

A Nutritional Supplement Formulated with Peptides, Lipids, Collagen and Hyaluronic Acid Optimizes Key Aspects of Physical Appearance in Nails, Hair and Skin

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Abstract

Symptoms of dryness in the skin, hair and nails increase with age, and with certain medical, environmental and physiologic conditions—affecting a significant portion of the population. Topical therapies can be limited by the skin's inherent barrier function, and simply ingesting a balanced and varied diet may not be enough to prevent nutritional deficiencies.

The authors describe two double-blinded, placebo vs. control clinical studies, including one 60-week cross-over study, on the effect of a nutritional supplement formulation on hair, skin, and nails. The supplement formulation, that contained peptides, lipids, hyaluronic acid, and collagen as its active ingredients, was given to participants in 20-gram oral doses once daily, and the results show the magnitude of its effectiveness.

The data showed statistically significant improvement in nail cracking, nail brittleness, hair dullness, hair dryness, and nail softness after 8 weeks. There was a significant decrease in skin dryness over the same period. The cross-over study showed that those receiving the supplement had statistically significant benefits for as long as 52 weeks, then when the cross-over was performed and the supplement was withdrawn, there was a significant decline in benefits. Of those subjects with more severe symptoms at the outset, 95% saw significant improvement in hair dryness and dullness, 85% in nail splitting and peeling, and 65% in nail hardness. The authors conclude that this nutritional supplementation should be considered as an important, effective and perhaps necessary component of complete hair, nail and skin care regimens.

Keywords: Absorption; Aging; Beauty; Nutrition; Physiognomy; Supplementation

Introduction

Symptoms of dryness in the skin, hair and nails increase with age and with certain medical, environmental and physiologic conditions—affecting up to 40% of people over 18 years old [1-5]. Topical therapies can be limited by the skin's inherent barrier function, and simply ingesting a balanced and varied diet may not be enough to prevent nutritional deficiencies.

According to the Center for Disease Control, nutritional deficiencies could impact as many as 33% of the population as a result of altered gastrointestinal absorption [6].

In as early as 1968, Bender noted the effect of age on absorption, [7] and others noted an increase in amino acids following graded dietary intake of whey protein [8]. A deficiency in dietary protein was determined to cause reduced cellular turnover, decreased DNA repair, fragmentation of collagen and elastin, and the resultant skin wrinkling and laxity [9]. In addition, dietary proteins were noted to control lipid metabolism [10] and affect intercellular water retention in the stratum corneum [11]. As a result, a decrease in the level of skin lipids was noted to cause skin dryness [9].

Hydrolyzed collagen was shown to stimulate chondrocytes in vitro, [12] in human serum, [13] and in animal models [14-16]. Additionally, dietary supplementation with hyaluronic acid was shown to increase skin moisture content and smoothness, and decrease wrinkles [17].

Beauty nutritional supplementation in a powder formulation containing peptides and lipids—the building blocks necessary for

healthy skin, hair and nails—as well as hyaluronic acid and collagen, was clinically evaluated to determine its benefits for the skin, hair and nails.

Materials and Methods

Inclusion/Exclusion criteria

A total of 54 women were selected for two trials of the supplement formula, one lasting 8 weeks, the other 60 weeks. Ages of study participants ranged from 26 to 68 years old (mean=49). To qualify for participation, each individual was required to exhibit one or more **severe or moderately-severe** skin, hair or nail **problem in one or more areas** (dullness, dryness, brittleness, unmanageability of the hair; dryness, cracking, breaking and splitting of the nails; and, dryness, roughness, cracking, peeling and scaling of the skin), or **mild to moderate problem in two or more areas**, where problem severity was rated as follows: 0=none; 1-2=mild; 3-4=mild-to-moderate; 5-6=moderate; 7-8=moderately-severe; 9-10=severe.

