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Research Article

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Emerging Evidence for the Effectiveness of Profhilo® Figura Body Cream in Enhancing Skin Hydration, Elasticity, and Firmness

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Abstract

Aging generates an undesirable skin appearance, including laxity and a crepe-like appearance. Profhilo® Figura body cream is a multi-active remodelling and firming cream comprising low- and high-molecular-weight hyaluronic acids and Matrixyl® 3000. The objective of this study was to investigate the effectiveness of Profhilo® Figura body cream to moisturize and improve skin elasticity and firmness. Women aged 30-65 years, with a tendency for dry skin and mild-to-moderate skin atony (characterized by elasticity loss) applied the body cream daily for 28 days on their leg area. Skin moisturization, elasticity, and firmness were assessed on Day 14 and Day 28 by non-invasive bioengineering instrumental techniques, and skin tolerability was assessed on Day 28. Participants also completed a product satisfaction questionnaire. On Day 28 versus Day 0, there was a significant 42.4% increase in moisturization ($P<0.0001$), 6.3% increase in overall elasticity ($P<0.0001$), 8.9% increase in net elasticity ($P<0.0001$), and 51.6% decrease in protein content ($P<0.0001$; indicating improved cohesivity and firmness). On Day 28, 96.7% of participants reported smoother and firmer skin, 93.3% reported brighter skin, and increased moisturization and elasticity were reported by all participants. No adverse events occurred during the study.

Keywords: Skin moisturization; Skin elasticity; Skin firmness; Profhilo® Figura; Hyaluronic acid; Body cream.

Introduction

The skin is the largest, multifunctional organ in the body, comprising an outermost epidermis and an inner dermis [1]. The epidermis, predominantly composed of keratinocytes, performs most barrier skin functions, retaining its water content [1]. Environmental, physical, and nutritional changes can modify the structure and function of the epidermis [1]. The dermal skin layer, consisting of complex extracellular matrix proteins and collagen fibers, provides skin strength and elasticity [1]. Both intrinsic factors (influenced by genetics) and extrinsic components (chronic exposure to environmental aggressors, such as ultraviolet radiation) induce skin aging [2]. Intrinsically aged skin is characteristically thin and dry, with increased laxity and a crepe-like texture, while extrinsically aged skin is typically thick, coarse, leathery, and has uneven pigmentation [2]. Overall, the aging process in the body generates an undesirable skin appearance, including laxity and a crepe-like appearance, as well as increased localized fat

accumulation [2].

There is evidence linking the loss of extracellular matrix components in connective tissues to skin roughness and laxity [3]. Skin laxity and roughness involve several body areas, such as the arms, knees, abdomen, neck, décolletage, and hands [3]. These body areas are sensitive to changes in skin laxity and roughness due to genetics, ageing, body weight changes, sunlight exposure, and lifestyle changes [3].

In general, severe skin laxity and roughness cases can be treated using surgical intervention [3].On the other hand, mild to moderate cases can be improved using energy-based devices, such as lasers, radiofrequency, or ultrasonic devices [3].However, energy-based devices can be expensive, require repeat procedures, can cause pain and burns, and its use is associated with restrictions, such as no sunlight exposure between treatments [3]. Alternatively, hyaluronic acid-based injectable treatments have also been shown to be effective as hyaluronic acid can maintain hydration (by binding to and retaining water), turgidity, viscosity, and plasticity of the connective tissue [3-7]. Other benefits of hyaluronic acid include its bio-stimulatory or nutricosmetic effect, which can promote collagen formation, and its low allergenic potential [3,8].

Profhilo® Figura body cream is a multi-active remodelling and firming cream designed to maintain cell vitality, improve skin tone and its elasticity, and deeply hydrate the skin [9]. This body cream comprises low-and-high molecular weight hyaluronic acids in high concentrations, as well as Matrixyl® 3000 (a complex of a combination of two peptides that promote tissue remodelling and help restore the dynamism of cellular functions) [9]. Per the treatment protocol, participants receive the Profhilo® Body injection [10] and Profhilo® Figura body patch on Day 0 and Day 30 only and apply the Profhilo® Figura body cream daily between the two injections.

To our knowledge, no published studies have investigated the effectiveness of the Profhilo® Figura body cream alone. The objective of this study was to investigate the effectiveness of Profhilo® Figura body cream to moisturize and improve the elasticity and firmness of the skin. Skin tolerability and participant satisfaction with the cream were also assessed.

