Clinical evaluation of GelcoPEP Beauty: a new hydrolyzed collagen that provides improvements in the skin, including firmness factors, fine lines, wrinkles, and elasticity

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Abstract

Summary: The dietary supplements industry emphasizes the clinical trials importance to ensure the products safety and efficiency. Comparing various products and validating claims are crucial to guarantee market's credibility and trust.

Objective: The aim of the study was to compare the effects of GelcoPEP Beauty hydrolyzed collagen with the benchmark product, through a single-blind, randomized, placebo-controlled study, analyzing and comparing the supplementation effects.

Method: A questionnaire was administered, elasticity and firmness measurements by Cutometer® Dual MPA 580 and image analysis for wrinkles and fine lines captures by VISIA® CR.

Results: The tests showed general improvement in skin aesthetics, including elasticity, firmness, and reduction in expression lines.

Conclusion: GelcoPEP Beauty hydrolyzed collagen demonstrated significant benefits for skin health, especially increasing elasticity, comparable result with the benchmark product.

Key words: hydrolyzed collagen; dietary supplement; skin; comparative study; placebo-controlled.

Introduction

In recent years, the dietary supplement industries have grown, as well the concern to develop effective and safe products. The industry's awareness and the demands of consumers and regulatory institutes have led supplement manufacturers to adopt procedures to allow them to understand better their products. These include perform clinical safety and effects tests coordinated by specialists before marketing a product. These procedures provide companies with greater security, credibility, and reliability with their consumers (9).

Effects studies allow evaluating the product's characteristics, detecting complaints and additional comments regarding its performance, as well as testing quality control, competitor analysis and claims support. To assess whether a claim is appropriate, it is necessary to consider the general impression of consumers regarding the product presentation or advertisement (9).

Claims must be supported by solid, clear and relevant evidence. The evidence can be in experimental studies (biochemical/instrumental methods, sensory evaluations, technical evaluations, and evaluations without participation of research participants – in vitro tests in cell culture, use of hair strands) and consumer evaluations (1).

Clinical and/or self-assessment studies and instrumental studies can be used to evaluate the products effects. Cutaneous bioengineering or cutaneous biometry consists of studying the biological, mechanical, and functional characteristics of the skin by rigorously measuring certain variables using scientific and non-invasive methods (11).

The main parameters that can be used to evaluate a product's effectiveness on the skin are morphological changes to the skin's surface, stratum corneum hydration and sebum secretion. Due to variation in parameters between different anatomical regions in the same individual, and between different individuals, these techniques are used to comparatively measure variation in the same parameter, in the same local, before and after using a product (10).

The self-evaluation by the study participants is based on the "Standard Guide for Sensory Claim Substantiation" (1) through questionnaire application. The "Standard Guide for Sensory Claim Substantiation" is an ASTM norm that aims to disseminate good practices in sensory tests and approach reasonable practices for conducting tests that validate claims regarding product's attributes.

Objective

Compare the dietary supplement effectiveness under normal conditions of use, using the parameters of skin firmness and elasticity, fine lines and wrinkles analysis and participants effects evaluation.

Methods

A comparative, single-blind, randomized, clinical study was conducted with the investigational product, benchmark product and placebo.

Participants

84 participants were included, with the aim of completing the study with 60 responses, according to the criteria in the tables below.

Table 1. Participants characteristics

Characteristics of the selected participants Investigational Product	
Nº of participants included	28
Gender	F
Age (years)	46 - 69
Characteristics of the selected participants Benchmark Product	
Nº of participants included	28
Gender	F
Age (years)	47 - 70
Characteristics of the selected participants Placebo	
Nº of participants included	28
Gender	F
Age (years)	45 - 70

Table 2. Inclusion criteria

Inclusion criteria
• Healthy study participants; • Intact skin in the study region; • Agreement to adhere to the study procedures and requirements and to attend the Institute on the day(s) set for the evaluations; • Ability to consent to their participation in the study; • Age over 45 years; • Female participants; • Participants with facial sagging – verified by the specialist evaluator; • Participants with wrinkles/fine lines of, at least, grade II in the periorbital region - verified by the specialist evaluator, and according to the institute's scale; • Participants vaccinated for COVID-19.

