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Efficacy and Safety of a Food Supplement Containing L-cystine, *Serenoa repens* Extract and Biotin for Hair Loss in Healthy Males and Females. A Prospective, Randomized, Double-blinded, Controlled Clinical Trial

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Abstract

Background: Hair loss in both men and women can be a psychologically stressful condition. Dietary insufficiency of essential micronutrients has been associated with hair health and hair loss.

Objective: The aim of this clinical trial was to investigate the safety of use and the efficacy of a food supplement containing L-cystine, *Serenoa repens*, *Equisetum* extract, zinc, and vitamins (Lambdapil® Anti Hair Loss capsules, ISDIN, Provençals, Barcelona, Spain) in improving hair loss in both women and men.

Patients/Methods: Men with androgenic alopecia and women with acute telogen effluvium were randomized to receive two capsules per day of the test product or the placebo product during a 6 months treatment period. Hair resistance to pulling and count were measured in women and men, respectively, by pull testing and phototrichogram. The overall hair volume and overall hair appearance were assessed before and after the treatment as were subject's self-assessment *via* a standardized questionnaire.

Results: In women, the number of hairs removed in the pull test decreased earlier for test product treated group over the 6-month period with a significantly greater decrease ($p<0.05$) for the treated group (12.9 at baseline *vs.* 6.5 hairs at 6 M) compared to the placebo group (12.8 at baseline *vs.* 8.8 hairs at 6 M). For men, the anagen/telogen ratio increased in the Lambdapil® treated group by 23.4% over baseline (1.93 *vs.* 2.36 at baseline and 6 M, respectively) indicating that there were more hair in the growing phase *vs.* placebo treated group (1.81 *vs* 1.75 at baseline and 6 M, respectively; $p<0.05$). The hair volume and aspect in Lambdapil® treated group improved at 1, 3 and 6 months significantly more than placebo group ($p<0.05$). The treatment was well tolerated.

Conclusion: Dietary supplementation with Lambdapil® Anti Hair Loss capsules for 6-months was safe and effective in both women and men suffering from hair loss.

Keywords: Hair loss; Androgenic alopecia; Acute telogen effluvium; L-cystine; *Serenoa repens*; Biotin

Introduction

Hair loss, represented by acute Telogen Effluvium (aTE) in women and androgenetic Alopecia (AGA) in men, is a frequent reason for dermatology consultation. Despite their being benign and mild conditions, the associated psycho-emotional stress may impact the subjects quality of life, and may sometimes lead to secondary morbidity [1-3]. The main factors contributing to psycho-emotional stress are inability to style hair, dissatisfaction with appearance, concern about the continuing hair loss and concern about others noticing hair loss [4].

Telogen Effluvium (TE) is an increased loss of normal club hairs that occurs by a perturbation of the hair cycle [5]. Whatever the cause of hair loss, it results in increased disruption of hair cycle leading to synchronized telogen shedding. It can occur in both genders, but is overrepresented in women [6]. aTE was first described as an acute onset scalp hair loss occurring 2-3 months after a triggering event, which is unidentifiable in up to 33% cases [6]. A number of factors have been implicated in the causation of TE, including high fever, surgery, hospitalization, hemorrhage, changes in medication, postpartum emotional stress, seasonal variation (July to October), changes in medication and heavy metals. However, clear evidence in their support is lacking [6].

Androgenic alopecia (AGA) is the most common hair loss disorder [6]. It is characterized by the miniaturization of the large, thick pigmented terminal hair with a diameter of >0.03 mm to small, fine, non-pigmented vellus hair with a diameter of ≤ 0.03 mm [7]. In most men, AGA develops with a distinctive "patterned" hair-line recession [8-10]. It affects 50% of male by the age of 50 years and up to 70% of all males in the later life [10]. It is caused by the overproduction of 5a-dihydrotestosterone (5a-DHT), a potent androgen, within the hair follicle, specifically the dermal papilla cells that are the main regulators of hair growth and are the site of 5a-DHT action [10]. It occurs after puberty in men with an inherent sensitivity to the effects of androgens on androgenetic sensitive scalp hair follicles. It does not develop in men without testosterone or in men with a genetic deficiency of the

enzyme 5-alpha-reductase type II which converts testosterone to DHT [6].