Precluded from the study was anyone with a dermatological

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diagnosis of skin, nail or hair disorder, anyone pregnant, or anyone with an allergy to soy or milk products. Participants were restricted from using additional topical or medically prescribed hair, skin or nail products during the trial period with the exception of over-the-counter, non-medicated shampoo and conditioner and non-salicylated or glycolated cleanser. Participants were also restricted from using additional nutritional supplements; any topical hair strengthening and/or hair growth products; and topical and/or internal nail products. All patients were instructed to report any deviation from the above restrictions, as well as any weight loss or illness during the trial period.

Blinding and dosing

Each of the 54 participants meeting the inclusion criteria was randomly assigned into either a placebo or active group for one of the two studies. Both the 8-week study and the 60 week cross-over study were double-blinded studies. In the 8-week study, participants were randomized at a ratio of 2:1, with double the number of participants assigned to the active group.

Active and placebo products were independently labeled by subject number, so that neither the investigator nor the subject knew which subjects were getting which test materials. Both active and placebo powders were packaged in identical 1-pound cans, with aluminum lids and aluminum protected, cardboard sides. Each can had a pull-tab to open the can and a plastic lid to close it. Each can contained a pre-calibrated scoop to measure the 20-gram daily dose.

(1) Active=Protein/Oil in a Carbohydrate containing vehicle. The formula contained safflower and canola oils, both unsaturated, as the lipid sources; hydrolyzed soy, whey protein concentrate and collagen as the protein sources; and maltodextrins as the carbohydrate sources. The powder was flavored with vanilla and off-white in color. There were approximately 5 grams of lipid and 5 grams of protein in each 20-gram dose. Additional ingredients included calcium, lecithin, magnesium, vitamin E, zinc, copper, manganese, biotin and riboflavin.

(2) Placebo=The Carbohydrate vehicle alone was matched to the Active Protein/Oil/Carbohydrate powder in color and flavor.

Additional ingredients included calcium, lecithin, magnesium, vitamin E, zinc, copper, manganese, biotin and riboflavin.

Each participant was instructed to take 20 grams of powder every morning before breakfast, 7 days each week, by filling the provided 20 gram scoop with the respective powder, dispersing it in 3-4 ounces of water, and then swallowing the dispersion all at once.

Evaluation schedule

In the 8-week study, there were 34 participants with 23 randomly placed into the active group, and 11 in the placebo group. Evaluations were performed at Baseline and at weeks 3, 4, 6 and 8.

In the 60-week double-blinded cross-over study, there were 20 participants enrolled with 10 randomly placed in the active group, and 10 in the placebo group. Evaluations were performed at Baseline and at week 4, 8, 14, 20, 26, 34, 38, 44, 52, and 60. 8 of the 10 in the active group completed the study as two were relocated for work. In this cross-over study, one group of 10 was given active for 52 weeks, and then switched to placebo for an additional 8 weeks. The other group of 10 was given placebo for 52 weeks, and then switched to active for an additional 8 weeks.

Rating

The skin, hair and nails of each participant were evaluated on each rating day by two trained clinical investigators: Elias Packman, Sc.D., Professor of Pharmacology, Philadelphia College of Pharmacy and Science, and Ruth Jeffkin, RN, of the Institute for Applied Pharmaceutical Research, Limited.

Clinical investigators rated 6 symptoms: dullness and dryness of the hair; softness, cracking and brittleness of the nails; and dryness of the skin. They used a 10-point rating scale where 0=none; 1-2=mild; 3-4=mild-to-moderate; 5-6=moderate; 7-8=moderately-severe; 9-10=severe (Figure 1).