Table 3. Exclusion criteria

Exclusion Criteria
• Pregnancy and/or breastfeeding; • Skin pathology in the valuation area; • Type 1 diabetes mellitus; insulin-dependent diabetes; presence of diabetes related complications (retinopathy, nephropathy, neuropathy); presence of diabetes-related dermatoses (plantar ulcer, lipoid necrobiosis, granuloma annulare, opportunistic infections); history of episodes of hypoglycemia, diabetic ketoacidosis and/or hyperosmolar coma; • Immune insufficiency; • Current use of the following topical or systemic medications: Corticosteroids, immunosuppressants and antihistamines; • Skin diseases: vitiligo, psoriasis, atopic dermatitis; • Previous history of reaction to the category of products tested; • Other diseases or medications that could directly interfere with the study or put the study participant's health a risk.

Table 4. Restrictions during study

Restrictions during study
• Do not apply any product to the experimental area that could interfere with the evaluation of the study; • Do not change cosmetic habits, including hygiene; • Do not change eating or exercise habits during the study period.

Products

Investigational Product - GelcoPEP Beauty
Name: E004121A-01
Batch: 04CH2300039
Composition: Hydrolyzed collagen

Benchmark Product
Name: E004121A-03
Batch: H4508072
Composition: Hydrolyzed collagen

Placebo
Name: E004121A-04
Batch: DE 2815
Composition: Maltodextrin

Participants received a kit containing sachets with the investigational, benchmark product or placebo, according to randomization, and were instructed to use the product according to the instructions: Dissolve the entire content of 1 sachet in a glass of water, mix and drink. Use the product every day, once a day, preferably at the same time.

Consent of Research Participants

At the first visit (T0), the study participants were informed of the aim of the study, methodology and duration, risks, possible expected benefits and restrictions linked to the study and signed the Informed Consent Form and the Image Disclosure Consent Form (2).

Application and Investigation Period

The total study duration per participant was 60±2 days.

Analyzed Parameters

At the initial visit (T0), a specialist assessor evaluated the participants to verify the inclusion or exclusion criteria for the study. Participants were supervised by trained technicians throughout the study and evaluated by specialist doctors if any symptoms or signs appeared, to confirm the correct use of the products and detect any possible adverse events.

Wrinkles and Fine Lines

Facial images where taken using the equipment VISIA® CR, which takes digital photographs of the face and emits different types of light beams to evaluate wrinkles and fine lines at T0 (before using the products) and T60 (after 60 ± 2 days of using the products), by comparing and analyzing the images using specific software.

The participant identity was preserved and the consent to obtain and disclose the images was given in writing by signing the Consent Form for Image Disclosure.

To assess wrinkles and fine lines were used Standard 2 images. A region of interest (ROI) was selected on the participants' image and the parameters were measured within the ROI. To ensure that the software does not consider irregularities and points that are not relevant to the analysis, the parameters are adjusted.

The analysis was performed using FrameScan® software and the following parameter were assessed: visibility coefficient (number of wrinkles/fine lines visible within the area assessed) and occupancy rate (area occupied by the wrinkle/fine line within the area assessed). A value reduction of each parameter indicates a reduction in wrinkles/fine lines.

Firmness and Elasticity

To analyze skin firmness and elasticity, the Cutometer® Dual MPA 580 was used. The measurement principle with the equipment is based on skin suction and stretching (*3, 4*).

The equipment generates a negative pressure and the evaluated skin area penetrates the probe. The skin penetration length into the opening is

determined by contact with an optical measuring system, composed of glass prisms that transmit light from the emitter to the detector, the amount of light reaching the receiver is proportional to the skin penetration length into the opening. The process is repeated immediately, obtaining consecutive curves.

The obtained curve reflects the skin viscoelastic properties. This curve consists of two parts in the suction phase and a relaxation phase. In the first part of suction, the curve slope is perpendicular. In the second part, there is a progressive flattening until it reaches a maximum at the end of the suction phase (figure 1).