Currently two active pharmacological ingredients are approved by the US Food and Drug Administration (FDA) for the treatment of AGA, finasteride and minoxidil. Finasteride acts by inhibiting 5-alpha-reductase and minoxidil, a potassium channel opener, hypothetically, acts by widening blood vessels and opening potassium channels, thus allowing more oxygen, blood, and nutrients to the follicles. Although both have demonstrated efficacy for the treatment of androgenic alopecia in men [6], both drugs have side effects and are effective in less than 50% of the patients. Moreover, some people are intimidated by the pharmacological approach to treat a non-life-threatening disease such as alopecia. Food supplements are a non-pharmacological approach that is easy to fit into everyday routine without significant side effects to treating this sometimes emotionally taxing condition.

In the present study we tested the efficacy of dietary supplements in capsule form (Lambdapil® Anti Hair Loss capsules, henceforth Lambdapil®; currently marketed by Isdin, Spain) containing a unique combination of plant extracts: *Serenoa repens* extract, *Equisetum arvense* extract, essential minerals: zinc, vitamins: B3, B5, B6, D-biotin and amino acids: L-cystine and taurine in improving the signs of alopecia in both men and women. *Serenoa repens* extract has been reported to inhibit 5-alpha reductase activity, an enzyme involved in the hair loss in alopecia [8]. *Equisetum arvense* is a plant rich in highly bioavailable silicon which is purported to aid in improving the resilience of hair and nails [9]. Other components of the capsules such as biotin, zinc, amino acids and vitamins are thought to contribute to the maintenance of normal hair by normalizing protein synthesis including keratin and collagen synthesis which is essential for hair growth [11]. Vitamin B6 has been described to contribute to the regulation of hormonal activity [12]. This combination of plant extracts, vitamins, trace minerals and amino acids has been designed to replenish these where a possible deficiency might have led to a hair loss and regulating the hormonal balance to favor hair growth.

The primary objective of this randomized, double-blind, placebo-controlled study was to assess the efficacy of Lambdapil® capsules in decreasing the clinical signs of hair loss in female and male subjects.

Materials and Methods

Study design

This monocentric, prospective, randomized, parallel-group, double-blind, placebo controlled study was carried out in accordance with the Declaration of Helsinki and the Good Clinical Practice guidelines E6 (R1). The study protocol and the informed consent form were approved by the "Independent Ethical Committee for Non-Pharmacological Clinical trials" during its meeting on February 06 th, 2014. This study was not registered as the tested product was a food supplement. All subjects provided written informed consent and a consent release for photo publication before initiation of any study-related procedures. The study took place at Farcoderm s.r.l. dermatological facilities in San Martino Siccomario (PV), Italy. Farcoderm s.r.l. is an independent testing laboratory for *in vitro* and *in vivo* safety and efficacy assessment of cosmetics, food supplements and medical devices.

Subjects

Eligible subjects were enrolled and screened in the study under the supervision of a board certified dermatologist. All subjects were adult Caucasian male and females subjects aged between 18 and 65 years old showing the clinical signs of AGA grade II to III vertex according to Hamilton Norwood scale [13] or aTE, respectively. The participants were enrolled (recruitment and treatment) between March and September 2014. The inclusion criteria were as follows: i) adequate rest period between two similar study (at least 6 months from the last study), ii) willingness to not use products for hair care (both topic and systemic) likely to interfere with the product to be tested, iii) willingness to not use, during all the study period, products for hair care other than the products supplied, iv) willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, including haircut, etc.), v) subject under effective contraception (oral/not oral); not expected to be changed during the trial. Exclusion criteria included pregnancy or intention to become pregnant, lactation, food intolerances/allergy, and participation in another similar study within 6 months prior to enrolling in the study, subjects unwilling or unable to comply with the requirements of the study protocol. The study further excluded subjects using topical products or food supplements containing actives that could have an influence on hair physiology. Changes in hairstyle or dyeing of the hair were not allowed during the trial.

