

Safety and Efficacy of Deeply Rooted® Nutraceutical for Hair Growth in Women

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Abstract

Hair loss can significantly affect quality of life. Patients seeking treatment for hair loss find that many surgical or medication options involve significant risks or side effects. DEEPLY ROOTED® is a nutritional supplement that combines botanical and natural ingredients with the goal of effectively reducing hair loss and stimulating hair growth—without the side effects of many standard treatments. DEEPLY ROOTED's active ingredients have both anti-inflammatory and adaptogenic properties, and inhibit dihydrotestosterone without the use of hormones, drugs, or industry by-products. This 3-month prospective study evaluates the effectiveness of DEEPLY ROOTED® for the prevention of hair loss. Healthy female subjects complaining of hair loss were enrolled, and supplied with three months of DEEPLY ROOTED®, without other compensation. The primary endpoint was a significant increase in hair growth. This was measured using anonymously collected patient data to evaluate hair growth and quality, as well as blinded Investigator hair assessment data. Patients who ingested DEEPLY ROOTED® over a three-month period reported noticeable improvement of hair growth (91%), increased hair volume (86%), and improved hair quality (86%). Subjects were noted to exhibit an increase in the number of new hairs, hair thickness and scalp coverage. No significant adverse effects were reported. DEEPLY ROOTED® safely helped over 90% of otherwise healthy women with self-perceived hair thinning to improve hair quality and quantity. The unique combination of botanical and natural ingredients provided a drug-free alternative for the management of hair loss.

Keywords

Hair Loss, Alopecia, Supplement, Hair Growth, Wellness, Vitamins

1. Introduction

Hair loss, known as alopecia, affects more than 50% of men and women over age

50. Although not life-threatening, such hair loss impacts a patient's quality of life, self-esteem, and overall sense of wellness.

Female pattern hair loss (FPHL) is the most common form of alopecia in women. Affected women may experience psychological distress and impaired social functioning. Early diagnosis and treatment are desirable to avoid the progression of hair loss, and to stimulate regrowth. Typically, a diagnosis of FPHL can be confirmed by reviewing a patient's medical history and a physical examination [1].

Considering the impact of alopecia on well-being, there is a growing interest in novel therapeutic options. To date, two medications—minoxidil and finasteride—are approved by the FDA for the treatment of alopecia. Unfortunately, these drugs carry the risk of significant side effects ranging from dermatitis to male sexual dysfunction and female infertility [2].

As an alternative to prescription medications, a number of plant-based supplements, vitamins and minerals are available to reduce or even help reverse hair loss. Determining what products are effective is challenging in this less regulated free-market environment.

This study aims to evaluate the effectiveness of the nutraceutical DEEPLY ROOTED® on hair growth and quality by monitoring three-month outcomes on otherwise healthy females, using direct observation and photography, as well as through patient questionnaires.

2. Materials and Methods

To evaluate the safety, efficacy and physiological effects of DEEPLY ROOTED® supplement, 40 female subjects with FPHL were enrolled over a 4-week period. Symptomatic volunteers were solicited among patients at a plastic surgery office/med spa and a dermatology practice. Patients complaining of female pattern hair loss were offered the opportunity to participate, which was voluntary and involved no compensation other than free product. The study was designed as a single arm study and approved by institutional review board. The total duration of the study was 4 months as patients took supplements for 3 months. Inclusion criteria for patients was: female gender, age 21 - 65, no major comorbidities, self-perceived thinning hair determined on initial study assessment, Fitzpatrick I-IV photo skin types. Exclusion criteria was any known allergy or sensitivity to any shampoo/conditioner, women who were nursing, pregnant, planning to become pregnant during the study or who have been pregnant within the last 6 months, females with known stressful incident within the last six months (*i.e.* death in family, miscarriage), females who have recently (within the last 6 months) started the use of hormones for birth control or hormone replacement therapy (HRT), women who had regularly used Rogaine (Minoxidil) within the last 3 months or oral prescription medications, females suffering from other hair loss disorders, such as alopecia areata, scarring alopecia, androgenetic alopecia and telogen effluvium [3].