Participants and Methods

Eligibility criteria

Eligible participants were females aged between 30 and 65 years with a tendency to have dry skin and mild-to-moderate skin atony (characterized by loss of elasticity) in their leg area. Contraindications to the treatment (according to the Instructions for Use of the product) include a history of atopy, skin hypersensitivity, or allergy/sensitivity to cosmetics, toiletries, and solar or topical medications. Pregnant or lactating women were also excluded from the study.

Treatment and outcomes from the study

This study was performed in agreement with the Declaration of Helsinki and registered in the ISRCTN registry with study ID ISRCTN13271825. Participants provided their informed consent before study participation.

Participants applied Profhilo® Figura body cream daily for 28 days on the skin area of their legs. The effectiveness of the Profhilo® Figura body cream was assessed on Day 14 and Day 28 of using the cream by non-invasive bioengineering instrumental techniques to evaluate the moisturization, elasticity, and firmness of the skin. On Day 28, skin tolerability was also clinically assessed by the dermatologist as well as by the participants who also completed a self-assessment questionnaire to evaluate their satisfaction with the product (**Figure 1**).

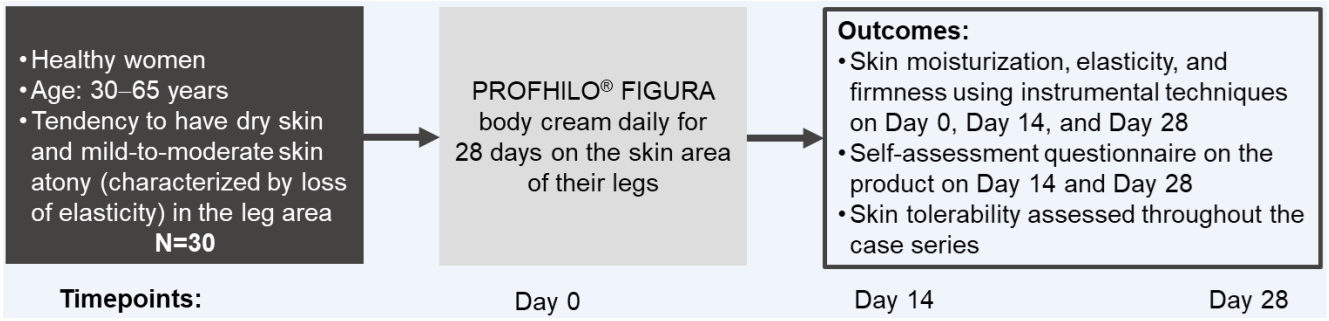


Figure 1: Participants, treatment, and outcomes from the study.

Assessments

Skin moisturization

Skin moisturization was measured using the CORNEOMETER CM 825® (Courage+Khazaka electronic GmbH, Köln, Germany) [14]. Measurement using the CORNEOMETER CM 825® is based on the difference between the dielectric constant of water (81) versus other substances, which mostly have a dielectric constant of less than 7 [14]. The measuring capacitor of the CORNEOMETER CM 825® demonstrates changes in capacitance in line with the sample's moisture content [14]. A glass lamina in the probe head of the device separates two metallic (gold) tracks in the probe head from the skin, preventing current conduction in the skin [14]. During the measurement, an electric scatter field penetrates the first layers of the skin to determine the dielectric constant [14].

Skin elasticity

Skin elasticity was determined using the Cutometer® MPA 580 (Courage+Khazaka electronic GmbH, Köln, Germany) by the suction method, which involves applying a negative pressure (450 mbar) to deform the skin mechanically [15,16]. When the negative pressure is formed in the device, the skin is drawn into the probe's aperture for 2 seconds and rereleased after 2 seconds [15,16]. The penetration depth is determined inside the probe by a non-contact optical measuring system consisting of a light source and a light receptor, as well as two prisms on opposite sides that project light from the transmitter to the receptor [15]. The light intensity varies due to the skin's penetration depth [15]. The resistance of the skin to the negative pressure and its ability to return to its original position are displayed as curves of depth of penetration over time [15]. Gross or overall elasticity (R2) and net elasticity (R5) of the skin were measured using this device in this study. An increase in overall elasticity (R2) indicates an improvement in overall skin elasticity, and an increase in net elasticity (R5) indicates enhanced skin elastic components. Gross elasticity (R2) is the ratio, Ua/Uf (where Ua is final retraction and Uf is final deformation), measuring viscous changes (deformation and retraction) in the skin and includes the effects of elasticity of solid components (elastic fibers, etc.) of the skin and viscosity from the liquid content of the skin [17]. Net elasticity (R5) is the ratio, Ur/Ue (where Ur is immediate retraction and Ue is immediate deformation), that measures solid components of the skin instead of viscous changes [17].