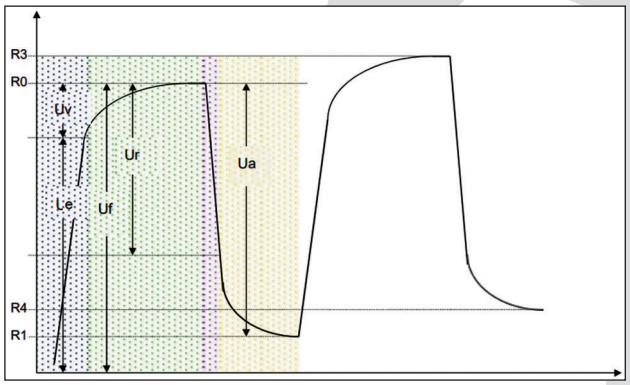

Figure 1. Curve generated by Cutometer® Dual MPA 580

After reading, the parameters R0 to R8 are obtained (table 5).

The parameters R0 and R5 were used to assess skin firmness and elasticity. The decrease of R0 value indicates an increase in firmness. The parameter R5 is related to skin elasticity and the higher and closer to one (01) the value is, the more elastic the skin is. Measurements were taken in the right or left malar region, according to randomization, at T0 (before using the products), T30 (after 30 ± 2 days of using the products) and T60 (after 60 ± 2 days of using the products).

Effectiveness Evaluation Questionnaire

Participants answered an effectiveness evaluation questionnaire, at T30 and T60, listed in table 6.

Statistical Analysis

Exploratory analyses were performed for the collected data, according to the analysis nature.

The effectiveness evaluation questionnaire results were reported by percentages and frequencies of positive responses.

The confidence level considered in the comparative analyses was 95%, the software used was XLSTAT 2023 and MINITAB 14. A detailed description is present in table 7.

Results

The general results of the participants are in the tables below.

Table 5. Parameters generated by Cutometer® Dual MPA 580

Parameter	Definition	Description
R0	Maximum curve amplitude	Highest point of the first curve.
R1	Minimum amplitude	Minimum point of the first curve.
R2	Ua/Uf	Gross elasticity. The closer to one (01), the more elastic the curve.
R3	Last maximum amplitude	-
R4	Last minimum amplitude	-
R5	Ur/Eu	Liquid elasticity. The closer to one (01), the more elastic the curve.
R6	Uv/Eu	Elasticity. The lower the value, the greater the elasticity. Can be related to skin hydration (*8*).
R7	Ur/Uf	Viscoelastic portion compared to the curve. The closer the value is to one (01), the greater the elasticity.
R8	Viscoelastic part	Area above the fixed curve by Uf x Suction time. Lower the value, more elastic the curve.

Table 6. Effectiveness Evaluation Questionnaire

Period	Proposition	Scale
T30 / T60	1. The product improves skin firmness.	1.Totally disagree
	2. The product improves skin elasticity.	2. Disagree
	3. The product provides younger-looking skin.	
	4. The product improves wrinkles and expression lines.	3. Neither agree nor disagree
	5. The product helps combat facial sagging.	4. Agree
	6. The product improves skin general appearance.	
	7. The product helps combat the appearance of lines and wrinkles.	5. Totally agree

Table 7. Detailed Statistical Analysis

Data Types		Statistical Methods	Reported Data	Sample Size
Wrinkle and Fine Line Analysis - VISIA® CR		Descriptive statistics Student's t test to compare T30/T60 vs T0. ANOVA-LSD to compare treatments	Average Average standard error % improvement in average % of participants with improvement p-value	E004121A-01: 21 E004121A-03: 24 E004121A-04: 24
Skin Firmness and Elasticity Analysis - Cutometer® Dual MPA 580	R0			E004121A-01: T0=24 / T30=22 / T60=24 E004121A-03: T0=23 / T30=20 / T60=23 E004121A-04: T0=21 / T30=20 // T60=21
	R5			E004121A-01: T0=24 / T30=22 / T60=24 E004121A-03: T0=23 / T30=20 / T60=23 E004121A-04: T0=22 / T30=21 / T60=22
Effectiveness Evaluation Questionnaire by Study Participants		Descriptive statistics Z test for two proportions	Percentage and frequency of positive responses p-value	E004121A-01: T30=26 / T60=28 E004121A-03: T30=23 / T60=26 E004121A-04: T30=24 / T60=25

