nutritional supplement that ameliorates skin aging, especially wrinkles. (11)

Vitamin C & Biotin: Vitamin C is acknowledged to make an important contribution to normal collagen formation which in turn supports the normal function of skin. Biotin contributes to the maintenance of normal skin too meaning that these are both valuable additions to any skin formula.

Results

30 individuals completed the study, compliance was good and the main reason for leaving the study was loss of interest. All measurements reported are the mean of three assessments obtained at the selected sites on a participant's skin on days 0 and 84. Data are presented as mean and SD. Results of every data point recorded were compared using Student's t-test for numerical values of each parameter. All comparisons were made two tailed, and p values of <0.05 were considered statistically significant. There were no adverse events reported.

Trans-epidermal water loss

TEWL was improved from day 0 to day 84 by 16.4%, this was statistically significant (p<0.01) by paired t test.

Table 1: Trans-epidermal water loss at Baseline (D0) and end of trial (D84)

Trans-epidermal water loss (g/h/m ²)							
	Time	N	Median	Mean	SD	Min	Max
	0D	30	5.5	6.63	3.84	2.6	19.4
	84D	30	5.0	5.56	3.08	1.8	17.3

Hydration

Hydration was improved from day 0 to day 84 by 14.1%, this was statistically significant (p<0.01) by paired t test.

Table 2 : Hydration at Baseline (D0) and end of trial (D84)

Hydration (AU)							
	Time	N	Median	Mean	SD	Min	Max
	0D	30	39.0	39.83	5.85	29.9	53.6
	84D	30	45.52	45.44	7.03	31.2	58.0

Elasticity

Elasticity was improved by 5.6%, this was statistically significant ($p < 0.01$) by paired t test.

Table 3: Elasticity at Baseline (D0) and end of trial (D84)

Elasticity (AU)							
	Time	N	Median	Mean	SD	Min	Max
	0D	30	0.895	0.880	0.122	0.472	0.969
	84D	30	0.916	0.930	0.133	0.596	0.991

Skin roughness

Skin roughness was improved by 4.1%, this was statistically significant ($p < 0.01$) by paired t test.

Table 4: skin roughness at Baseline (D0) and end of study (D84)

Roughness (AU)							
	Time	N	Median	Mean	SD	Min	Max
	0D	30	1.47	1.46	0.24	1.03	1.84
	84D	30	1.53	1.53	0.23	1.19	1.88

Skin Smoothness

Skin smoothness was improved by 8.65%, this was statistically significant ($p < 0.01$) by paired t test.

Table 5 : Smoothness at Baseline (D0) and end of trial (D84).

Smoothness (AU)							
	Time	N	Median	Mean	SD	Min	Max
	0D	30	30.63	31.21	5.48	22.23	41.57
	84D	30	28.4	28.52	4.88	21.06	37.57

Discussion

It is well-known that the aging process includes the decline of the dermal collagen and elastic fibres. Wendling reported the oldest age group had the least skin elasticity (12) possibly because skin collagen content shows a peak between the ages of 20 and 40 years and decreases from 40 years onwards (13). A negative correlation between forearm skin elastic properties and age in women has been demonstrated and Sumino et al. (14) reported that skin elasticity decreased after menopause at 0.55% per year.

A negative correlation between age and TEWL has been reported in several studies (15). TEWL and skin hydration have a significant correlation in which the increase in skin hydration is associated with lower TEWL value indicating intact skin barrier function (16,17). A significant relationship exists between skin hydration and age the oldest individuals had the least hydrated skin (18).

Aged skin is drier than younger skin and has a more rigid epidermis and Dobrev (19) demonstrated how skin visco-elasticity is affected by epidermal hydration level. Because improved hydration increases not only increases moisture levels in the epidermis but also in the dermis, more dermal interstitial fluid is thought to loosen the connections between fibres, making the tissue less viscous and more fluid-like. This finding confirms the theory (20), that only the water-swollen elastic fibres gain elastic recoiling ability and that in the physiologic range, skin hydration diminishes wrinkles, with a negative correlation between hydration level and wrinkle parameters.

Conclusion

In this current open-label clinical trial, healthy volunteers with healthy skin were supplemented twice daily with Skin Within™ for 12 weeks. There were statistically significant beneficial changes for trans-epidermal water loss, hydration and elasticity, skin smoothness and roughness. 29 of the 30 participants reported a subjective improvement in their hair and nails. This study demonstrates that Skin Within has the potential to deliver significant benefits in skin condition and reverses objective measures of skin function associated with skin aging. It also demonstrates that the changes observed as a result of supplementation

of the combination of ingredients present in Skin Within™ are greater than those reported for any individual compound alone used in the formulation.

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The author declares no conflict of interest.