Skin firmness

Tape stripping uses the concept of determining product permeation through the stratum corneum after its application to human skin [18]. Adhesive tape strips are used in this procedure to consecutively remove layers of corneocytes to quantitatively measure product content in each layer of stripped skin or calculate the cumulative amount of product present in all the skin strips [18]. Tape stripping is considered a relatively non-invasive technique because of the homeostatic nature of the skin in which the stratum corneum reforms very quickly [18].

Skin cohesivity was indirectly measured by evaluating the protein content of the first layers of the skin (stratum corneum). Using Corneofix® F 20 patches (Courage+Khazaka electronic GmbH, Köln, Germany) [19], samples of the first layers of the stratum corneum were collected from a clean area of the skin using a tape stripping procedure where ten consecutive tape strips were collected under standardized pressure from the same skin area to take serial layers of the stratum corneum. The first, fifth, and ninth tape strips of the ten consecutive strips (Corneofix® F 20 patches) were then used to determine the protein content (cutaneous cohesivity) of the skin to assess the compacting effect of the cosmetic product (i.e., a reduction in keratin and therefore a decrease in the number of proteins [20] that remain adherent to the strip). The Corneofix® F 20 patches were stored at -20°C before biochemical evaluation of protein content using the Lowry method. In the Lowry assay, cuprous (Cu^+) ions complex with proteins under alkaline conditions, catalysing the oxidation of tyrosine and tryptophan residues and causing a reduction in the reagent, Folin–Ciocâlteu, changing its colour from yellow to blue [21,22]. The intensity of this colour is proportional to the protein content [21]. Quantitative determination of protein content uses a calibration curve consisting of increasing concentrations of a known standard, albumin [22]. The lower the protein content on the collected, sequential tape strips, the higher the degree of skin cohesivity [23], which is related to skin firmness [24].

Self-assessment questionnaire

Participants completed self-assessment questionnaires (specifically designed for this study) on Day 14 and Day 28 to rate their satisfaction with the body cream. Specific questions of this questionnaire are detailed in **Supplementary Appendix, Table S1** and **Supplementary Appendix, Table S2**.

Skin tolerability

The occurrence of skin reactions (including erythema, edema, dryness, and desquamation) on treated areas was recorded using a clinical score scale where 0, 1, 2, 3, and 4 represented absence of skin reactions, very slight skin reactions, slight skin reactions, moderate skin reactions, and evident/strong skin reactions, respectively. Feelings of tightness, itchiness, burning, or other sensations post-treatment were also recorded.

Statistical analysis

Skin moisturization, elasticity, and firmness data obtained using instrumental techniques were assessed using the two-way t-test for paired data to compare values for those parameters on Day 14 versus Day 0 and Day 28 versus Day 0. Statistically significant values were determined by p values <0.05. The statistical software used for this analysis was the NCSS 10-PROFESSIONAL, version 10.0.7 (Kaysville, UT, United States).