Interventions

The tested product was a commercially available food supplement named Lambdapil® capsules (ISDIN, Provençals, Barcelona, Spain). The product composition is presented in Table 1. The placebo product was a 100% maltodextrin capsule. Active and placebo products were identical in appearance without any visible difference. Subjects were instructed to take both the active and the placebo products as follows: 2 capsules a day in the morning at breakfast, to be swallowed as a whole with plenty of water. For the duration of the study period, subjects washed their hair using a neutral shampoo.

Components	Per 2 capsules	%NRV* (2 capsules)
L-Cystine	1000 mg	-
Serenoa repens	100 mg	-
Equisetum arvense L.	7.14 mg	-
Silicon	0.50 mg	-
Zinc (zinc sulphate)	10 mg	100%
Vitamin B3 (nicotinamide)	16 mg	100%
Vitamin B5 (calcium D-pantothenate)	6 mg	100%
Vitamin B6 (pyridoxine hydrochloride)	1.4 mg	100%
D-biotin	50 µg	100%
Taurine	40 mg	-
*Nutrient reference Value		

Table 1: Product Composition.

Endpoints

The primary outcome measured was the hair loss after pull testing for female subjects with aTE and the anagen/telogen hair ratio for male subjects with AGA. All measurements were carried out on cleansed hair (1 day before the visit) under temperature (22 ± 2°C) and humidity (50 ± 10%) controlled conditions. Pull test (in female subjects) consisted in a gentle traction exerted on a cluster of hair (approximately 60 hairs) on three different areas of the scalp (frontal, temporal, and occipital), and the number of hairs was counted. Normally, less than three telogen-phase hairs should come out with each pull. If at least three hairs were obtained with each pull or if more than ten hairs total were obtained, the pull test was considered positive and suggestive of telogen effluvium.

For phototrichogram procedure (in male subjects), a transitional area (1.8 cm^2) of hair loss between normal hair and the balding area was defined using a stencil template and chosen for clipping. The clipped hairs within the target area were dyed for gray or fair hairs with a commercially available solution (RefectoCil®, GW Cosmetics GmbH, Leopoldsdorf, Germany) in order to enhance their contrast. Thereafter, the dyed hairs were cleansed using an alcoholic solution. Digital macrophotographs were taken using a Nikon D300 reflex camera digital camera (Nikon Corporation Tokyo, Japan) equipped with a macro objective (AF-S Micro NIKKOR 60 mm f/2.8G ED, Nikon Corporation Tokyo, Japan), an independent flash system (Kit R1C1, Nikon Corporation Tokyo, Japan) and cross-and parallel-polarized filters. Digital macrophotographs were taken at the time of clipping (0 h) and 48 afterwards (48 h). The resulting images were analyzed by using NIH software. After identifying the same hairs in the images taken at 0 h and 48 h following the clipping for all the experimental monitored times, the length of each hair was measured and the number of hair in the clipped area were counted. This allowed for the calculation of the anagen (growing)/telogen (not growing) hair ratio.

The overall hair volume and overall hair appearance were assessed by the dermatologist using a 7-point clinical score scale ranging from -3 (greatly decreased or worsened) to 3 (greatly increased or improved). The overall hair volume changes during the clinical trial were assessed by the dermatologist on digital images.

Subjects also answered a 10 question questionnaire on effect of treatment on aspects related to Quality of life (QoL) regarding hair loss [14]. The responses were scored according to a 7 point scale ranging from 1 (not affected at all) to 7 (extremely affected). A higher numerical score indicated a greater concern and a lower numerical score indicated a lesser concern for the items of the QoL questionnaire. In addition, subjects were also asked to score product efficacy according to a 10 points scale ranging from 1 (very poor) to 10 (very good).

Sample size

Sample size was calculated with a two-sided 5% significance level and a power of 80% taking into account a 20% variation of the primary endpoints due to both inter-individual human variability and error in the measurement techniques. A sample size of 20 subjects per group was necessary given an anticipated dropout rate of 20%.