Subjects were given a three-month supply of DEEPLY ROOTED supplement with instructions to take four capsules daily. The dose of ingredients of each capsule is listed on the product label (Table 1). The effects of the supplement were evaluated prospectively using standardized photography (before and after) combined with a patient questionnaire to evaluate results. Photographs, using a Canon Power Shot G16 camera with a standard 6.1 - 30.5 mm Canon zoom lens, were obtained of the scalp in five views (front, left, right, posterior and birds-eye). A Dermlite photo 3 camera was used to take close-up pictures of each patient's temporal area. At the end of three months, all patients completed a questionnaire evaluating the effects of DEEPLY ROOTED® on hair growth and quality.

3. Results

Of the 40 subjects initially enrolled in the study, two were later excluded: one because of a previously undisclosed diagnosis of autoimmune thyroid disease, and another patient with history of chronic rosacea. DEEPLY ROOTED® does

Table 1. DEEPLY ROOTED ingredient list.

Supplement Facts		
Serving size: four capsules		
Servings per container: 30		
	Amount Per Serving	%DV
Vitamin A (as beta-carotene)	750 mcg RAE	83%
Vitamin C (as camu camu)	80 mg	89%
Vitamin D (as cholecalciferol)	25 mcg	125%
Niacin (as nicotinic acid)	16mg	100%
Vitamin B12 (as cyanocobalamin)	6 mcg	250%
Biotin	2500 mcg	8333%
Pantothenic acid (as d-calcium pantothenate)	5 mg	100%
Iodine (as organic kelp <i>Laminaria digitate</i>)	100 mcg	67%
Zinc (as zinc oxide)	10 mg	91%
Selenium (as sodium selenate)	55 mcg	100%
Korean ginseng root (<i>Panax ginseng</i>)	500 mg	*
<i>Rhodiola rosea</i> root	100 mg	*
HAIR HEALTH COMPLEX™†	1456 mg	*
Amla fruit (from 20:1 concentrate) (<i>Phyllanthus emblica</i>), Horsetail whole extract (<i>Equisetum arvense</i>), Green tea leaf extract (<i>Camellia sinensis</i>), Cococin™ Coconut water (<i>Cocos nucifera</i>), Tocotrienol/Tocopherol complex, KSM-66® Ashwagandha root extract (<i>Withania somnifera</i> extract), PrimaVie® organic <i>Himalayan shilajit</i> , Pumpkin seed oil (<i>Cucurbita pepo</i>), Resvenox Resveratrol, Saw Palmetto 45% fatty acids, Natural Astaxanthin (2.5% astaxanthin), BioPerine®		
POLYPEPTIDE COMPLEX™†	803 mg	*
Hydrolyzed fish collagen I & III, Arginine HCL, L-Lysine, L-Cysteine HCL, L-Methionine, Hyaluronic acid		

contain green tea extract, which can exacerbate Rosacea in sensitive patients. The remaining 38 women took DEEPLY ROOTED[®] for three months. Two women reported non-adherence to instructions, often forgetting to take the supplement regularly, so they too were excluded from the study. Finally, three additional patients failed to return in a timely fashion for evaluation and questionnaire completion. Thus, 33 patients successfully completed the study.

All 33 patients were otherwise healthy women with female pattern hair loss. All underwent examination at the beginning of the study, and a health screening was completed to rule out other hair loss disorders or other treatments. Ethnicity of the patients was 26 Caucasian (79%), 3 Hispanic (9%), 4 Asian (11%) and one African American (3%). None of the patients were taking other supplements or hair growth medications and none had undergone surgical hair restoration. All patients were given a three-month supply of DEEPLY ROOTED[®] supplement, and a 24-hour hotline was established for patients to call with questions or to report any side effects. No adverse events were reported. After three months of supplementation, these 33 participants completed an anonymous questionnaire (see **Addendum 1** for questionnaire) to assess the effects of DEEPLY ROOTED[®].