Results

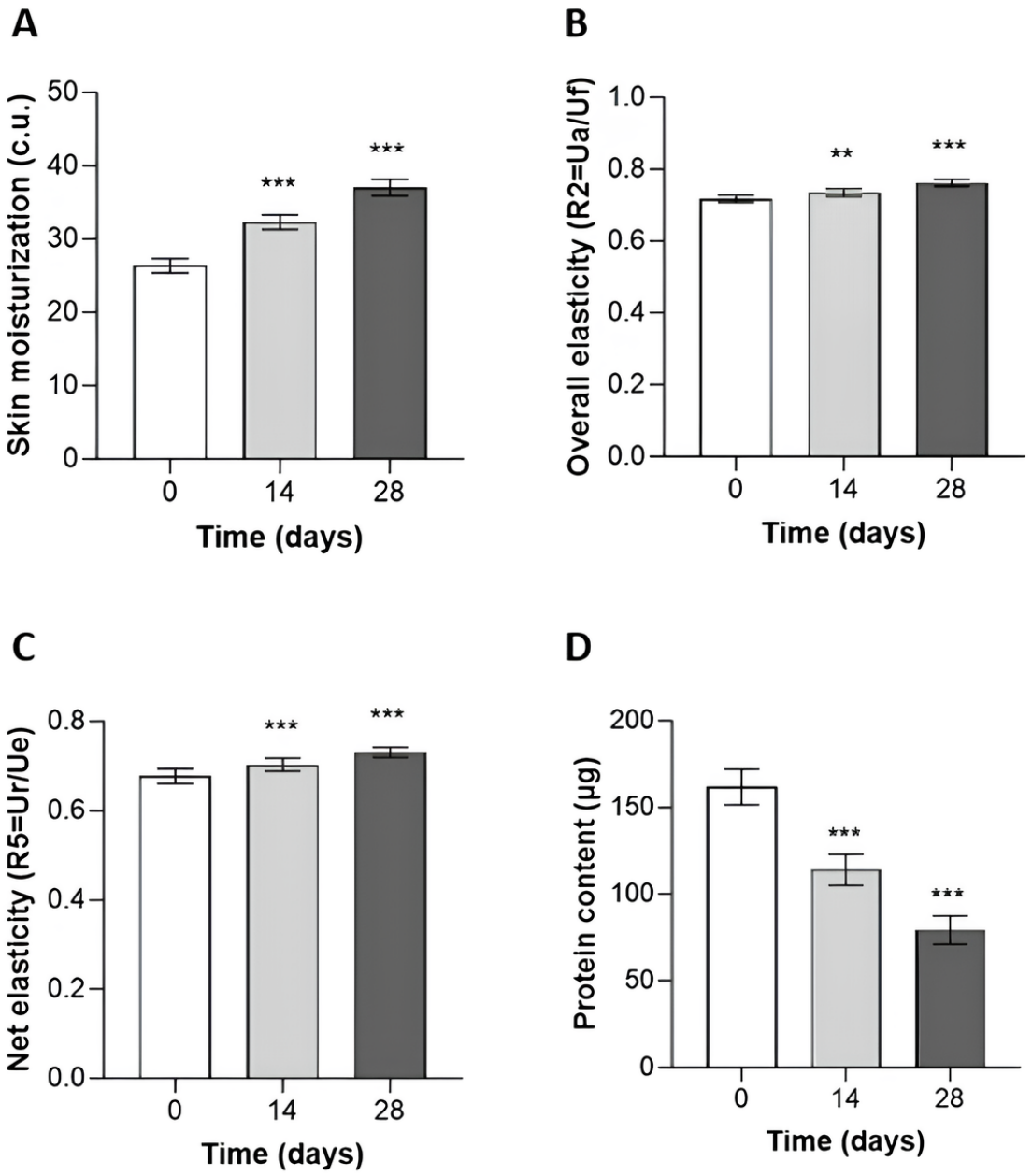
Skin moisturization, elasticity, and firmness

For 30 female participants included in this study, there was a statistically significant increase in mean skin moisturization with daily use of Profhilo® Figura body cream from Day 0 to Day 14 (P<0.0001) and from Day 0 to Day 28 (P<0.0001; **Table 1**; **Figure 2**).

	Mean (SEM)			Mean percentage change vs Day 0 (%)		P-value	
	Day 0	Day 14	Day 28	Day 14 vs Day 0	Day 28 vs Day 0	Day 14 vs Day 0	Day 28 vs Day 0
Skin moisturization	26.37 (0.93)	32.30 (0.99)	37.02 (1.12)	24.2	42.4	<0.0001	<0.0001
Overall elasticity (R2)	0.72 (0.01)	0.74 (0.01)	0.76 (0.01)	2.5%	6.3%	0.0037	<0.0001
Net elasticity (R5)	0.68 (0.02)	0.70 (0.01)	0.73 (0.01)	4.2%	8.9%	<0.0001	<0.0001
Skin cohesivity (protein content)	161.89 (10.24)	114.05 (8.91)	79.31 (8.17)	-30.0%	-51.6%	<0.0001	<0.0001

P values were assessed using the Two-paired t-test. An increase in skin moisturization indicates an improvement in this parameter. An increase in overall elasticity (R2) indicates an improvement in overall skin elasticity and an increase in net elasticity (R5) indicates an improvement in skin elastic components. A decrease in protein content indicates an improvement in skin cohesivity, which is related to an improvement in skin firmness. SEM, standard error of the mean.