Randomization

A restricted randomization list was generated using PASS 11 (version 11.0.8 for Windows; PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64 bit Edition (Microsoft, USA) by a biostatistician and stored in a safe place. Randomization sequence was stratified using the biased coins Efron's algorithm with a 2:1 allocation ratio. The allocation sequence was concealed from the in site study director in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on subject entry number in the study). The A4 sheet reporting the unblinded treatment was folded to render the envelope impermeable to intense light. After acceptance of the subject in the study the appropriate numbered envelope was opened. An independent technician dispensed either active or placebo products according to the card inside the envelope. The study adhered to established procedures to maintain separation between the investigator and its collaborators and the staff that delivered the intervention. Investigator and its collaborators who obtained outcome measurements were not informed on the product group assignment. Staff who delivered the intervention did not take outcome measurements. Subjects, investigator and collaborators were kept masked to products assignment.

Statistical Methods

Statistical analysis was performed using NCSS 8 (version 8.0.4 for Windows; NCCS, LLC) running on Windows Server 2008 R2 64 Edition. Data normality was checked using Shapiro-Wilk W normality test and data shape. A p value <0.05 was considered statistically significant. Intragroup comparisons for normally distributed data (phototrichogram and pull test) were analyzed by two-way paired t test. Intergroup comparisons for normally distributed data (phototrichogram) were analyzed by two-way unpaired t test, while for not normally distributed data a Mann-Whitney U test was performed. Efficacy analyses were performed on the Per Protocol (PP) population, i.e., on all subjects who completed the study without any major protocol violations. Intergroup statistical analysis was performed on baseline parameters. There were no statistically significant differences were between groups. Safety analyses were performed on the Safety population, i.e. on all subjects who were assigned a subject number and who received at least one dose of study treatment. For phototrichogram results the percent variation was calculated as the mean of each single variation for each treatment group.

Results

The study was conducted between March and September 2014. A total of 70 subjects, 35 men and 35 women, were randomized in the study, and 23 men and 23 women received the active treatment while 12 men and 12 women received the placebo (Figure 1). No major deviation was observed in the treatment regimen. All subjects were included in the safety analysis data set. In general, the treatment was well tolerated. There was only one premature study termination in 1 woman who received the active treatment, due to bloating symptoms. Demographic and baseline characteristics (Table 2) were similar across treatment arms, indicating an unbiased randomization and the absence of covariates. No significant differences were observed between the two groups (active and placebo) regarding age, scalp conditions, hair length, and hair loss related parameters. Due to early study termination, one female subject receiving the active treatment was not included in the efficacy population. Therefore this population comprised 22 subjects in the active group and 12 in the placebo group. All randomized male subjects were included in the efficacy population.