Results of the questionnaire revealed 30 out of 33 women (91%) reporting overall improved hair growth; 26 (78%) reported increased hair volume, 27 (81%) reported improved hair quality, and 25 (76%) noted new hair growth with DEEPLY ROOTED[®]. Of these, 24 (73%) perceived an increase in total hair amount and 23 (70%) noticed improved scalp coverage. Finally, 22 (67%) of patients perceived their hair as thicker with DEEPLY ROOTED[®] (see **Table 2**).

In addition to the patients' self-reported results, all photos were evaluated in a blinded fashion. Images were de-identified and the evaluator was not aware of the patients' self-reported results (which were collected anonymously). Three sets of images were excluded from patients who had dramatically altered their hair color and style, making the before and after images difficult to compare. The evaluators were asked to compare the before and after scalp images (see patient photographs, **Figure 1** and **Figure 2**) and determine if the patient's hair appeared as improved, without noticeable change, or worsened. Seventy percent

Table 2. Results of the patient questionnaire.

	YES	No/not sure	total	%
Improved overall hair growth	30	3	33	91%
Increased hair volume	26	7	33	78%
Improved hair quality	27	6	33	81%
More new hairs	25	8	33	76%
Increased hair amount	24	9	33	73%
Improved scalp coverage	23	10	33	70%
Thicker hair	22	11	33	67%



Figure 1. Representative photos of patients before and after three months of supplementation with DEEPLY ROOTED®.

of the images were rated as improved, 30% as no change, and none were deemed worsened. The study subjects did not undergo tattooing to mark the close-up scalp area to precisely identify the hair-bearing area compared. Sample microscopy



Figure 2. Representative macroscopy photos of study patients showing higher hair density after three months of DEEPLY ROOTED[®] supplementation.

images are presented, but were not used for assessment of the results, since the scalp locations were not exactly the same.

4. Discussion

Hair loss is a complex problem that affects millions of men and women worldwide, causing many to experience lower quality of life and decreased self-esteem. Treatment has mostly relied on prescription medications and/or hair transplantation.

The frequency of FPHL varies among population groups and ordinarily increases with age. The age of onset for FPHL is during the reproductive years, which is later than in men. Twelve percent of women first develop clinically detectable FPHL by age 29 years, 25% by age 49 years, and 41% by 69 years. For women over 70, FPHL reaches a rate of 42% and >50% have some element of FPHL by age 79 [4]. Nevertheless, there is a greater demand for treatment among patient's ages 25 to 40 years [5].

FPHL and male balding share a final common pathway of follicular regression, but current knowledge suggests that the etiology is not necessarily the same

in both sexes. Androgens are a key driver of male balding and also involved in the etiology of pattern hair loss in some women. However, other non-androgenic factors that are still unidentified likely play a role in causing FPHL [6].

Hair loss in women is polygenic and multifactorial, with the additional influence of environmental factors. Several studies focused on the importance of several genes related to alopecia. FPHL involves progressive hair follicle miniaturization and subsequently the conversion of terminal follicles into vellus-like follicles. These vellus-like follicles have a shortened hair cycle because of a reduction in the anagen phase, which leads to the production of short and fine hair shafts. The miniaturization is not as uniform nor as intense in women. For this reason, areas of complete baldness are very rare in women [2]. The aim of FPHL treatment should reverse or at least stabilize the process of hair follicle miniaturization.

As an alternative to prescription medication, many botanical products and dietary supplements are available, but often lack scientific evidence to support their efficacy. Low-quality supplements are sometimes produced without scientific guidance and without appropriate quality control. Some products have been recalled by the FDA because of patient illness or other side effects.

This study demonstrates that a significant majority of healthy women with FHLP reported improved hair growth, volume, quality and increased new hair after supplementing with DEEPLY ROOTED®. None of the participants reported any significant adverse effects. This study was purposefully designed to replicate prior studies reporting high efficacy for nutraceuticals. The investigators in this study took the conscious decision to not enroll paid participants, and to gather feedback on a de-identified basis to minimize any participant bias.

