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SHORT TERM TEST

PRELINE - RAPID BRONZ

Assessment of soothing efficacy of a cosmetic product called

RAPID BRONZ

MATERIALS AND METHODS

PRODUCT

Cosmetic product of the company Preline (called Rapid Bronz) containing different functional substances with a hydratation and soothing activity. The main functional soothing substances in the product are: LINSEED ACID and PROPOLIS EXTRACT.

LINSEED ACID is an extract obtained through cold pressing of ripe linseeds. It is a rich source of valuable natural bioactive substances, such as A, B and E vitamins, amino acids, as well as many other minerals. This extract contains about 35% oil, which is characterized by its high content in polyunsaturated fatty acids. Oil contains about 20% oleic, 55% linolenic acid (Omega 3) and 15% linoleic acid (Omega 6). It is one of the few vegetable oils with a high linolenic content.

Traditional medicine has been using linseed oil to heal burns and chilblains and to repair the damaged, dry and desquamated skin. Moreover, it is used as moisturising and anti-inflammatory agent.

PROPOLIS EXTRACT is a propolis extract, a resinous substance collected by bees, Apis mellifera, from different vegetable sources. Bees use the propolis as building and insulating material to protect their beehives. Propolis has been used by traditional medicine and complementary therapies since 3000 BC in Egypt and has become one of the most functional foods throughout the world. Propolis has shown a wide range of bioactivity, as antioxidant (Sulaiman 2011), antimicrobic (Mascheroni 2010), antitumoral (Szliszka 2011), antiviral (Nolkemper), antiulcer (De Barros 2007), immunomodulator (Sforcin 2007), heart-protector (Zu 2011) and anti-inflammatory agent.

Different studies have shown anti-inflammatory effects both in vivo and in vitro (Hu 2005, Paulino 2006, Machado 1012). The chemical analysis of the propolis extract has shown that it contains an abundance of flavonoids, among which are rutin, miricetin, quercetin, kaempferol, apigenin, pinocembrin, crisin and galangin. These substances seem to be able to inhibit the production of NO, IL-1ß, IL-6 and suppress the mRNA expression of iNOS, IL-1ß, IL-6 in a dose-dependent manner by cells being cultured.

SUBJECTS

For these trial 20 female volunteers were recruited, between 20 and 60 years old, with a normal skin. All the volunteers had the following characteristics: good health, absence of skin pathologies and of topical or systemic treatments in progress, negative medical history for atopy and ACD. The following were excluded: pregnant, breast-feeding or under-age women. Every subject was informed of the modality of the test and signed a written consent form prior to the treatment.

TOOLS USED

The healing efficacy was assessed as: colorimetric index E measured through the Multiprobe Adapter System MPA5 sensor of Courage & Khazaka Electronic GmbH (Cologne, Germany).

Assessment of the soothing activity

The effects on the reduction of redness were assessed through the Mexameter MX 16 probe (Courage + Khazaka Electronic GmbH). This probe has a 4 mm hole.

4 measurements were made for each volunteer, in the corners of an area marked with a tape, expressed in units of hemoglobin (parametre E) where the minimum value corresponds to 500. The principle of measurement of skin redness is based on a source of light, with three specific wavelengths, whose radiation is absorbed by the skin and reflected diffusely. A sensor analyzes the reflection diffused by the skin. If the skin is well-vascularized the hemoglobin value increases. As a consequence thereof, it is possible to evaluate the stimulation of microcirculation before and after a topical application by measuring the hemoglobin value. The probe itself is used to quantify skin redness (erythema) and to determine the skin tanning degree (melanin).

MODE OF PERFORMANCE

The sample was applied based on its characteristics of use: applied once on the forearm with a light massage 7 days prior to the trial. Its efficacy was assessed with a Short Term Test of 1 hour.

The area used for the test is a skin area of the forearm volar region at about 2 cm from the elbow bend. The surface to be analyzed was marked with a surgical tape, where a square cut was made, with an area of 6 cm2. Measurements were 4 for each area starting from the superomedial corner clockwise.

Prior to the measurements, the subjects stayed for 30 minutes with bare forearms to get their skin accustomed to the temperature and dampness of the air-conditioned room where the tests were being carried out.

Before the t0 each volunteer was asked not to wash her forearms for at least 2 hours before the experiment. After said period the colorimetry basal values were measured. After colorimetric measurement, on the area under trial of the subjects, 10% lactic acid in occlusion was applied for 10 minutes. Afterwards, the E colourimetry values were measured (t0 after lactic acid). Then a standard dose of preparation was spread on the area to be studied. After 15 minutes (t15), 30 minutes (t30) and 60 minutes (t60) colorimetry variations were studied. For each trial time a dermatologic examination was carried out to assess any side effects.

MATHEMATICAL ELABORATION

Data were analyzed through Student t tests for paired data. Data were considered statistically significant when the test value was lower than 0.05 ($p<0.05$). In particular:

$p< 0,05$ *significant

$p< 0,01$ ** very significant

$p< 0,001$ *** extremely significant

RESULTS

All the 20 subjects have completed their trial and their demographic characteristics are in chart 1. All instrumental tests were carried out in the same ward, at an average temperature of 20° ± 1.2° and at an average dampness of 47% ± 2% between 9 am and 11 am. Measurements were performed always by the same investigator.