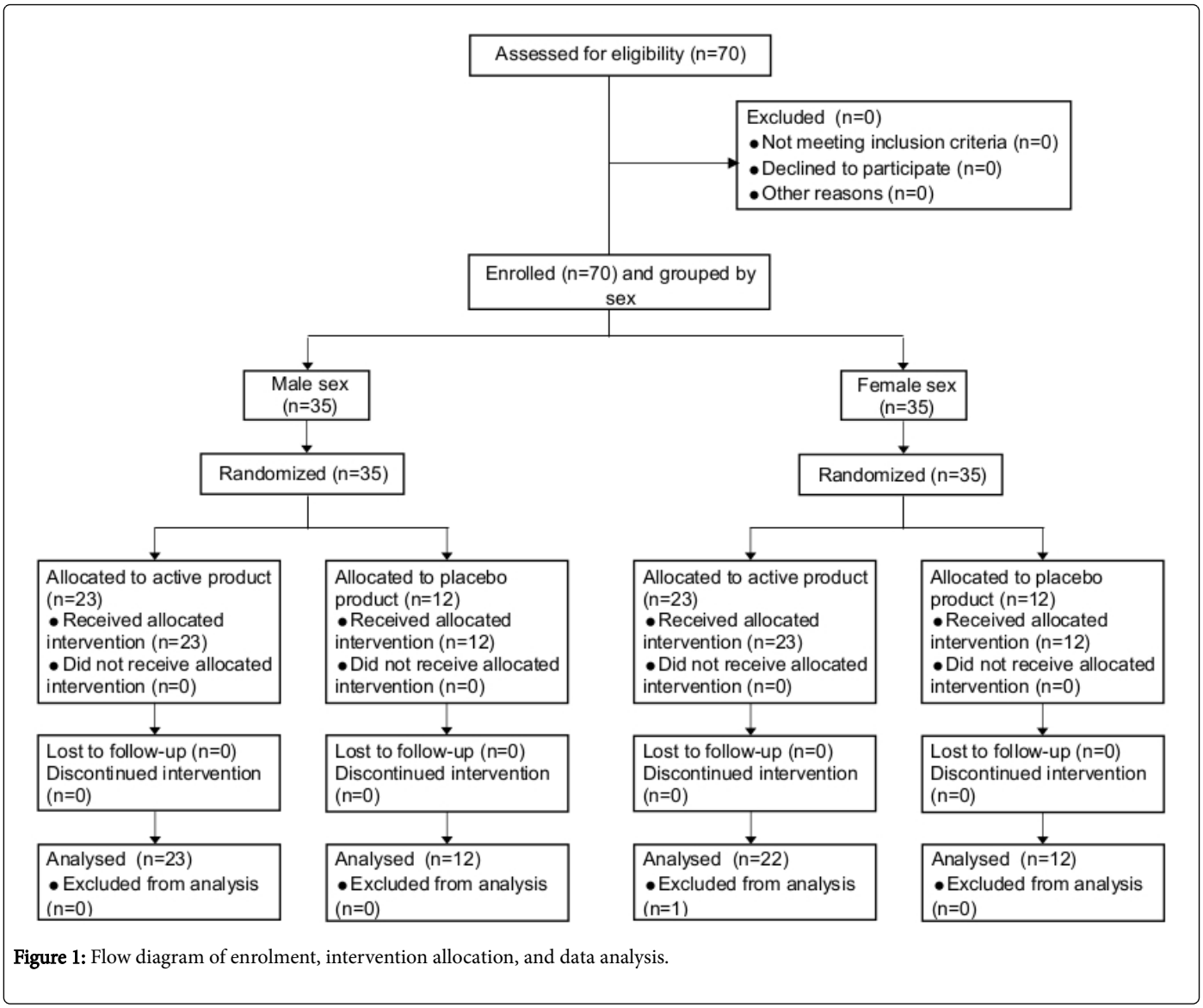

Figure 1: Flow diagram of enrolment, intervention allocation, and data analysis.

	Female subjects, N=35		**Male subjects, N=35**	
	Active Treatment N=23	**Placebo N=12**	**Active Treatment N=23**	**Placebo N=12**
Age	46.5 ± 2.6	44.2 ± 3.7	40.6 ± 2.5	46.4 ± 2.5
Scalp condition				
Sensitive skin	21.7%	16.7%	21.7%	33.3%
Normal skin	4.3%	16.7%	8.7%	8.3%
Oily skin	39.1%	25.0%	34.8%	33.3%
Burning, itching sensation	4.3	8.3%	0.0%	0.0%
Sensitive skin, stinging sensation	4.3	0.0%	0.0%	0.0%
Sensitive skin, Burning sensation, Itching sensation	4.3	0.0%	0.0%	0.0%
Oily skin, Desquamation	0.0%	8.3%	0.0%	0.0%
Sensitive skin, itching sensation	17.4%	0.0%	13.0%	0.0%
Desquamation		8.3%	8.7%	8.3%
Oily skin, itching sensation	0.0%	8.3%	0.0%	0.0%

Dry dandruff, itching sensation	0.0%	8.3%	13.0%	16.7%
Hair Length				
Short	4.3%	8.3%	95.7%	100%
Medium	65.2%	41.7%	4.3%	0.0%
Long	30.4%	50.0%	0.0%	0.0%
Hair Loss Characteristics				
Pull test	12.9 ± 0.4	12.8 ± 0.5	na	na
AGA scoring n (%)				
II	na	na	7 (30.4%)	3 (25.0%)
III	na	na	8 (34.8%)	4 (33.3%)
III vertex	na	na	8 (34.8%)	5 (41.7%)
Anagen hair (%)	na	na	64.5%	63.9%
Telogen hair (%)	na	na	35.5%	36.1%
Data are means ± SE or percentage of subjects. na: not applicable.				

Table 2: Demographic and baseline characteristics of study population.

