Effect of a nutritional supplement on hair loss in women

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Summary

Background Female pattern hair loss is a frequent and distressing condition.

Aim To evaluate *vs.* control, the effects on hair loss of a 6-month supplementation with specific omega 3&6 and antioxidants.

Methods One hundred and twenty healthy female subjects participated in this 6-month, randomized, comparative study. The primary endpoint was the change in hair density evaluated on standardized photographs. Secondary endpoints included changes in telogen hair percentage and diameter distribution of anagen hair (>40 μm *vs.* ≤40 μm) measured by trichogram. Overall changes in hair density and diameter were also measured by trichometer and by subjects' self-assessment.

Results After 6 months of treatment, photograph assessment demonstrated a superior improvement in the supplemented group ($P < 0.001$). The telogen hair percentage was significantly ($P < 0.001$) reduced in the supplemented group. The proportion of nonvellus anagen hair (>40 μm) increased compared to the control group. The trichometer index increased in the supplemented group, while it decreased in the control group. A large majority of supplemented subjects reported a reduction in hair loss (89.9% of subjects at 6 months), as well as an improvement in hair diameter (86.1%) and hair density (87.3%).

Conclusion A 6-month supplementation with omega 3&6 and antioxidants acts efficiently against hair loss in improving hair density and reducing the telogen percentage and the proportion of miniaturized anagen hair. Objectively measured improvements were confirmed by the subjects' perception of efficacy.

Keywords: female pattern hair loss, hair condition, nutritional supplement, omega 3&6, antioxidants

Introduction

Female pattern hair loss (FPHL) is a broad term for the decrease in central scalp density that is frequently observed after puberty in females.[1] FPHL is character- ized by a diffuse reduction in hair density which mainly affects the crown and the frontal scalp. Although FPHL has no serious health consequences, it is distressing and has been reported to affect up to 50% of women over 50.[2,3]

Female pattern hair loss is a complex process with a poorly understood etiology that has been described as an accelerated aging process in the course of which the environment of hair follicles is modified by heredi- tary, inflammatory, hormonal, or vascular factors.[4–6]

This process leads to an alteration of the hair cycle, with a shortening of the anagen phase, a lengthening of the latency period, and a miniaturization of the hair shaft turning from terminal into velluslike hair.[1,7] FPHL is often precipitated and exacerbated by conditions that can induce telogen effluvium including drugs, acute stress, weight loss, and partum.[8]

The only current pharmacologic therapeutic option for the treatment of FPHL is topical minoxidil,[9] but its mode of action is not well understood.[10] Some but not all FPHL-affected women respond to anti-androgens or 5α-reductase inhibitors. This indicates an androgen-related etiology in at least several cases, but the precise role of androgens in FPHL still remains to be explored.[1]

There is no doubt that nutrition influences hair loss and hair condition, as illustrated by the hair problems observed in disorders caused by severe malnutrition, such as *dermatitis enteropathica*, kwashiorkor, anemia, anorexia nervosa, or bulimia.[11,12]

Vitamins, minerals, and other nutrients are frequently used in a large range of products claiming to be efficient against hair loss.[12] However, data from prospective intervention studies on the role of nutrition in general and nutritional supplements in particular in the pathogenesis of FPHL remain scarce.[9]

The purpose of this comparative study was to evaluate *vs.* a nonsupplemented control group the efficacy of a nutritional supplement combining specific omega 3&6 from fish and blackcurrant seed oils with antioxidants (lycopene, vitamin C, and vitamin E) in improving hair loss and hair characteristics (volume, shine, softness).

Material and methods

Cohort and study design

This 6-month, comparative, randomized, expert-blinded study was conducted from January to September 2012 at one site in Italy. The aim was to evaluate the efficacy of a nutritional supplement on hair loss and hair condition *vs.* control.

A total of 120 healthy female volunteers aged 18–65 years, with a body mass index (BMI) between 18 and 27 kg/m^2 and presenting a stage I hair loss according to the Ludwig scale, were recruited after providing written informed consent. Volunteers presenting telogen effluvium (telogen rate >30%) or any confirmed or suspected condition or pathology that, in the opinion of the investigator, might induce hair disorders or interfere with the results of the study (such as iron, zinc, and/or B6 vitamin deficiencies, hypo- or hyper-thyroidism, metabolism, or lipid absorption disorders) were excluded. Furthermore, subjects that had recently modified their diet or used any product (topical or systemic) known to have an impact on hair or scalp were also excluded, along with pregnant or nursing women or women in the immediate postpartum period (6 months).