Separately, all participants rated themselves using the same rating scale. Neither the investigators nor the participants knew the other's score. In cases of non-concurrence, the lower of the two

	Problem	Scale
Hair	Degree of Dryness	severe (10) to none (0)
	<i>[as this improves, hair becomes perceptually softer]</i>	
	Degree of Dullness	very high (10) to none (0)
		<i>[as this improves, hair has more luster]</i>
Nails	Degree of Softness	very soft (10) to very strong (0)
	<i>[as this improves, nails better resist bending and tearing]</i>	
	Degree of Cracking	severe (10) to none (0)
	<i>[as this improves, number/degree of cracking is reduced]</i>	
		Degree of Brittleness
		severe (10) to none (0)
		<i>[as this improves, nails are flexible/resistant to stress]</i>
Skin	Degree of Dryness	severe (10) to none (0)
	<i>[as this improves, skin becomes softer/smooth]</i>	

Figure 1: Sample 10 Point Rating Scale for Double-Blinded Studies.

ratings was used— i.e., the smaller benefit/change. Both investigators and participants were trained to use the rating scale in Table 1 in a standardized and reproducible fashion using published methods [18-20].

Results

54 participants were enrolled in the studies and 52 participants completed the full trials. No participants were disqualified from the study, but two withdrew from the double-blinded cross-over study when they were relocated for employment purposes.

No significant adverse effects were reported. One participant reported minimal gas and bloating on the first day of product consumption, but there were no other reported incidences by this participant associated with subsequent ingestion, or by any other participant.

8 week study

In the 8-week study, the severity of **nail cracking and brittleness** decreased by 79.1% ($p < .001$) and 80.7% ($p < .001$), respectively, in the active group, while those in the placebo group experienced a respective 62.3% ($p = .001$) and 68.5% ($p = .002$) improvement over the same 8-week time period. **Nail softness, cracking and brittleness**, all statistically and significantly decreased from baseline over the course of 8 weeks, with a corresponding increase in strength. In the active group, the severity of **nail softness** decreased by 43.2% ($p < .001$),

while those in the placebo group experienced only 23.6% ($p = .03$) improvement (Table 1).

Hair dryness and dullness at baseline statistically and significantly decreased in each group over the course of the study, with a corresponding increase in softness and luster. The severity of **dullness** decreased by 48.4% ($p < .001$) in those taking active product, but only 22.7% ($p = .006$) in those taking placebo. The active group experienced a 47.3% ($p < .001$) decrease in the severity of **dryness**, while those in the placebo group experienced only a 17.8% ($p = .013$) improvement over the same 8-week time period.

Skin dryness at baseline decreased in each group over 8 weeks, with a corresponding increase in softness. In the active group, the severity of dryness decreased by 21.7% ($p = .004$) while those in the placebo group experienced a 19.5% ($p = .009$) improvement over the same 8-week time period.

In participants taking active who started with moderately-severe to severe symptoms, 95% ($p < .001$) of those saw significant improvement in hair dryness and dullness within 8 weeks, 85% ($p = .001$) in nail splitting and peeling, 65% ($p < .001$) in nail hardness, and 60% ($p < .004$) in skin dryness. When starting with mild to moderate symptoms, those taking active also saw significant results in hair dryness and dullness and nail splitting, peeling and brittleness, and skin dryness, but to a lesser degree. While improvement was often seen with the placebo, it was to a significantly lesser degree than those improvements seen with the active. We believe that there was a design error in creating the