Pull testing

The number of hairs removed in the pull test decreased steadily for both treated and placebo group over the 6-month period.

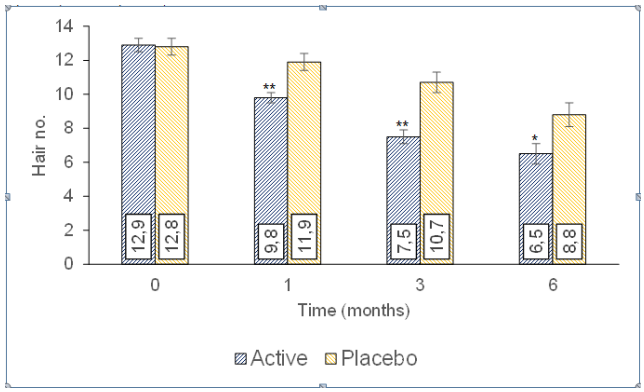

Figure 2: Changes over time in Pull Test (female subjects). Data are means ± SE of number of hair. *p<0.05 and **p<0.01 (active *vs.* placebo).

However, at 1 (M1), 3 (M3) and 6 (M6) months the decrease was significantly greater for the treated group compared to the placebo group (p<0.05; Figure 2). At M3 and M6, the mean number of pulled hairs was below the threshold for definition of aTE in the active treatment group while this is the case only at 6 months in the placebo group (Figure 2).

Phototrichogram

Endpoint	Time	Active	Placebo
Anagen hair count	M0	102.9 ± 2.2	102.1 ± 3.6
	M3	102.9 ± 2.1	98.8 ± 4.9
	M6	109.5 ± 2.1	101.1 ± 3.5
Telogen hair count	M0	57.6 ± 3.4	57.5 ± 2.5
	M3	56.6 ± 3.5	59.4 ± 2.2
	M6	52.4 ± 3.8	58.8 ± 2.2
Anagen/telogen ratio[a]	M0	1.93 ± 0.12	1.81 ± 0.11
	M3	1.97 ± 0.13	1.71 ± 0.14
	M6	2.36 ± 0.18**	1.75 ± 0.10

Table 3: Phototrichogram results (male subjects). Data are mean ± SE. aAnagen/Telogen ratio=(Anagen hair count)/(Telogen hair count). **p<0.01.

In men, there was a statistically significantly increase (23.4% increase) in the anagen/telogen ratio in the active treatment group at M6 as compared with baseline (Table 3). There was a statistically significant difference (p<0.05) between the active treatment group and the placebo with a +3.7% increase in the total percent of anagen hair in the active treatment group from baseline to M6, *vs.* -0.8% decrease in the placebo group, and a -3.7% decrease in the total percent telogen hair in the active treatment group *vs.* a +0.8% increase in the placebo group (Table 3).

Hair volume and hair aspect

Hair volume and hair aspect changes over time are reported in Figure 3. For both women and men, a majority of subjects described an increase in hair volume (slight or moderate) in the active treatment group as compared with the placebo group from M3 (p<0.01) to M6 (p<0.01). The difference *vs.* placebo was statistically significant from M1. Hair aspect was significantly improved (p<0.05) at M6 with more improved subjects in the active group as compared with the placebo group.

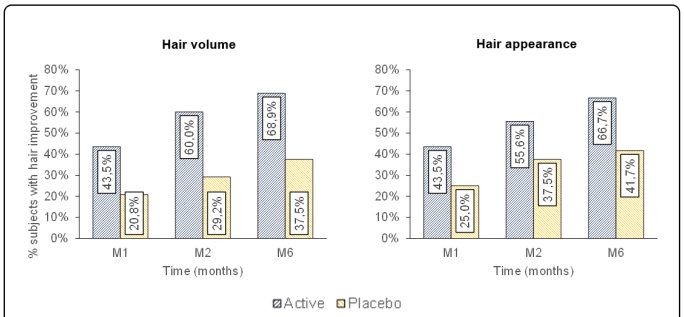

Figure 3: Changes over time in overall hair volume and hair aspect (female and male subjects). Data are % of subjects showing an improvement. *p<0.05 and **p<0.01 (active *vs.* placebo).

