The role of hydrolyzed collagen type I & III (GelcoPEP) in skin health: a randomized, single-blind, and placebo-controlled investigation

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Abstract

Summary: Collagen, including hydrolyzed type I-III and native (undenatured) collagen type II sources, is recognized as a safe food ingredient, whose combination of amino acids stimulates collagen synthesis in extracellular matrix of several tissues, including skin.

Objective: The aim of the study was to develop a randomized, single-blind, placebo-controlled clinical study to investigate the effects of supplementation with GelcoPEP hydrolyzed collagen.

Method: Several questionnaires were administered with medical monitoring to measure the benefits of GelcoPEP hydrolyzed collagen on the skin.

Results: The tests showed improvement in hydration and elasticity, less appearance of expression lines and wrinkles, improving the appearance of hair and nails, reduction in the degree of cellulite, as well as a reduction in pores. Collagen supplementation had positive effects on skin aesthetics.

Conclusion: The use of hydrolyzed collagen type I & III (GelcoPEP) food ingredient improves the firmness and elasticity of the skin, reducing sagging. In this way, it can be used to stimulate anabolic processes in the skin, making it important for new studies to link it with aging.

Key words: hydrolyzed collagen; type I collagen; type II collagen; skin; randomized trial; placebo-controlled.

Introduction

In recent years, the cosmetics industry has grown considerably, as has its interest in developing effective and safe products. The creation of the Consumer Protection Code, the requirements of the Health Surveillance Secretariat of the Ministry of Health and competition itself have led the industry to take a more cautious attitude with regard to the action and benefits of its products, seeking to associate its claims to scientific work.

Industry awareness and consumer demands have resulted in the adoption of a new procedure by cosmetics manufacturers: currently, companies are concerned with carrying out clinical allergenicity and efficacy tests before marketing, which are coordinated by dermatologists. This procedure offers the company credibility and trust among consumers.

A growing concern of the cosmetics industry is to avoid possible adverse reactions in users of their products. After all, consumers are much more critical of skin irritation caused by a cosmetic product than by a topical medication.

An adverse reaction is considered to be any sign or symptom triggered by a cosmetic product used correctly (Fisher, 1995). The irritation potential of a product depends on a series of variables: components used, concentration of ingredients, absorption, amount of product applied, condition of the skin, mode and frequency of application and cumulative effect (Dooms-Goossens, 1993).

Tests carried out on human beings are regulated according to very strict laws, with the aim of protecting and safeguarding individuals. These laws vary by country. In Brazil, these researches are permitted, as long as they have protocols approved by a Medical Ethics Committee and follow the precepts of the Declaration of Helsinki and Resolution 466/12 (Conselho nacional de saúde, 2012).

Use tests with the finished product, before its introduction to the market, are important to evaluate the safety of the product in real conditions of use (Baran & Maibach, 1994). It is also possible to

evaluate, through this test, in addition to allergenicity, the sensorial characteristics of the product, detecting additional complaints and comments regarding its "performance".

The company is aware of the possible considerations and complaints that will arise during the marketing of the product, and can develop strategies, such as, for example, specific training of the Customer Service (SAC), prior to the launch of the product (BARAN & MAIBACH, 1994).

Objective

Evaluate the effectiveness of the use of collagen considering the parameters of the participants' appreciation, under normal conditions of use.

Methodology

Selection of participants

Caractheristics of the selected participants Collagen			
Number of participants included in the study	51	Phototypes	II to IV
Gender	F	Age	40 to 62

Caractheristics of the selected participants Placebo			
Number of participants included in the study	51	Phototypes	II to IV
Gender	F	Age	40 to 65

Inclusion criteria

- Gender: female
- Age: 40 to 65 years old
- Phototypes: I to IV
- Intact skin in the study region (nails and hair)
- Occasional user of category products