Nail Cracking	Baseline	Week 3	Week 4	Week 6	Week 8
Active	6.7 ± 3.4	3.8 ± 3.5 (<.001)	2.5 ± 3.2 (<.001)	1.6 ± 2.9 (<.001)	1.4 ± 2.8 (<.001)
(% improvement)		43.3	62.7	76.1	79.1
Placebo	6.9 ± 2.7	3.6 ± 3.4 (.002)	2.9 ± 3.0 (.004)	3.0 ± 3.6 (.001)	2.6 ± 3.6 (.001)
(% improvement)		47.8	58.0	56.5	62.3
Nail Brittleness	Baseline	Week 3	Week 4	Week 6	Week 8
Active	8.3 ± 1.6	4.7 ± 3.0 (<.001)	2.9 ± 3.4 (<.001)	1.6 ± 3.1 (<.001)	1.6 ± 2.7 (<.001)
(% improvement)		43.4	65.1	80.7	80.7
Placebo	7.3 ± 2.0	5.0 ± 2.5 (.008)	3.9 ± 3.1 (.002)	2.6 ± 3.8 (.001)	2.3 ± 3.8 (.002)
(% improvement)		31.5	46.6	64.4	68.5
Nail Softness	Baseline	Week 3	Week 4	Week 6	Week 8
Active	8.1 ± 2.3	6.6 ± 2.3 (<.001)	6.2 ± 2.3 (<.001)	5.2 ± 2.1 (<.001)	4.6 ± 2.1 (<.001)
(% improvement)		18.5	23.5	35.8	43.2
Placebo	7.2 ± 1.8	6.8 ± 1.7 (NS)	6.4 ± 1.9 (.08)	5.4 ± 1.7 (.001)	5.5 ± 2.2 (.03)
(% improvement)		5.6	11.1	25.0	23.6
Hair Dullness	Baseline	Week 3	Week 4	Week 6	Week 8
Active	9.1 ± 1.0	7.5 ± 1.7 (<.001)	6.9 ± 1.8 (<.001)	5.6 ± 2.0 (<.001)	4.7 ± 2.0 (<.001)
(% improvement)		17.6	24.2	35.0	48.4
Placebo	9.7 ± .65	8.7 ± 1.9 (.07)	8.8 ± 1.8 (.08)	7.5 ± 2.6 (.01)	7.5 ± 2.3 (.006)
(% improvement)		10.3	9.3	22.7	22.7
Hair Dryness	Baseline	Week 3	Week 4	Week 6	Week 8
Active	9.1 ± 1.0	6.8 ± 1.7 (<.001)	6.0 ± 1.6 (<.001)	5.3 ± 1.7 (<.001)	4.8 ± 1.7 (<.001)
(% improvement)		25.3	34.1	41.7	47.3
Placebo	9.6 ± .67	8.6 ± 1.9 (.046)	8.3 ± 1.8 (.031)	7.6 ± 2.3 (.014)	7.9 ± 1.8 (.013)
(% improvement)		10.4	13.5	20.7	17.8
Skin Dryness	Baseline	Week 3	Week 4	Week 6	Week 8
Active	6.0 ± 3.1	5.5 ± 2.7 (.05)	5.1 ± 2.3 (.008)	4.8 ± 2.4 (.007)	4.7 ± 2.5 (.004)
(% improvement)		8.3	15.0	20.0	21.7
Placebo	7.7 ± 2.8	7.0 ± 2.5 (NS)	6.8 ± 2.6 (.10)	6.0 ± 3.0 (.003)	6.2 ± 2.6 (.009)
(% improvement)		9.1	11.7	22.1	19.5

Table 1: Effects of Active vs. Placebo (represented as mean scores with standard deviations and p-values) on skin, hair and nails.

Figures above were taken using the 10-point rating scale, wherein severity of the problem increases from 1-10, with 1 being least severe and 10 being most severe.

placebo in that it was not completely inactive. In fact, the carbohydrate vehicle in the placebo likely provided unexpected nutritional benefits (Table 2).

Double-blinded 60-week cross-over study

Tables 3 and 4 pertain to the double-blinded 60-week cross-over study. The participants in the active group received 52 weeks of active and then were switched to placebo for an additional 8 weeks. The participants in the placebo group received 52 weeks of placebo and then were switched to active for an additional 8 weeks.

Table 3 shows that, when starting with moderately-severe to severe symptoms, participants taking active experienced significant improvement in hair dryness and dullness, nail hardness and peeling at various times throughout the course of the 12-month study. After the first 8 weeks of treatment, 80% of participants saw improvement in hair dryness, and 90% saw improvement in both hair dullness and nail peeling. After 6 months of treatment, 88% saw improvement in hair dryness and nail peeling, while 100% saw improvement in hair dullness. After 9 months, 100% of participants saw improvement in **hair dryness, hair dullness, and nail peeling**.

During the course of the 12-month study, at least 75% of participants experienced significant improvement in nail splitting, and at least 50-75% experienced significant improvement in skin dryness.