Quality of life

The cumulative results from QOL questionnaire showed an improvement in the Lambdapil® treated group compared to baseline values after 3 and 6 months of treatment.

Month	Active	Placebo	Intergroup stat. analysis
0	19.7 ± 1.4	20.6 ± 2.6	n.s.
3	18.3 ± 1.2	28.5 ± 3.3	*
6	18.2 ± 1.2	24.0 ± 3.1	n.s.

Table 4: Quality of life questionnaire (male and female subjects). Data are reported as the sum of the score given to each question ± SE. Statistical analysis is reported as follows:*p<0.05 I.

This was opposed to the placebo group where a worsening in QOL cumulative scores was at the same time points (Lambdapil® *vs.* placebo, p<0.05 at 3 months; Table 4).

Self-Assessment of Efficacy All subjects responded to questionnaire regarding their perception of efficacy of treatment. Results from the questionnaire are presented in Table 5. Overall, Lambdapil® treated subjects noticed a greater improvement in indicators of hair growth compared to the placebo group.

Item	Active (n=45)	Placebo (n=25)
Have you noticed a decrease of hairs loss?	66.7% (n=30)	54.2% (n=13)
Have you noticed the growth of new hairs?	57.8% (n=23)	37.5% (n=9)
Have you noticed an increase of hairs thickness?	57.8% (n=26)	37.5% (n=9)
Do your hairs grow faster?	62.2% (n=28)	58.3% (n=14)
Has the treatment reinforced your hair?	68.9% (n=31)	41.7% (n=10)
Has the treatment increased of brightness of hair?	64.4% (n=29)	45.8% (n=15)
Has the treatment increased hair volume?	64.4% (n=29)	45.8% (n=11)
Has the treatment reinforced your nails?	51.1% (n=23)	58.3% (n=14)

Table 5: Self-assessment questionnaire (male and female subjects). Data are reported as % of subjects scoring product efficacy ≥ 6 (sufficient).

Global photographic assessment

Figure 4 shows the macroscopic effect of the product on hair volume. An increase in hair volume was seen in the frontal and parietal area (vertex) of the scalp.

Digital photography-T0 baseline, T3 3 months, T6 6 months (a-b).

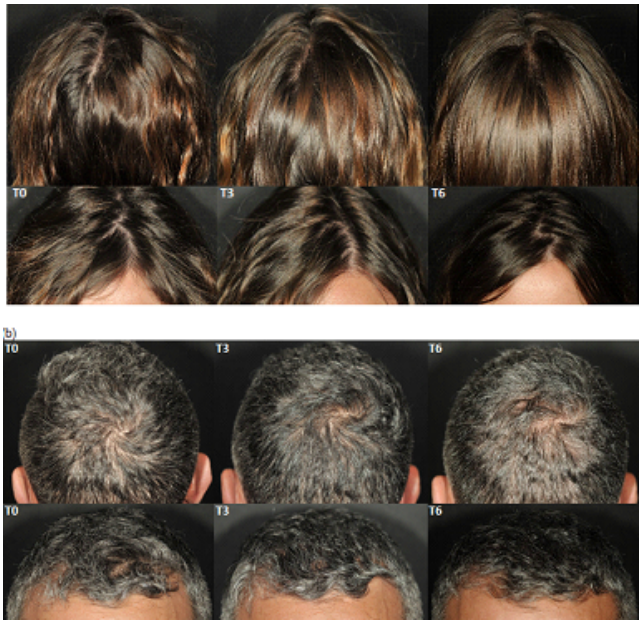

Figure 4: Digital photography. T0-baseline, T3-3 months, T6-6 months (a-b).

Discussion

There is little doubt that nutrition influences hair loss pathologies [15,16] and that food supplements work on several factors of this complex etiology can help in the management of hair loss [17,18]. This randomized, double-blind, placebo-controlled trial studied the efficacy of Lambdapil®, a food supplement containing *Serenoa Repens* and *Equisetum arvense* extract (rich in silicon), vitamins (B3, B5, B6, D-Biotin), amino acids (L-cystine, taurine), and zinc, in women with aTE and in men with AGA. aTE involves intense hair loss that usually lasts a few months but is reversible. Women seem to be more prone to this kind of hair loss that usually happens 2-5 months after a trigger event. Women suffering from aTE find the condition stressful as they notice a large number of hair being lost daily. Although aTE eventually reverses naturally, in the present study Lambdapil® supplementation helped the reversal of this condition in a shorter time span compared to placebo controls as evidenced by the results from the pull test.