Women meeting the inclusion criteria were randomly assigned either to the nutritional supplement group (n = 80 subjects, of which 40 premenopausal and 40 postmenopausal) or to the control group (n = 40 subjects, of which 20 premenopausal and 20 postmenopausal). Supplemented subjects received a nutritional supplement providing a daily dose of 460 mg fish oil, 460 mg blackcurrant seed oil, 5 mg Vitamin E, 30 mg Vitamin C, and 1 mg Lycopene for 6 months. Control subjects did not receive any product.

Volunteers were asked not to modify their nutritional and hairstyling habits during the entire duration of the study. They were further asked not to use any topical or oral product or dietary supplementation known to reduce hair loss and improve hair condition other than the investigational product. Additionally, each participant was provided with a neutral shampoo (Kerium, La Roche Posay, France) to be used every other day. Hair bleaching or perms were not allowed.

Evaluation procedures

The primary efficacy measure for this trial was the change in hair density after 6 months, evaluated from global photographs. Standardized photographs of a vertex view of the whole scalp, with hair parted in the center and combed away (Fig. 1), were taken at the beginning and at the end of the study (i.e., after 6 months). Pairs of photographs of each subject were examined by an independent expert, following a confirmed procedure[13] by grading the change in hair density using a 7-point scale (3: greatly increased, 2: moderately increased, 1: slightly increased, 0: no change, −1: slightly decreased, −2: moderately decreased or −3: greatly decreased).

The same photographs and grading scale were also used for the subject self-assessment.

The trichogram technique[14] was used to study hair loss and hair diameter distribution. About 50 hairs were plucked 2 cm off the frontal line and 2 cm off the midline to avoid the risk of a transitory small spot of alopecia in women parting their hair at the midline. Telogen and anagen proportions were defined as

Figure 1 Global photographs of subjects #115 (above), #91 (center), and #35 (below) at baseline (left) and after 6 months of supplementation (right).

the percentage of plucked hair in the telogen and anagen phases, respectively. Anagen hairs were divided into two categories based on diameter (nonvellus > 40 μm *vs.* "velluslike" or miniaturized ≤40 μm). Measurements were made at baseline and after 6 months.

A trichometer, measuring the cross-sectional area of a hair bundle (trichometer index),[15] was used to estimate indirectly the hair density and diameter at baseline and after 6 months.

A self-assessment questionnaire focusing on hair loss, hair density, and hair shaft condition (hair diameter, shiny appearance, volume, and softness) was given to all subjects after 3 and 6 months. Further questions concerning overall satisfaction with the treatment were put to the supplemented subjects.

Statistical analysis

All statistical analyses were performed on the intent-to-treat population. Two-sided statistical tests were conducted with a significance level of 5%.

Intergroup comparison of the subjects' baseline characteristics was analyzed using Student's *t*-test. Intergroup comparisons of qualitative variables (scores of pair photograph comparisons and questionnaires) were analyzed using Chi-square or Fisher's exact test. Between-group differences of continuous variables (trichogram values and trichometer index) were analyzed by covariance analysis (ANCOVA) with group as a fixed effect and baseline values as covariate. Paired *t*-tests were used to compare mean values after 3 and 6 months with baseline values within each of the two groups (intragroup analysis).

Results

Demography

A total of 120 women, 60 premenopausal and 60 postmenopausal, were enrolled in the study. Two subjects withdrew their consent for personal reasons, one subject before the 3 months visit and the other, who also took prohibited concomitant medication, during the 3 months visit. Therefore, the intent-to-treat population consisted of 118 women: 79 in the supplemented group (of which 40 premenopausal and 39 postmenopausal) and 39 in the control group (of which 19 premenopausal and 20 postmenopausal). At baseline, both groups were well matched regarding age, BMI, telogen percentage, and trichometer index (Table 1).

Efficacy

Global photograph review

Photograph review showed a statistically significant difference between the supplemented group and the control group ($P < 0.001$; Table 2). After 6 months, 62% of supplemented subjects had an increased hair

Table 1 Baseline characteristics of women included in the study

	Supplement group	Control group
N	79	39
Age (years, mean ± SD)	48.6 ± 11.2	46.0 ± 14.9
BMI (kg/m², mean ± SD)	22.6 ± 2.6	22.2 ± 2.6
Telogen hair (%, mean ± SD)	20.0 ± 4.1	21.1 ± 3.4
Trichometer index (arbitrary unit ± SD)	75.71 ± 16.56	78.01 ± 16.95

Table 2 Change in hair density after 6 months evaluated from photographs by the expert

	Supplement group* N = 79 (%)	Control group N = 39 (%)
−3: greatly decreased	0	0
−2: moderately decreased	0	5.1
−1: slightly decreased	5.1	23.1
0: no change	32.9	43.6
1: slightly increased	32.9	28.2
2: moderately increased	27.8	0
3: greatly increased	1.3	0

*Indicates a statistically significant distribution between the supplemented group and the control group, $P < 0.001$.

density compared to only 28.2% of subjects in the control group.