Table 1: Mean (SEM) skin moisturization, overall elasticity (R2), net elasticity (R5), and skin cohesivity (protein content) for 30 female participants as assessed by instrumental techniques over time. Mean percentage changes in those values at Day 14 and Day 28 versus Day 0 are also shown.



Mean and SEM values are shown. *** indicates P<0.0001 and ** indicates P=0.0037, as measured by Two-paired t-test, where the value at Day 14 was compared with that at Day 0 and the value at Day 28 was compared with that at Day 0. An increase in skin moisturization indicates an improvement in this parameter. An increase in overall elasticity (R2) indicates an improvement in overall skin elasticity and an increase in net elasticity (R5) indicates an improvement in skin elastic components. A decrease in protein content indicates an improvement in skin cohesivity, which is related to an improvement in skin firmness. SEM, Standard error of the mean.

Figure 2: Skin moisturization (A), overall elasticity – R2 (B), net elasticity – R5 (C), and protein content (D) measured using instrumental techniques.

The mean percent increase in skin moisturization versus Day 0 was 24.2% on Day 14 and 42.4% on Day 28. Overall elasticity (R2), indicating an improvement in overall skin elasticity, also significantly increased with time (P=0.0037 for Day 14 versus Day 0 and P<0.0001 for Day 28 versus Day 0). The mean percent increase in overall elasticity (R2) versus Day 0 was 2.5% on Day 14 and 6.3% on Day 28. Similarly, net elasticity (R5), indicating an improvement in skin elastic components, significantly improved on Day 14 (a 4.2% increase) and Day 28 (an 8.9% increase) versus Day 0 (P<0.0001 each; **Table 1**; **Figure 2**).

There was a decrease in protein content removed by sequential tape strips with daily use of the Profhilo® Figura body cream on Day 14 (mean percent change, -30.0%) and Day 28 (mean percent change, -51.6%) compared with Day 0 (P<0.0001 each; **Table 1**; **Figure 2**), indicating an improvement in skin cohesivity and firmness.

Findings from the self-assessment questionnaire

The proportion of participants who rated specific questions in the self-assessment questionnaire after daily use of the product on Day 14 and Day 28 are shown in **Supplementary Appendix, Table S1** and **Supplementary Appendix, Table S2**. Most participants (>70%) gave positive responses to all questions of the questionnaire (**Figure 3**).