Table 8. Investigational Product Participants

Nº of included participants	28	**Nº of participants that finalized the study**	28
Nº of absent participants	0	**Reason**	N/A
Nº of withdrawn participants	0	**Reason**	N/A

Table 9. Benchmark Product Participants

Nº of included participants	28	**Nº of participants that finalized the study**	26
Nº of absent participants	0	**Reason**	N/A
Nº of withdrawn participants	2	**Reason**	Protocol deviation

Table 10. Placebo Participants

Nº of included participants	28	**Nº of participants that finalized the study**	25
Nº of absent participants	3	**Reason**	Personal reasons
Nº of withdrawn participants	0	**Reason**	N/A

Wrinkle and Fine Line Analysis - VISIA® CR Visibility Coefficient Parameter

A significant improvement in the visibility coefficient parameter was observed for product E004121A-01 after 60 days of use, indicating a reduction in wrinkles / fine lines.

No significant difference was observed in the visibility coefficient parameter for E004121A-03 and E004121A-04 (table 11).

No significant difference was observed in the visibility coefficient parameter between treatments after 60 days of use (table 12).

Occupancy Rate Parameter

A significant improvement in the occupancy rate parameter was observed for product E004121A-01 after 60 days of use, indicating a reduction in wrinkles / fine lines. No significant difference was observed in the occupancy rate parameter for E004121A-03 and E004121A-04 (table 13).

No significant difference was observed in the occupancy rate parameter between treatments after 60 days of use (table 14).

Firmness and Elasticity Measurements - Cutometer® Dual MPA 580
Firmness (R0)

A significant improvement in skin firmness was observed for product E004121A-03 after 30 days of use. No significant difference was observed in skin firmness for E004121A-01 and E004121A-04 (table 15).

No significant difference was observed in skin firmness between treatments after 30 and 60 days of use (table 16).

Elasticity (R5)

A significant improvement in skin elasticity was observed for product E004121A-01 after 30 days of use.

Table 11. Descriptive statistics and comparison results – Visibility Coefficient

Treatment	Statistic	T0	T60	T60-T0
E004121A-01	**n**	21	21	21
	Average	3,79	3,55	-0,24
	Standard error	0,41	0,39	0,10
		% improvement (average)		6,3
		% participants with improvement		33,3
		p-value		0,011
E004121A-03	**n**	24	24	24
	Average	4,35	4,24	-0,11
	Standard error	0,53	0,50	0,08
		% improvement (average)		2,5
		% participants with improvement		33,3
		p-value		0,097
E004121A-04	**n**	24	24	24
	Average	4,68	4,64	-0,04
	Standard error	0,42	0,39	0,16
		% improvement (average)		0,9
		% participants with improvement		45,8
		p-value		0,403

Table 12. Result of comparison between treatments – Visibility Coefficient

Comparisons	p-value
E004121A-04 vs E004121A-01	0,252
E004121A-04 vs E004121A-03	0,666
E004121A-03 vs E004121A-01	0,464

Table 13. Descriptive statistics and comparison results –Occupancy Rate

Treatment	Statistic	T0	T60	T60-T0
E004121A-01	n	21	21	21
	Average	0,124	0,118	-0,006
	Standard error	0,009	0,009	0,003
		% improvement (average)		4,8
		% participants with improvement		33,3
		p-value		0,011
E004121A-03	n	24	24	2
	Average	0,129	0,126	-0,003
	Standard error	0,012	0,011	0,003
		% improvement (average)		2,3
		% participants with improvement		33,3
		p-value		0,125
E004121A-04	n	24	24	24
	Average	0,130	0,131	0,001
	Standard error	0,008	0,007	0,004
		% improvement (average)		-0,8
		% participants with improvement		50,0
		p-value		0,586

Table 14. Result of comparison between treatments - Occupancy Rate

Comparisons	p-value
E004121A-04 vs E004121A-01	0,097
E004121A-04 vs E004121A-03	0,360
E004121A-03 vs E004121A-01	0,432

Table 15. Descriptive statistics and comparison results - Firmness (R0)