In men with AGA, an increase of 23.4% in the anagen/telogen ratio from baseline to the end of the 6-month treatment period was observed in patients taking Lambdapil® whereas no such increase was observed in the placebo group. The anagen hair count increase after a 6-month period treatment corresponding to 6.7 new hairs in the area of phototrichogram which when roughly extrapolated to whole scalp area translates to 2,159 new hairs after 6 month supplementation (scalp area 580 cm^2; RIVM data). In contrast, there was no increase in hair count in placebo-treated subjects, even if a negative variation (not statistically significant) of anagen hair count was recorded.

Finally, body image is a psychological concept that refers to a person's perception related to his or her physical appearance. For many people, hair is a physical attribute that forms a large part of the feeling of attractiveness or unattractiveness. In this respect the findings related to improvement in both hair aspect and hair volume in Lambdapil®

group are considered very relevant as are the improved score for the subject's self-perception of improvement in hair quality and strength from the results of the survey that the subjects responded to.

Although many of the components of the food supplement used in this study are supported by scientific literature for their use in alleviating signs of alopecia, in our knowledge this is the first report of a controlled, randomized clinical study that reports benefits for women with aTE and men with AGA with supplementation with a product that contains these ingredients. In Morgantil et al. a combination of *Serenoa repens* extract and gelatin-cystine *via* oral route, increase significantly (around 25%) hair number/cm² and total hair mass/cm² *vs.* placebo at 30 weeks in patients with androgenic alopecia [19].

Lambdapil® oral supplements had a good safety profile with only 1 adverse event reported. Although the drug treatments for alopecia available today are efficacious against both male and female alopecia, they are associated with sexual and non-sexual side effects reported in younger men with finasteride [20]. Oral supplements such as Lambdapil® are a practical option for persons wanting to address alopecia but without the side effects associated with drugs.

The strength of this study was the high-level methodology employed: placebo-controlled, double-blind, 6-month duration study; use of digital photographs for assessments of changes in AGA.

Although the research has reached its aim, there were some unavoidable limitations. Firstly, the use of the pull test to assess the changes for aTE may be considered as a limitation, as it was described to be a test difficult to standardize due to the intrinsic variability of the technique [6]. We justify its use as the only parameter available to assess aTE in a clinical setting. Secondly, the small sample size may be considered a limitation. Even if a priori sample size was calculated, to generalize the results for larger groups, the study should have involved more participants in order to take into account possible faults of the stratified random sampling design and the power of statistical tests. Finally, the self-assessment questionnaire is subjective. However even if the output of a self-assessment questionnaire is not robust itself, when associated to clinical/instrumental measurements it is useful to understand if products effects are perceived by the subjects participating in the study.

In conclusion, the oral supplementation with Lambdapil® capsules, for 6 months, was efficacious in improving the signs and symptoms related to aTE in women and AGA in men, and was suitably well tolerated with negligible adverse events. It appears to be a safe and efficacious way to address hair loss that fits in comfortably with the daily routines of persons suffering from this condition.

Contributors

SA designed the study protocol and was responsible for manuscript reviewing; EC performed the experiments. VN wrote the study protocol/manuscript and was responsible for data analysis and interpretation. MN was responsible for writing and reviewing the manuscript.

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Conflict of Interest and Funding

This study was funded by Isdin SA. Isdin SA was involved in the design of the study protocol and provided the test products samples. Employees of the Sponsor were not involved in data analysis. The manuscript was prepared by Dr. Vincenzo Nobile. Isdin SA was permitted to review the manuscript and suggest changes, but the final decision on content was exclusively retained by Dr. Vincenzo Nobile. Dr. Vincenzo Nobile is the guarantor for this manuscript, and takes responsibility for the integrity of the work as a whole. SA and MN work for Isdin SA.

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