The effect of the cross-over is noted in Table 4. Those in the active group experienced a reversal of effects in hair dryness and dullness, nail hardness, splitting and peeling when switched to placebo, and those in the former placebo group showed improvement in those areas when switched to active. Since participants were unwilling to refrain from using sunblock during the summer months of the study, evaluation of their skin was only performed for the first nine months. As a result, the effects of cross-over on **skin dryness** could not be made.

While participants in the 60-week cross-over study clearly experienced significant benefits related to hair dryness and dullness, nail hardness, splitting and peeling, and skin dryness when taking active, the amount of improvement represented in Table 4 reflects a cohort with a mixed baseline severity of symptoms. Because inclusion criteria only required participants to have a **severe or moderately-severe** skin, hair or nail problem *in one or more areas* (dullness, dryness, brittleness, unmanageability of the hair; dryness, cracking, breaking and splitting of the nails; and, dryness, roughness, cracking, peeling and scaling of the skin), or **mild to moderate problems in two or more areas**, some

Severity of Initial Symptoms	# of Subjects	Hair Dryness	Hair Dullness	Nail Hardness	Nail Splitting	Nail Peeling	Skin Dryness/Face
Moderately-severe to severe†	10	95%*	95%*	65%*	85%*	85%*	60%**
Mild to moderate	13	44%*	56%*	36%*	80%*	60%*	48%**

Table 2: Percent of subjects (divided by severity of symptoms) who were taking active for 8 weeks, who demonstrated statistically significant improvement (8-week study). (* (p<.001); (p<.004)).

Time of Evaluation	# of Subjects w/Active‡	%Improvement in					
		Hair Dryness	Hair Dullness	Nail Hardness	Nail Splitting	Nail Peeling	Skin Dryness/Face
8 weeks	10	80%	90%	100%	80%	90%	60%
6 months	8	88%	100%	88%	88%	88%	50%
9 months	8	100%	100%	88%	75%	100%	75%
12 months	8	100%	88%	88%	75%	100%	---¶

† To be included in the moderately-severe to severe categories, participants were rated in the 7-10 range initially on a scale similar to the one shown in "Figure 1." A significant change was defined to be a 2-point or greater improvement. ‡ There were 10 participants in the active group and 10 participants in the control group at the start of each study but only 8 participants completed the study as two were relocated for employment reasons.

¶ Skin dryness was only evaluated for 9 months (and no cross-over data is available) because participants were unwilling to refrain from using sunblock during the summer months.

Table 3: Percent of Subjects Taking Active Ingredients with Significant Changes† from Baseline when starting with Moderately-severe to Severe Problems (60-week crossover study).

		Week 4	Week 8	Week 14	Week 20	Week 26	Week 34	Week 38	Week 44	Week 52	Crossover to vehicle + 8 wks
Hair Dryness	A	33	36	41	34*	40†	42†	43†	43†	42†	3†
	P	-5	-5	2*	-3*	5*	6†	6‡	5‡	-1‡	27‡
Hair Dullness	A	33	37	43	43*	37†	44†	42†	39†	38†	14†
	P	10	7	9*	-3*	7*	14†	1‡	-2‡	11‡	35‡
Nail Hardness	A	32	46	47	33*	42†	42†	43†	31†	25†	18†
	P	1	-2	4*	6*	16*	14†	16†	9‡	-1‡	35‡
Nail Splitting	A	74	78	81	74*	67†	88†	71†	72†	54†	39†
	P	-2	7	17*	-6*	7*	16†	17‡	4‡	12‡	95‡
Nail Peeling	A	73	91	84	95*	84†	94†	10†	98†	90†	73†
	P	-4	11	14*	30*	42*	45†	64‡	43‡	43‡	95‡
Skin Dryness	A	20	32	36	20*	23†	36†	¶	¶	¶	¶
	P	-3	-3	4*	13*	20*	14†	¶	¶	¶	¶

Table 4: A Comparison of Active to Placebo: Percent of Improvement From Baseline (60-week crossover study). A=Active; P=Placebo (9 subjects); †(8 subjects); ‡(7 subjects) ¶ Skin dryness was only evaluated for 9 months (and no cross-over data is available) because participants were unwilling to refrain from using sunblock during the summer months.

participants may have had no problem in one or more areas initially.