Non-inclusion/exclusion criteria

- Skin marks in the experimental area that interfere with the assessment of possible skin reactions (pigmentation disorders, vascular malformations, scars, increased hairiness, large quantities of ephelides and nevus, sunburn)
- Active dermatoses (local and disseminated) that may interfere with the study results
- Pregnant or breastfeeding women
- History of allergic reactions, irritation or intense sensations of discomfort to topical products: cosmetics and medicines
- Participants with a history of allergy to the material used in the study
- History of atopy
- History of pathologies aggravated or triggered by ultraviolet radiation
- People with immunodeficiencies
- Kidney, heart or liver transplants
- Intense sun exposure or tanning session up to 15 days before the initial assessment
- Anticipated intense sun exposure or tanning session during the study period
- Plan to take a swim in the sea, swimming pool or sauna during the study
- Participants who practice water sports
- Use of the following systemic topical medications: immunosuppressants, antihistamines, non-steroidal anti-inflammatory drugs, and corticosteroids up to two weeks before the selection
- Treatment with acid vitamin A and/or its derivatives orally or topically up to 1 month before the start of the study
- Expected vaccination during the study or up to 3 weeks before the study
- Be participating in another study
- Any condition not mentioned above that, in the opinion of the investigator, may compromise the evaluation of the study
- History of lack of adherence or unwillingness to adhere to the study protocol
- Professionals directly involved in carrying out this protocol and their families.

Restrictions imposed on participants

- Do not undergo aesthetic or dermatological treatments during the study. Medications prohibited during the study:
  - Anti-inflammatories
  - Antihistamines
  - Immunosuppressants
  - Acidic vitamin A and derivatives

Product information

Treatment

Product's name: CCG TYPE.

Directions of use: Stir 10g of the product (two scoops) in your preferred drink, once homogeneous, ingest. Consume once a day.

Composition: protein (≥ 90%), water (≤ 10%), other salts.

Placebo

Product's name: CMT TYPE.

Directions of use: Stir 10g of the product (two scoops) in your preferred drink, once homogeneous, ingest. Consume once a day.

Composition: maltodextrin.

Consent of Research Participants

The objective and methodology of the research were explained to the participants and they signed an Informed Consent Form.

Application of the Investigational Product

The product was given to participants to be used at home for 180 ± 2 days and they were duly instructed on how to use it according to the method of use informed.

Dermatological Medical Assessment of Clinical Signs and Sensations of Discomfort

An initial medical evaluation was carried out at the time of inclusion of participants to verify the absence of initial clinical signs incompatible with the inclusion of participants. After using the product, participants returned to the Institution for a final medical evaluation of the clinical signs presented and questioning of the sensations of discomfort felt.

The medical evaluation data were recorded in the investigation notebook. The doctor was available throughout the study to evaluate possible adverse events. The results were evaluated as follows:

- Sensations of discomfort: participants were asked about the sensations of discomfort they felt, in parallel with the clinical examination. The discomfort sensations reported were described in relation to nature (example: burning, itching, itching, tightness, cooling, heating, etc.); they were classified according to intensity as: light, moderate or intense; regarding location; and as for duration; and imputability to the test product was verified.
- Clinical signs: they were classified according to Table 1 and the causal link of reactions to the product was investigated.

Table 1. Classification of clinical signs – Dermatological Assessment

Clinical Signs			
(/) Nothing to report	(Ed) Edema	(Pu) Pustules	(Dr) Dryness/peeling
(E) Erythema	(Pa) Papules	(Bu) Bubbles	(Cr) Crust
(S) Soap effect	(C) Coloration	(No) Nodules	(V) Vesicle

Classification of Clinical Signs								
Vesicles or papules	1	N = 1 or 2	**Edema and erythema**	1	Light	**Appearance of erythema and edema**	d	Diffuse
				2	Moderate		p	Ponctual
	2	N > 2		3	Severe		peri	Peripheral

Table 2. Parameters evaluated for hair and nails.

	Parameters – Hair and Nails	**Answers**
1	Have you noticed your nails are more resistant?	Y = Yes N= No
2	Did you think the product improved the general appearance of your nails?	
3	Did you notice that there was a reduction in hair loss?	
4	Have you noticed your hair is thicker and more resistant?	
5	Have you noticed a reduction in damaged hair strands?	
6	Did you think the product improved the general appearance of your hair?	
7	Did you like the product?	
8	Would you buy the product?	

Participant opinion questionnaire (cosmetic appreciability)

Participants were instructed to answer a questionnaire on D90 and D180 containing the questions listed in table 2.

Results

The main results are shown in the tables below:

Table 3. Main collagen markers

N. of included participants	51	**N. of participants that finalized the study**	50

N. of participants dropping out	1	**Reason**	Did not return for personal reasons
N. of excluded participants	0	**Reason**	N/A

Table 4. Main placebo markers

N. of included participants	51	**N. of participants that finalized the study**	51

N. of participants dropping out	0	**Reason**	N/A
N. of excluded participants	0	**Reason**	N/A

Dermatological acceptability

No participant reported feelings of discomfort and no clinical signs were detected after applying the product.