Treatment	Statistic	T0	T30	T60	T30-T0	T60-T0
E004121A-01	n	24	22	24	22	24
	Average	0,238	0,231	0,232	0,001	-0,006
	Standard error	0,011	0,012	0,011	0,008	0,006
		% improvement (average)			2,9	2,5
		% participants with improvement			54,5	50,0
		p-value			0,531	0,185
E004121A-03	n	23	20	23	20	23
	Average	0,267	0,242	0,263	-0,016	-0,004
	Standard error	0,013	0,013	0,015	0,006	0,011
		% improvement (average)			9,4	1,5
		% participants with improvement			80,0	60,9
		p-value			0,007	0,379
E004121A-04	n	21	20	21	20	21
	Average	0,260	0,257	0,254	-0,008	-0,005
	Standard error	0,015	0,014	0,013	0,007	0,008
		% improvement (average)			1,2	2,3
		% participants with improvement			75,0	71,4
		p-value			0,108	0,253

No significant difference was observed in skin elasticity for E004121A-03 and E004121A-04 (table 17).

A significant improvement in skin elasticity was observed after 60 days of use for E004121A-01 compared to E004121A-04, indicating the superiority of E004121A-01. No significant difference was observed between other treatments (Table 18).

Effectiveness Evaluation Questionnaire

The tables present the participants percentage who reported agreeing (answers with values equal to 4 - Agree and 5 - Totally agree) with the statements evaluated after 30 and 60 days of using the products.

T30

No significant difference was observed between the treatments for all statements evaluated.

T60

No significant difference was observed between the treatments for all statements evaluated.

Table 16. Result of comparison between treatments - Firmness (R0)

Comparisons	p-value	
	T30	T60
E004121A-04 vs E004121A-01	0,328	0,988
E004121A-04 vs E004121A-03	0,416	0,895
E004121A-03 vs E004121A-01	0,073	0,879

Table 17. Descriptive statistics and comparison results - Elasticity (R5)

Treatment	Statistic	T0	T30	T60	T30-T0	T60-T0
E004121A-01	**n**	24	22	24	22	24
	Average	0,434	0,469	0,434	0,027	0,000
	Standard error	0,018	0,018	0,020	0,015	0,015
		% improvement (average)			8,1	0,0
		% participants with improvement			68,2	54,2
		p-value			0,039	0,489
E004121A-03	**n**	23	20	23	20	23
	Average	0,421	0,440	0,385	0,005	-0,036
	Standard error	0,018	0,013	0,014	0,014	0,014
		% improvement (average)			4,5	-8,6
		% participants with improvement			50,0	26,1
		p-value			0,359	0,993
E004121A-04	**n**	22	21	22	21	22
	Average	0,437	0,440	0,390	-0,002	-0,047
	Standard error	0,014	0,018	0,014	0,014	0,014
		% improvement (average)			0,7	-10,8
		% participants with improvement			42,9	36,4
		p-value			0,545	0,998

Table 18. Result of comparison between treatments - Elasticity (R5)

Comparisons	p-value	
	T30	T60
E004121A-04 vs E004121A-01	0,146	0,023
E004121A-04 vs E004121A-03	0,741	0,605
E004121A-03 vs E004121A-01	0,268	0,073

Table 19. Percentages and frequencies of positive responses per treatment – T30

Proposition	E004121A-01	E004121A-03	E004121A-04
1) The product improves skin firmness.	92,3%	87,0%	79,2%
2) The product improves skin elasticity.	88,5%	87,0%	83,3%
3) The product provides younger-looking skin.	88,5%	73,9%	75,0%
4) The product improves wrinkles and expression lines.	80,8%	73,9%	75,0%
5) The product helps combat facial sagging.	92,3%	78,3%	79,2%
6) The product improves skin general appearance.	88,5%	87,0%	83,3%
7) The product helps combat the appearance of lines and wrinkles.	80,8%	73,9%	70,8%