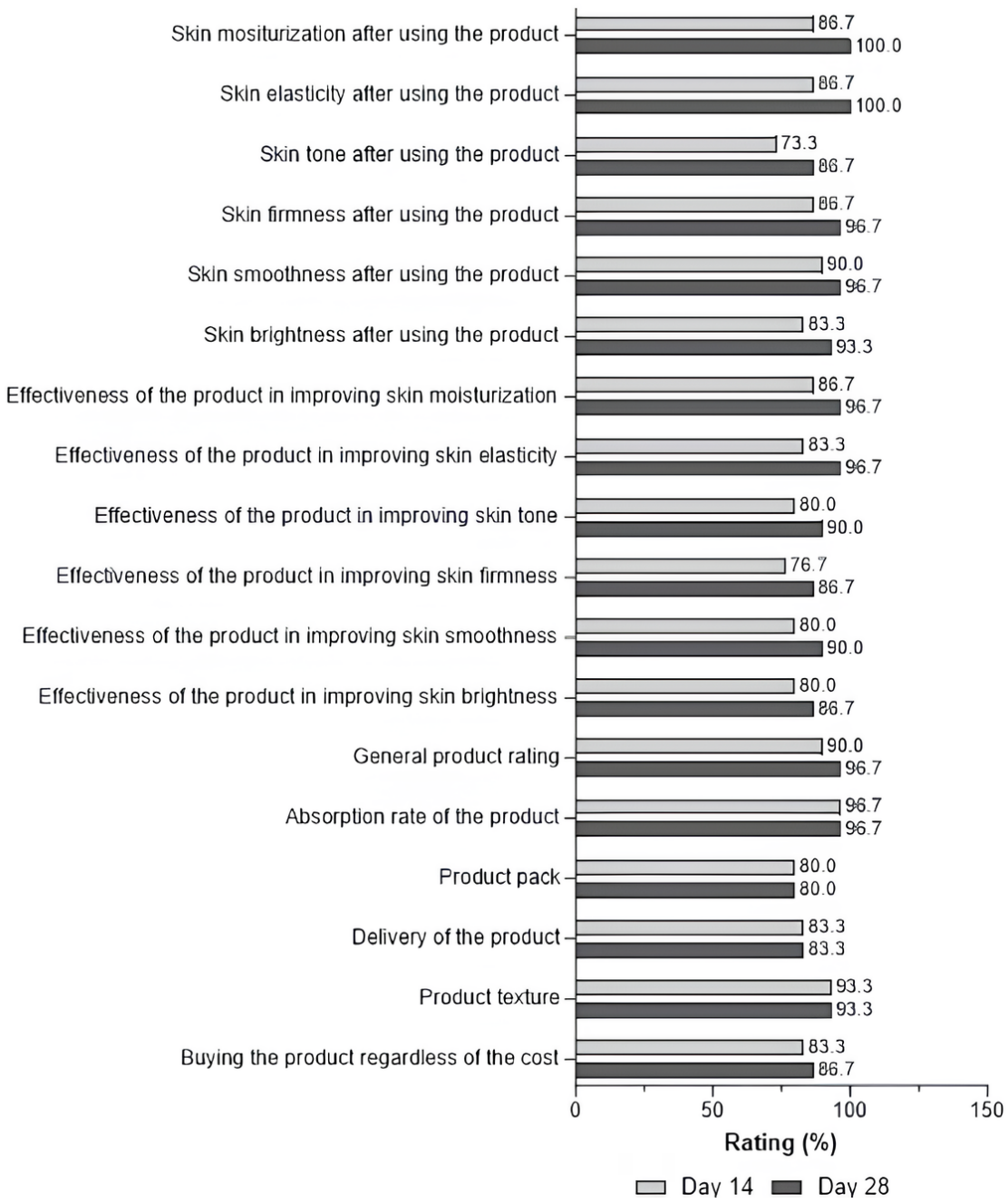


Figure 3: The proportion of positive answers given to questions in a self-assessment questionnaire to rate the product and its effectiveness after using the product.

Following daily use of the Profhilo® Figura body cream, the proportion of positive answers increased from Day 14 to Day 28 for participant skin moisturization (86.7% to 100.0%), elasticity (86.7% to 100.0%), tone (73.3% to 86.7%), firmness (86.7% to 96.7%), smoothness (90.0% to 96.7%), and brightness (83.3% to 93.3%). The proportion of positive answers also increased from Day 14 to Day 28 for the effectiveness of the product in improving skin moisturization (86.7% to 96.7%), elasticity (83.3% to 96.7%), skin tone (80.0% to 90.0%), firmness (76.7% to 86.7%), smoothness (80.0% to 90.0%), and brightness (76.7% to 86.7%), as well as the general rating for the product (90.0% to 96.7%) and whether the participants thought that they would buy the product irrespective of its cost (83.3% to 86.7%). Although there was no change in the proportion of positive answers given on Day 14 and Day 28 for the absorption rate of the product, product pack, delivery of the product, and product texture, the percentage of positive answers remained high (≥80%).

Skin tolerability

The product was well tolerated by all participants, with no adverse events reported.

Discussion

In this study to investigate the effectiveness of daily use of Profhilo® Figura body cream to moisturize and improve the elasticity and firmness of the skin, there was an improvement in all these parameters, as measured using quantitative techniques. There was a statistically significant increase in mean skin moisturization (P<0.0001 for Day 14 and Day 28 versus Day 0), overall elasticity (R2; P=0.0037 for Day 14 versus Day 0 and P<0.0001 for Day 28 versus Day 0), and net elasticity (R5; P<0.0001 for Day 14 and Day 28 versus Day 0). In addition, there was a statistically significant decrease in protein content (P<0.0001 for Day 14 and Day 28 versus Day 0), indicating improved skin cohesivity, which is related to improved skin firmness. On Day 28, compared with Day 0, there was a 42.4% increase in skin moisturization, a 6.3% increase in overall skin elasticity, an 8.9% increase in skin net elasticity, and a 51.6% decrease in protein content removed by sequential tape strips. Furthermore, in a qualitative analysis, most participants (>70%) responded positively to all questions of a questionnaire specifically designed to assess participant satisfaction with the product and its effectiveness. On Day 28, smoother and firmer skin was reported by 96.7% of participants, brighter skin was reported by 93.3% of participants, and increased moisturization and elasticity were reported by 100.0% of participants. Notably, the product was well tolerated by all participants with no reported adverse events following the use of Profhilo® Figura body cream.