Cosmetic Appreciability (Participants' Opinion)

The results obtained are shown in Graphs 1 and 2, which represent the percentages of participants for each answer to the questions presented in the cosmetic appreciability questionnaire applied after 90 and 180 ± 2 days of product use.

After 90 days of using the product, among participants who completed the survey:

- Have you noticed your nails are more resistant?
- 80% of people who used the CCG Type product agree, compared to 47% who used the CMT Type.
- Did you think the product improved the general appearance of your nails?
- 78% of people who used the CCG Type product agree, compared to 67% who used the CMT Type.
- Did you notice that there was a reduction in hair loss?
- 68% of people who used the CCG Type product agree, compared to 33% who used the CMT Type.
- Have you noticed your hair is thicker and more resistant?
- 68% of people who used the CCG Type product agree, compared to 47% who used the CMT Type.
- Have you noticed a reduction in damaged hair strands?
- 78% of people who used the CCG Type product agree, compared to 55% who used the CMT Type.
- Did you think the product improved the general appearance of your hair?
- 94% of people who used the CCG Type product agree, compared to 55% who used the CMT Type.
- Did you like the product?
- 100% of people who used the CCG Type product agree, compared to 63% who used the CMT Type.
- Would you buy the product?
- 96% of people who used the CCG Type product agree, compared to 63% who used the CMT Type.

After 180 days of using the product, among participants who completed the survey:

- Have you noticed your nails are more resistant?
- 88% of people who used the CCG Type product agree, compared to 47% who used the CMT Type.
- Did you think the product improved the general appearance of your nails?
- 82% of people who used the CCG Type product agree, compared to 65% who used the CMT Type.
- Did you notice that there was a reduction in hair loss?
- 78% of people who used the CCG Type product agree, compared to 47% who used the CMT Type.
- Have you noticed your hair is thicker and more resistant?
- 88% of people who used the CCG Type product agree, compared to 51% who used the CMT Type.
- Have you noticed a reduction in damaged hair strands?
- 88% of people who used the CCG Type product agree, compared to 51% who used the CMT Type.
- Did you think the product improved the general appearance of your hair?