Hush and Hush® DEEPLY ROOTED® is designed for management of hair loss. The botanical and natural ingredients were chosen with the goal of effectively reducing hair loss and to stimulate new hair growth. DEEPLY ROOTED® contains no hormones, drugs, or industry by-products. Notably, many of the ingredients in DEEPLY ROOTED® have shown effects on scientific studies that were comparable to prescription medications—without the side effects of these standard treatments.

DEEPLY ROOTED® is a formulation of botanicals with potent anti-inflammatory, anti-stress adaptogenic, antioxidant and DHT-inhibiting properties—combined to synergistically combat the multiple underlying factors that compromise hair growth and health. Some patented ingredients include Amla fruit, Ashwagandha, Horsetail whole extract, Green leaf tea extract, Coconut water, Tocotrienol, Pumpkin seed oil and Saw Palmetto, all of which are standardized and clinically tested.

The benefits of nutritional supplementation with amino acids, biotin, zinc, and other micronutrients in hair loss have been previously described. A relationship between low levels of serum ferritin or vitamin D resulting in FPHL has been described [7]. Vitamin D has been suggested as a micronutrient necessary to delay aging phenomena, including hair loss. Vitamin D receptor activation

plays an important role in anagen initiation, and recent data suggested that vitamin D receptors regulate the expression of genes that are required for hair follicle cycling. The combination of micronutrients and botanical supplements contained in DEEPLY ROOTED® may have anti-androgenic and anti-inflammatory properties. Taken as a nutritional supplement for three months, DEEPLY ROOTED® promoted increased hair growth in 91% of volunteers.

5. Conclusion

Supplementation with DEEPLY ROOTED® over a three-month period appears to successfully improve symptoms of self-perceived thinning hair, resulting in increased hair growth, strength, volume, quality, thickness, and improved scalp coverage. Supplementation resulted in no adverse events or side effects reported. DEEPLY ROOTED® supplementation should be considered as an appropriate treatment option in the management of female pattern hair loss.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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Addendum 1

PATIENT QUESTIONNAIRE DEEPLY ROOTED STUDY

Instructions: Please complete the following questions by circling the number in the column which best describes your opinion of the change you have seen throughout the durations of the study (compared to baseline) for each characteristic.

	Greatly Improved	Moderately Improved	Slightly Improved	No Change	Slightly Worsened	Moderately Worsened	Greatly Worsened
Overall hair growth	+3	+2	+1	0	1	2	3
Overall hair volume	+3	+2	+1	0	1	2	3
Scalp coverage	+3	+2	+1	0	1	2	3
Thickness of hair body	+3	+2	+1	0	1	2	3
Hair amount	+3	+2	+1	0	1	2	3
Hair quality	+3	+2	+1	0	1	2	3
Hair color	+3	+2	+1	0	1	2	3
Hair dryness	+3	+2	+1	0	1	2	3
Hair shine	+3	+2	+1	0	1	2	3
Hair strength	+3	+2	+1	0	1	2	3
Hair breakage	+3	+2	+1	0	1	2	3
Softness of hair body	+3	+2	+1	0	1	2	3
Hair shedding/loss	+3	+2	+1	0	1	2	3
Amount of noticeable new hair	+3	+2	+1	0	1	2	3
Hair growth rate	+3	+2	+1	0	1	2	3
Hair length (ability to grow longer than usual)	+3	+2	+1	0	1	2	3
Ease of styling	+3	+2	+1	0	1	2	3
Overall appearance (does hair sit better on head)	+3	+2	+1	0	1	2	3
Sleep quality	+3	+2	+1	0	1	2	3
Stress levels	+3	+2	+1	0	1	2	3
Anxiety level	+3	+2	+1	0	1	2	3
Overall well-being	+3	+2	+1	0	1	2	3
Nail strength	+3	+2	+1	0	1	2	3
Nail growth rate	+3	+2	+1	0	1	2	3
Growth of eyebrow hair	+3	+2	+1	0	1	2	3
Growth of eyelashes	+3	+2	+1	0	1	2	3
Skin smoothness	+3	+2	+1	0	1	2	3
Overall skin health	+3	+2	+1	0	1	2	3