Demographic characteristics of the patients	
Patients characteristics	
	n = 20
Male	0 (0%)
Female	20 (100%)
Age (range)	23 - 48
Age (mean and SD)	30,2 ± 6,9

Table 1

Assessment of the soothing activity
After the application of the lactic acid the area being studied became more erythematous with a statistically significant increase equal to 3.2% of the colorimetric parametre E. After the application of the product a progressive reduction of the redness manifested itself, which became statistically positive after 60 minutes (chart 2).

RAPID BRONZ	t0	t0 dopo ac. lattico	t15min	t30min	t60min
Colorimetry E measurement	527,4 ± 10,3	544,1 ± 12,3	541,2 ± 10,7	536,4 ± 7,54	529,4 ± 5,09
percentage change mean from t0		3,2%	-0,5%	-1,3%	-2,6%
p		0,03005964	0,08227880	0,06449978	0,02070752

Table 2

RAPID BRONZ

percentage change mean from t0 and t0 after lactic acid

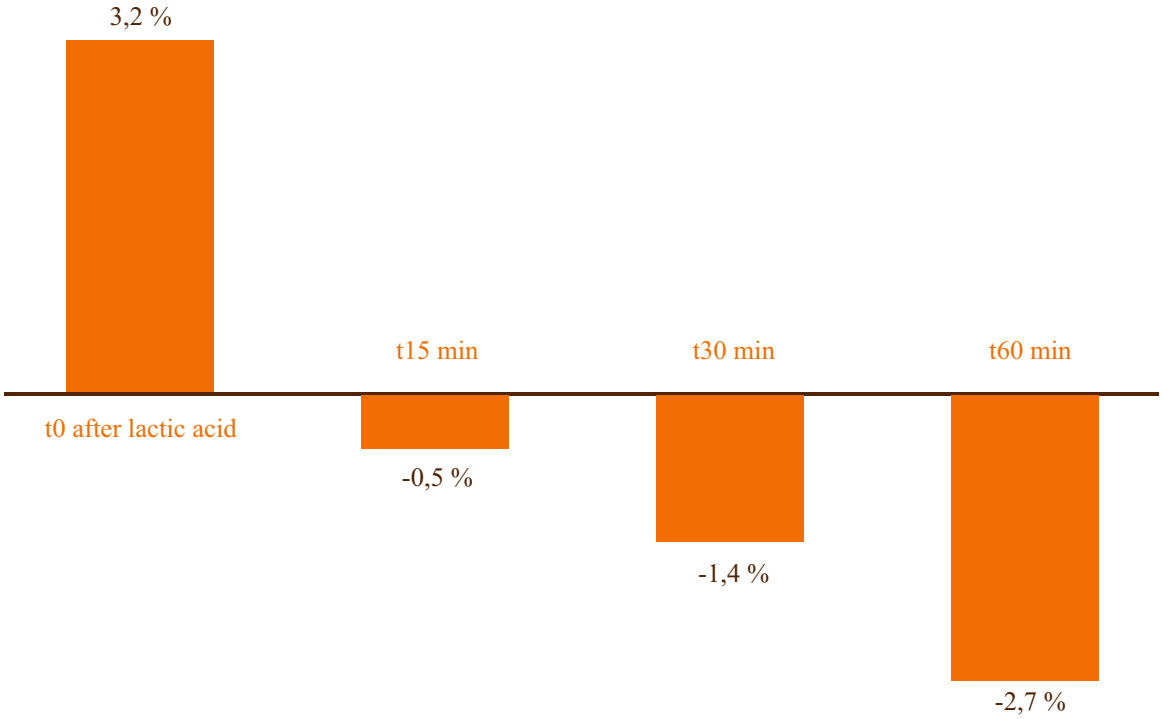

Figure1

DISCUSSION

Our trial aimed at assessing the efficacy of a soothing product called Rapid Bronz.
The effects of cosmetic soothing products to improve the degree of skin erythema have not been proved instrumentally in dermatologic literature. The anti inflammatory activity of some principles used in these products, such as propolis (Hu 2005, Paulino 2006, Machado 1012) has been demonstrated.
In our trial we wanted to test a product based on 2 associated soothing hydrating plant extracts active principles, in a short term test to assess their soothing efficacy and their tolerability.
The short term test is important in efficacy studies because it could have a high discriminating power since it can improve skin properties after one single application (Belo 2006). Long term studies were important to assess real effects on skin surface strata determined by the functional principles in the product (Prall 1986, Berardesca 1997). In both test types it is recommended to work with a sample of middle-aged volunteers whose skin presents major alterations. For these reasons we have studied the soothing effects on a wide range of population.
Efficacy measurements were carried out through the Mexameter probe, already approved at an international level for the trial of skin colour variations.
The interpretation of results highlighted the reduction of a lactic acid-induced erythema after one single application of the tested product.
The erythema reduction amounts to 2.6%, returning to basal values after 1 hour from the application of the product.

CONCLUSIONS

Our trial was aimed at assessing the cosmetic properties of a cream, called Rapid Bronz, especially its effect in the improvement of skin erythema.
The principles of this cream include substances with a hydrating and soothing activity. The results obtained show that this product respects the skin's physiological balance showing a good soothing efficacy and no skin intolerance phenomenon. These effects manifest themselves 60 minutes after one application of the product.