Hair density improvement grading by the subjects showed positive results and was significantly better in the supplemented group than in the control group ($P < 0.001$), confirming the clinical results. After 6 months, 88.6% of women in the supplemented group observed an increased hair density on photographs of their scalp: a slight increase for 13.9%, a moderate increase for 45.6%, and a large increase for 29.1%. In the control group, only 51.3% of women observed an increase.

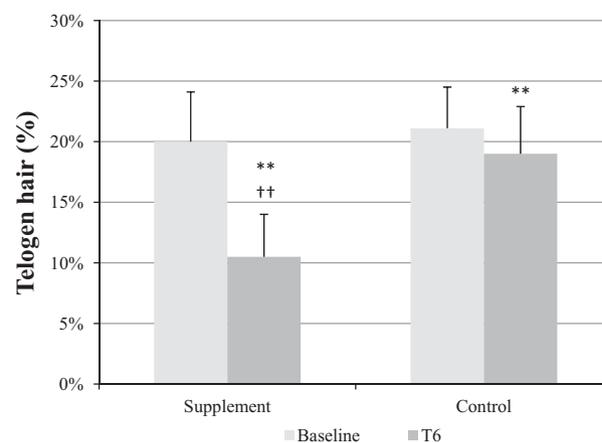Representative photographs of supplemented subjects are shown in Figure 1.

Figure 2 Telogen hair proportion (% of plucked hair) at baseline and after 6 months. **Indicates a statistically significant change compared to baseline, $P < 0.001$. ††Indicates the statistically significant greater change from baseline in the supplemented group compared to the change from baseline in the control group, $P < 0.001$.

Telogen hair
Although the percentage of telogen hair decreased in both groups during the study, the decrease was significantly more marked ($P < 0.001$) in the supplemented group (Fig. 2).

Diameter diversity of anagen hair
The proportion of nonvellus anagen hair (>40 μm in diameter), representing 79.7% of the anagen hair at baseline in the supplemented group, increased significantly ($P < 0.001$) after 6 months of supplementation reaching 87.7%. There was no change in the control group (81.5 % of anagen hair at baseline; 81.1% after 6 months).

Trichometer index
After 6 months of supplementation, a statistically significant increase ($P < 0.001$) in the trichometer index was observed, indicating an increase in hair density and thickness. Conversely, the index had decreased in the control group (Table 3).

Subjects' assessment
A reduction in hair loss was reported by a large majority of supplemented subjects after 3 and 6 months. This difference compared to the control group was statistically significant at both visits ($P < 0.001$; Table 4). Furthermore, a larger number of subjects reported an improvement of hair diameter in the supplemented group after 3 ($P < 0.05$) and 6 months ($P < 0.001$; Table 4) compared to the control group. For the other parameters tested (hair density, shiny appearance, hair volume, and hair softness), there was no significant difference between the perception of subjects in the supplemented and the control group at 3 months. After 6 months, there was a statistically significant difference in favor of the supplemented group for all parameters ($P < 0.05$; Table 4).

Table 3 Trichometer index (arbitrary unit, mean ± SD)

	Baseline	After 6 months
Supplement group	75.71 ± 16.56	80.21 ± 17.14*†
Control group	78.01 ± 16.95	75.88 ± 17.55‡

*Indicates a statistically significant change compared to baseline, $P < 0.001$.
†Indicates the statistically significant greater change from baseline in the supplemented group compared to the change from baseline in the control group, $P < 0.001$.
‡Indicates a statistically significant change compared to baseline, $P = 0.002$.

Overall satisfaction and tolerance
Three months after the beginning of supplementation, 85.9% of subjects were satisfied with the overall efficacy of the supplement. After 6 months of use, 92.4% of the subjects were satisfied with this product. The supplement was well tolerated, and no serious adverse events were reported.

Discussion

This study demonstrated a positive effect of a nutritional supplement on the overall scalp coverage through a reduced telogen percentage and reduced perceived hair loss, suggesting an increase in hair density. Furthermore, after 6 months of daily intake, the hair thickened, as demonstrated by the reduced miniaturized hair ratio and the increased perceived diameter. Among the different methods used in this study, pair photograph comparison and trichometer index were best suited to evaluate at the same time the quantitative (number of hairs) and qualitative (diameter, thickness) components of the overall scalp coverage.