Table 20. Percentages and frequencies of positive responses per treatment -T30

Proposition	E004121A-01 vs E004121A-03	E004121A-01 vs E004121A-04	E004121A-03 vs E004121A-04
1) The product improves skin firmness.	0,541	0,180	0,473
2) The product improves skin elasticity.	0,873	0,603	0,726
3) The product provides younger-looking skin.	0,190	0,214	0,932
4) The product improves wrinkles and expression lines.	0,567	0,623	0,932
5) The product helps combat facial sagging.	0,163	0,180	0,940
6) The product improves skin general appearance.	0,873	0,603	0,726
7) The product helps combat the appearance of lines and wrinkles.	0,567	0,411	0,813

Table 21. Percentages and frequencies of positive responses per treatment – T60

Proposition	E004121A-01	E004121A-03	E004121A-04
1) The product improves skin firmness.	96,4%	92,3%	80,0%
2) The product improves skin elasticity.	92,9%	92,3%	80,0%
3) The product provides younger-looking skin.	85,7%	84,6%	76,0%
4) The product improves wrinkles and expression lines.	92,9%	84,6%	80,0%
5) The product helps combat facial sagging.	89,3%	92,3%	76,0%
6) The product improves skin general appearance.	96,4%	92,3%	84,0%
7) The product helps combat the appearance of lines and wrinkles.	85,7%	88,5%	76,0%

Table 22. Percentages and frequencies of positive responses per treatment – T60

Proposition	E004121A-01 vs E004121A-03	E004121A-01 vs E004121A-04	E004121A-03 vs E004121A-04
1) The product improves skin firmness.	0,513	0,060	0,198
2) The product improves skin elasticity.	0,939	0,170	0,198
3) The product provides younger-looking skin.	0,910	0,369	0,437
4) The product improves wrinkles and expression lines.	0,337	0,170	0,666
5) The product helps combat facial sagging.	0,700	0,199	0,103
6) The product improves skin general appearance.	0,513	0,126	0,356
7) The product helps combat the appearance of lines and wrinkles.	0,763	0,369	0,239

Discussion

Recently, dietary supplements industries have sought to offer products with proven quality and efficacy through clinical studies and claims determinations (9). Hydrolyzed collagen is also included in this need for studies, aiming to prove its effects in relation to skin health, improving firmness, elasticity, wrinkles, expressions lines, sagging and youthfulness (7).

The study compares the efficacy of GelcoPEP Beauty product with the benchmark product with placebo control, for the skin health maintenance claim. Based on the study results of products E004121A-01, E004121A-03 and E004121A-04, is possible to verify that, for the visibility coefficient parameter, E004121A-01 showed a significant improvement. For the products E004121A-03 and E004121A-04, no difference was observed. The same occurred for the occupancy rate parameter.

For the measurements with Cutometer® Dual MPA 580, there was a significant improvement in R0 for E004121A-03, after 30 days of use. For E004121A-01 and E004121A-04, no significant difference was observed. However, no significant difference was observed in skin firmness through instrumental measurements between treatments, indicating that the investigational product, the benchmark product, and the placebo showed similar efficacy.

For R5, a significant improvement was observed after 30 days of use for E004121A-01. No significant improvement was observed for E004121A-03 and E004121A-04. After 60 days, a significant improvement was observed for E004121A-01 compared to E004121A-04, indicating the investigational product superiority over the placebo. No difference was observed between the other treatments, indicating that the investigational product has similar effect to the benchmark product.

For effectiveness evaluation questionnaire, no significant differences were observed between the treatments for all the statements evaluated.

The results presented in this study reinforce the results obtained in previous studies, which, in general, obtained results that the use of hydrolyzed collage provides an improvement in the appearance of the skin. With the tests conducted, it was possible to demonstrate that GelcoPEP Beauty hydrolyzed collagen provides improvements in firmness factors, the presence of fine lines, wrinkles and, especially, skin elasticity (6,12).

The limitation of the study was the placebo effect that occurred during the participants' answers to the questionnaires. Placebo effect can be defined as a phenomenon in which a person notices improvements in their health status after receiving a treatment that does not have the functionality to improve the patient's condition. Thus, the placebo effect may have interfered in the answers to the questionnaires, intervening in the evaluation of the collected results (5).

Conclusion

The use of GelcoPEP Beauty demonstrated positive effects in terms of maintaining skin health, such as improving wrinkles, fine lines, firmness and, mainly, skin elasticity, with similar effect to the benchmark product available on the market.

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