Discussion

Participants who ingested 20 grams of nutritional supplement daily experienced a significant improvement in their nails, hair and skin. Statistically significant benefits, albeit to a much lesser degree, were also often noted with the placebo. We believe this was because the placebo was not inactive: there were unexpected nutritional benefits from the carbohydrate-containing vehicle in the placebo. Overall, the greatest improvements were seen in participants in the active group, who started out with more severe problems.

The authors believe that nutritional supplementation with a special combination of *dosage bioavailability and amount* (20 grams of powder), *dosing interval* (once daily) and *consumption period* (30 minutes or less) provides benefit over a healthy diet and is critical for a supplement's rapid and intense results. Earlier studies by the authors showed that decreasing the dosage interval (i.e. 10 grams twice/day) or increasing the consumption time (more than 30 minutes) reduced the effectiveness both in terms of magnitude of results and onset of change. The authors theorize that as the dosing interval is increased and/or the consumption time is prolonged, the supplement's absorption is delayed and begins to mimic that which occurs with consumption of a typical diet. Note that pills, tablets and bars may have binders and additives that may delay and/or block absorption, while powder formulations lead to immediate bioavailability. With consumption of a typical diet, nutrients become bioavailable over a 4-6 hour digestion period, and may be "rationed" with only some allotted for synthesis, and the remainder set aside for repair. The authors postulate that nutritional supplementation provides additional bioavailable nutrients over a short interval, allowing the body to jumpstart its own biochemical synthesis pathway to increase moisture retention in the nails (decreasing splitting, dryness, breaking and peeling); to strengthen bonds in hair (reducing breakage and split ends, and increasing luster); and, to enrich the lipid content of the skin (enhancing softness and smoothness).

The implications of the study findings are clear: nutritional supplements with peptides, lipids, collagen and hyaluronic acid provide measurable and significant benefits and are an effective, important and perhaps even necessary component of a comprehensive nail care, hair care and skin care regimen.

The cosmetic and dermatological literature has a great many reports, using qualitative assessments, on the effects of topically applied agents on cosmetic properties of hair skin or nails. But this study is one of the first to report on the effects of orally ingested agents (not topically applied agents) on the important physical properties of the hair, skin and nails. Of further value, is the use here of quantitative scoring, rather than qualitative measures or opinions, to assess the validity of these changes. This report demonstrates, perhaps for the first time qualitatively, that a properly formulated nutritional supplement can have significant, positive, measurable effects upon the physical properties of hair, skin and nails.

Limitations of the study were the small study size, and the likelihood that the carbohydrate vehicle in the placebo may have rendered it active and provided unanticipated nutritional benefits. In addition, it was not possible to fully evaluate the effect of the nutritional supplement on the skin during the summer months of the 60-week crossover study because it proved to be unreasonable to expect participants to refrain from using sunblock during this time.

Possibilities for future research include the evaluation of the

effects of the carbohydrate vehicle alone, and the investigation of supplementation as an effective treatment for those with diseases of the skin, hair and nails. It would be worthwhile to investigate the bioavailability of peptides and lipids in the bloodstream after the ingestion of supplement in attempt to correlate benefits on a biochemical basis, in attempt to uncover the supplement's mechanism of action.

Conclusion

Beauty nutritional supplementation with peptides and lipids—the building blocks necessary for healthy skin, hair and nails —as well as hyaluronic acid and collagen, all in highly bioavailable powder formulation provides rapid, measurably significant, and long-lasting results. As a result, it should be considered a critical component of a comprehensive hair, nail and skin care regimen.

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Author Disclosure Statement

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