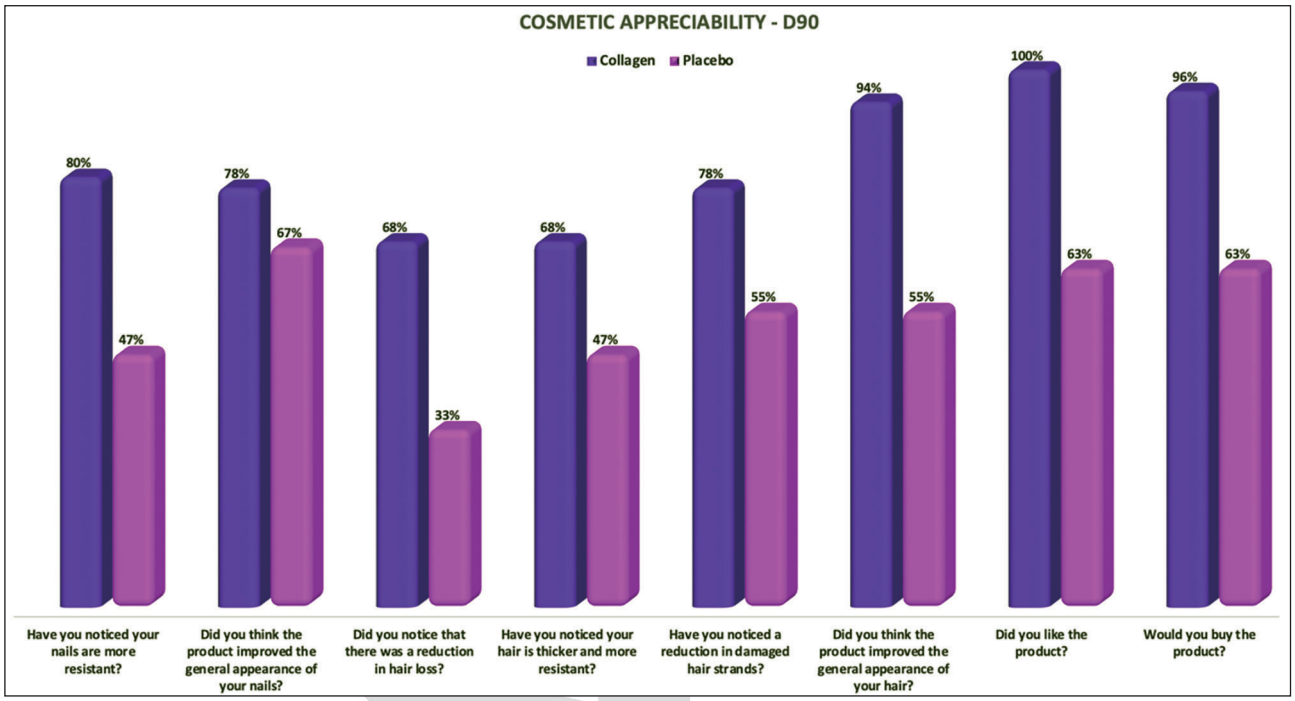

Figure 1. Participants' responses to the cosmetic appreciability questionnaires applied after 90 ± 2 days of product use (Part 1)

- 94% of people who used the CCG Type product agree, compared to 49% who used the CMT Type.
- Did you like the product?
- 100% of people who used the CCG Type product agree, compared to 67% who used the CMT Type.
- Would you buy the product?
- 98% of people who used the CCG Type product agree, compared to 61% who used the CMT Type.

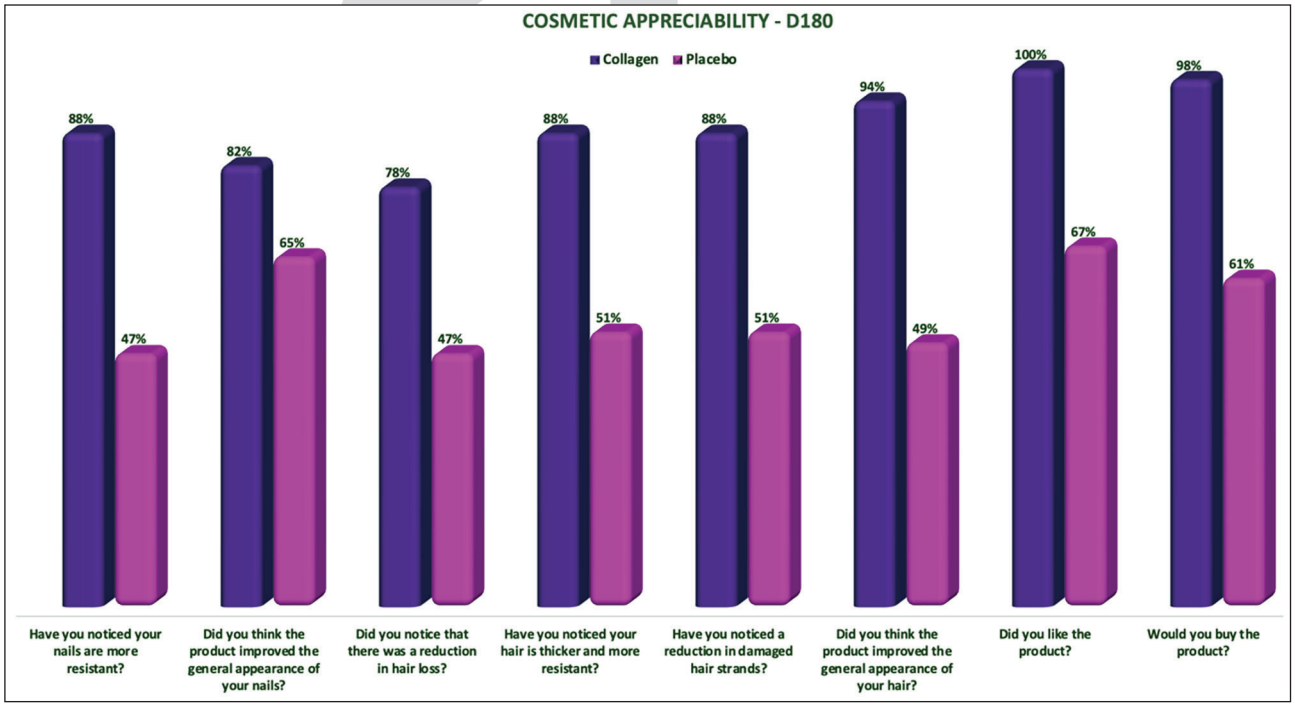

Figure 2. Participants' responses to the cosmetic appreciability questionnaires applied after 180 ± 2 days of product use (Part 2)

Conclusion

GelcoPEP supplementation showed positive effects in relation to skin aesthetic criteria, especially hydration, also covering criteria such as elasticity, reduced appearance of expression lines and wrinkles and reduction in the degree of cellulite, as well as strengthening hair and nails, standing out as an excellent nutri-cosmetic alternative.

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