Even though subjects in the nonsupplemented control group perceived some improvement in hair loss and hair condition, the difference between both groups was always statistically in favor of the supplemented group. This improvement could be due to either a positive impact of the neutral shampoo all subjects were provided with, or to positive changes caused by being singled out for participation in the study (Hawthorne effect). In the control group, only a slight improvement was observed in the telogen percentage, one of the objectively measured parameters. Although statistically significant compared to baseline, this improvement was inferior to the one measured for the supplemented group ($P < 0.001$) and its clinical significance is questionable. None of the other objective measurements, such as the anagen hair diameter distribution, trichometer index, or pair photograph comparison improved in the control group.

Several studies have highlighted the implication of follicular microinflammation and fibrosis in the pathogenesis of pattern hair loss.[16–19] In addition, there is circumstantial evidence that oxidative stress may be a pivotal mechanism contributing to hair loss.[18] The impact of poor nutrition through impaired vasculature around the hair bulb has also been postulated as a possible cause for hair loss.[5]

The nutritional supplement assessed in this study is a combination of specific omega-3 and omega-6 fatty acids from fish and blackcurrant seed oils, lycopene, vitamin C, and vitamin E. The potential efficacy of

Table 4 Self-assessment questionnaire – % of subjects in agreement (totally agree + agree + slightly agree) with the statement

	After 3 months (%)		After 6 months (%)	
	Control group	Supplement group	Control group	Supplement group
Overall hair loss is decreased	59.0	89.9*	69.2	89.9*
Hair density is improved	56.4	74.7 ns	64.1	87.3†
Hair diameter is improved	36.8	62.0†	33.3	78.5*
Hair shininess is improved	74.4	74.7 ns	66.7	86.1†
Hair volume is improved	59.0	79.7 ns	46.2	85.9*
Hair softness is improved	74.4	74.7 ns	64.1	84.8†

ns: no significant difference between both groups.
*Indicates a statistically significant distribution difference between supplement group and control group, $P < 0.001$.
†Indicates a statistically significant distribution difference between supplement group and control group, $0.001 \leq P < 0.05$.

polyunsaturated fatty acids (PUFAs) on hair loss and hair condition was first suggested by epidemiological data collected within the framework of the SU.VI.MAX cohort (L'Oréal, unpublished data).[20] This work showed a positive impact of a diet rich in omega-3 and omega-6 on sparse hair and hair condition. The main ingredients of the present supplement are fish oil, rich in omega-3 PUFAs (Eicosapentaenoic acid – EPA and Docosahexaenoic – DHA), and blackcurrant seed oil containing the optimal dietary balance of omega-6 (linoleic acid – LA and γ-linoleic acid – GLA) and omega-3 acids (α-linolenic acid – ALA and, to a lesser degree, stearidonic acid – SA). Studies have demonstrated the bioavailability of the PUFAs contained in both oils at the cutaneous level.[21,22] In the skin, these fatty acids could either be incorporated into membranes and thereby play an important role in cell growth and membrane fluidity[23] or be used as precursors of hormonelike molecules such as eicosanoids or hydroxy-FA which are essential regulators of skin physiological functions (i.e., inflammation, platelet aggregation, and vasodilatation or cell proliferation). PUFAs are known for their positive effect on blood circulation,[11] anti-inflammatory properties,[23–26] antioxidant activities,[27,28] and for modulating androgenic metabolism (activity on 5α-reductase).[29] Recent studies show that women with hair loss may have an increased risk of metabolic disease and heart disease.[30] Supplementation with omega 3&6 at an early stage may also help general health in these patients.

In addition to fatty acids, the tested nutritional supplement contains Vitamin C, which has a recognized beneficial impact on the structure of blood vessels,[31] Vitamin E, which presents a synergic antioxidant effect with Vitamin C,[32,33] and lycopene, which also has antioxidant properties.[34]

We are aware that the study design did not allow determining to what extent the observed beneficial effects may be attributed to either of these active ingredients. However, we hold that the present nutritional supplement combines the beneficial effects of each of its ingredients.

Conclusion

Due to the known psychological impact of hair loss, especially in women, solutions to improve scalp coverage are highly sought after. Through objective measurements and subjects' self-perception, this study demonstrated that supplementation with a combination of specific omega 3&6 and antioxidants improves the overall scalp coverage and hair condition. The nutritional supplement provides a new alternative in the treatment of FPHL.

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