The positive results of this study are likely due to the properties of Profhilo® Figura body cream. The cream contains low- and high-molecular-weight hyaluronic acids in high concentrations [9]. Hyaluronic acid has a strong water-binding potential and has been used as

a cosmeceutical for the treatment of a wide range of skin problems, including wrinkles, nasolabial folds, anti-aging, skin augmentation, skin hydration, and collagen stimulator [8]. In a study of 0.1% w/w hyaluronic acid cream of different molecular weights (50,130, 300, 800, and 2000 kDa) applied twice daily for 60 days on periocular wrinkles of 76 females aged between 30 and 60 years, a significant improvement in skin hydration and elasticity was observed [8,25]. In addition, low-molecular-weight hyaluronic acid was associated with significantly reduced wrinkle depth [8,25]. In another study investigating a topical low-molecular weight hyaluronic acid lotion, serum, and cream in 33 women (average age, 45.2 years), eight weeks of treatment in the periorbital region resulted in a significant improvement in moisturizing effect after use of the product range was observed, as well as significantly improved skin elasticity [8,26]. In that study, a significant decrease in the depth of wrinkles (≤40%), and a significant improvement in skin hydration (≤96%) and skin firmness and elasticity (≤55%) were observed following eight weeks of treatment [26]. In another study in 20 participants investigating the daily use of four different hyaluronic acid creams for three months, a significant 10-20% reduction in the depth of perioral and orbital wrinkles as well as a significant 13%-30% increase in skin tightness was observed in all groups [8]. However, minimal changes in skin elasticity were observed only with some of the hyaluronic acid-based creams tested [8].

Another component of Profhilo® Figura body cream is Matrixyl® 3000 [10]. Matrixyl® 3000 comprises a combination of Pal-GHK (palmitoyl tripeptide-1) and Pal-GQPR (palmitoyl tetrapeptide-7) and is available in the cosmetic market as an anti-wrinkle serum [27,28]. In a study of 24 volunteers who applied a cream containing Matrixyl® 3000 on one-half of their face and a placebo cream on the other half of their face twice a day for 56 days, Matrixyl® 3000 reduced skin roughness by 14%, the area occupied by deep wrinkles by 44% and the density of wrinkles by 37%, and improved skin tone by 15% [28,29].

A limitation of our investigation includes the fact that it was performed on a small sample size of participants. However, a strength of this study is the use of quantitative, instrumental techniques to assess the skin's moisturization, elasticity, and firmness. Overall, findings from this study suggest that the daily use of Profhilo® Figura body cream for 28 days on the leg area led to an improvement in the moisturization, elasticity, and firmness of the skin in healthy women with a tendency to have dry skin and mild-to-moderate atony. In addition, a participant satisfaction questionnaire complimented the results of the instrumental techniques, with all participants reporting improved moisturization and elasticity and most volunteers noting that they had firmer skin after using the product. On Day 28, smoother, firmer, and brighter skin were reported by most participants and increased moisturization and elasticity were reported by all participants. There were no reported adverse events in the study. In conclusion, our data demonstrate that Profhilo® Figura body cream effectively improves skin moisturization, elasticity, and firmness without adverse events in healthy women with a tendency for dry skin and mild-to-moderate atony.

Supplementary Appendix

Supplementary table S1: Proportion of participants rated the specific questions on the self-assessment questionnaire on Day 14 after daily use of the product.

Supplementary table S2: Proportion of participants rated the specific questions on the self-assessment questionnaire on Day 28 after daily use of the product.

Author contributions

Conceptualization, G.R.; Methodology, G.R..; Validation, G.R.; Investigation, G.R.; Data curation, G.R.; Writing original draft preparation, G.R.; Writing review and editing, G.R, L.T., C.B., and G.B.; Visualization, G.R, L.T., C.B., and G.B.; Supervision, G.R, L.T., C.B., and G.B. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board statement

The study was conducted according to the guidelines of the Declaration of Helsinki.

Informed consent statement

Participants provided their informed consent before study participation.

Data availability statement

The author confirms that the data supporting the findings of this study are available within the article. Further data can be provided upon reasonable request.

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Conflict of interest statement

G.R. and V.N. declares no conflict of interest. L.T., C.B. and G.B. are currently employees of IBSA Farmaceutici srl, Italy.

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Supplementary Appendix

Question number	Question	Dehydrated	Not very hydrated	Fairly hydrated	Well hydrated
1	How do you rate your skin moisturization?	3.3	10	50	36.7
		Not entirely*	Not very*	Fairly*	Very*
2	How do you rate your skin elasticity?	0	13.3	53.3	33.3
3	How do you rate your skin tone?	0	26.7	46.7	26.7
4	How do you rate your skin firmness?	0	13.3	66.7	20
5	How do you rate your skin smoothness?	3.3	6.7	56.7	33.3
6	How do you rate your skin brightness?	3.3	13.3	63.3	20
		Poor	Sufficient	Good	Excellent
7	How do you rate the effectiveness of the product in improving your skin moisturization?	3.3	10	56.7	30
8	How do you rate the effectiveness of the product in improving your skin elasticity?	3.3	13.3	46.7	36.7
9	How do you rate the effectiveness of the product in improving your skin tone?	3.3	16.7	50	30
10	How do you rate the effectiveness of the product in improving your skin firmness?	3.3	20	60	16.7
11	How do you rate the effectiveness of the product in improving your skin smoothness?	3.3	16.7	60	20
12	How do you rate the effectiveness of the product in improving your skin brightness?	3.3	16.7	70	10
13	In general, how do you rate the product?	3.3	6.7	60	30
		Very slow	Slow	Fast	Very fast
14	How do you rate the absorption rate of the product?	0	3.3	73.3	23.3
		I do not like it	I am indifferent about it	It is good	It is excellent
15	How do you rate the product pack?	6.7	13.3	56.7	23.3
16	How do you rate the delivery of the product?	10	6.7	60	23.3
17	How do you rate the product texture?	3.3	3.3	66.7	26.7

		Yes	No		
18	Would you buy the product regardless of the cost?	83.3	16.7		

Table S1: Proportion of participants rated the specific questions on the self-assessment questionnaire on Day 14 after daily use of the product. *Elastic/toned/compact/smooth/bright.

Question number	Question	Dehydrated	Not very hydrated	Fairly hydrated	Well hydrated
1	How do you rate your skin moisturization?	0	0	46.7	53.3
		Not entirely*	Not very*	Fairly*	Very*
2	How do you rate your skin elasticity?	0	0	53.3	46.7
3	How do you rate your skin tone?	0	13.3	56.7	30
4	How do you rate your skin firmness?	0	3.3	70	26.7
5	How do you rate your skin smoothness?	0	3.3	53.3	743.3
6	How do you rate your skin brightness?	0	6.7	66.7	26.7
		Poor	Sufficient	Good	Excellent
7	How do you rate the effectiveness of the product in improving your skin moisturization?	0	3.3	63.3	33.3
8	How do you rate the effectiveness of the product in improving your skin elasticity?	0	3.3	60	36.7
9	How do you rate the effectiveness of the product in improving your skin tone?	0	10	56.7	33.3
10	How do you rate the effectiveness of the product in improving your skin firmness?	0	13.3	63.3	23.3
11	How do you rate the effectiveness of the product in improving your skin smoothness?	0	10	60	30
12	How do you rate the effectiveness of the product in improving your skin brightness?	0	13.3	60	26.7
13	In general, how do you rate the product?	0	3.3	60	36.7

		Very slow	Slow	Fast	Very fast
14	How do you rate the absorption rate of the product?	0	3.3	73.3	23.3
		I do not like it	I am indifferent about it	It is good	It is excellent
15	How do you rate the product pack?	10	10	50	30
16	How do you rate the delivery of the product?	13.3	3.3	46.7	36.7
17	How do you rate the product texture?	0	6.7	53.3	40
		Yes	No		
18	Would you buy the product regardless of the cost?	86.7	13.3		

Table S2: Proportion of participants rated the specific questions on the self-assessment questionnaire on Day 28 after daily use of the