ABSTRACT

Objective: To evaluate the effectiveness of a novel oral supplement, Forti5®, containing green tea extract, omega 3 and 6 fatty acids, cholecalciferol, melatonin, beta-sitosterol, and soy isoflavones, and in the management of subjects with androgenetic alopecia. **Design:** A prospective case series of 10 subjects. **Setting:** Open-label, evaluator-blinded, proof-of-concept study. **Participants:** Ten adult subjects with androgenetic alopecia completed the study. Subjects were not allowed to use oral or topical hair growth products in the 24 weeks preceding the study or during the study. The nutritional supplement was administered at a dosage of two tablets daily for 24 weeks. **Measurements:** Clinical evaluations were performed at baseline and at 24 weeks. Efficacy was evaluated using hair mass index measured by cross section trichometer, terminal hair count measured with dermoscopy and Investigator Global Photography Assessment. **Results:** Overall 80 percent of subjects (8/10) were rated as improved after 24 weeks of supplementation (mean change of +1.4 equivalent to slightly-to-moderately increased). Forty percent of subjects (4/10) were rated as moderately improved (2+), and 10 percent (1/10) were rated as greatly improved (3+).

[Abstract continued on next page]

ORIGINAL RESEARCH

An Open-Label Evaluator Blinded Study of the Efficacy and Safety of a New Nutritional Supplement in Androgenetic Alopecia: A Pilot Study

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ANDROGENETIC ALOPECIA (AGA), a frequent reason for dermatology consultation is the most common cause of alopecia with up to 80 percent of men and 50 percent of women affected.[1–3] It is a non-scarring alopecia with an insidious onset that causes significant psychological distress.[4] The first sign of male pattern hair loss is often a recession of the hairline at the temples giving the hairline a characteristic "M" shape. This can be seen in conjunction with thinning at the crown.[1] In women, hair loss presents with thinning in the central region of the scalp. The first sign of female pattern hair loss is widening of the central part, which is often more evident at the hairline.[2–3]

The pathogenesis of AGA is complex with genetic, hormonal, inflammatory, and vascular factors thought to contribute to the onset and progression.[5–9] Dihydrotestosterone (DHT) is a metabolite of testosterone in a reaction driven by the enzyme 5-alpha reductase. When DHT binds to the androgen receptor on hair follicles in genetically susceptible individuals, it is the driving force that, over time, converts large, terminal hair follicles to smaller follicles with a shorter anagen phase.[8] This process is called follicular miniaturization and it is responsible for the clinical picture of AGA.

One of the mainstays of therapy for subjects with AGA are 5-alpha reductase inhibitors.[10–14] The purpose of this study is to evaluate the effectiveness of a new oral nutritional supplement that combines several ingredients that may have clinical utility in subjects with AGA; the main components include cholecalciferol, omega 3 and 6 fatty acids, melatonin, antioxidants, and botanical 5-alpha reductase inhibitors.[15–26]

Disclosure: Q-SkinScience® provided the nutritional supplement for the study. Dr. Martin Zaiac is a shareholder in Q-SkinScience®.

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[Abstract continued]

There was a significant improvement in terminal hair count (mean increase of 5.9% or 4.2 more terminal hairs in the area examined, p=0.014) and in Hair Mass Index (mean increase of 9.5% or 4.5 higher Hair Mass Index, p=0.003). **Conclusion:** These preliminary results indicate that Forti5® a novel nutritional supplement that contains cholecalciferol, omega 3 and 6 fatty acids, melatonin, antioxidants, and botanical 5-alpha reductase inhibitors, may be a useful adjunct in the treatment of androgenetic alopecia.

J Clin Aesthet Dermatol. 2017;10(2):52–56

MATERIALS AND METHODS

This clinical investigation was performed in accordance with Good Clinical Practices and the Declaration of Helsinki. A written informed consent was obtained from each subject before study procedures were started.

Study design and methodology. From September 2014 to June 2015, the authors conducted an open-label, prospective, proof-of-concept study on the efficacy and safety of a new oral supplement, Forti5® (Q-SkinScience®, Miami, Florida) in the management of subjects with AGA. All efficacy assessments were done by a single-blinded investigator.

Fourteen subjects were enrolled. Ten subjects completed the study, and four subjects were lost to follow up for reasons unrelated to the study. At baseline, subjects were instructed to take two tablets of the nutritional supplement daily for 24 weeks.

Inclusion/exclusion criteria. Enrolled subjects were male and female adults aged 18 to 65 years of age with a diagnosis of AGA. Clinical severity ranged from mild to severe. Subjects with evidence of hair loss for reasons other than AGA were excluded. Use of oral or topical hair growth products was not permitted in the 24 weeks preceding the study and during the study.

Subject demographics. Subject demographic data are shown in Table 1.

Clinical evaluation. Clinical evaluation and efficacy measures were performed at baseline and at 24 weeks by a single-blinded investigator.

Hair mass index was measured using a cross section trichometer. The cross section trichometer is a mechanical device that measures the cross-sectional area of a bundle of hair selected from a specific area of the scalp, which is recognized with a special template (trichometer tab).[27]

Terminal and vellus hairs were measured using dermoscopy and the cross section trichometer of hair selected from a specific area of the scalp, which is recognized with a special template.

For the Investigator Global Photography Assessment, the same blinded investigator scored changes in hair density by evaluating global photographs. Standardized photographs of a vertex view of the whole scalp, with hair parted and combed in the center were examined. Global images taken at Week 24 were compared with baseline photographs. Efficacy was assessed using the following 7-point scale (-3=greatly

Table 1. Basic characteristics of subjects completing the study, N=10 subjects

GENDER (% OF PATIENTS)	
Female	40%
Male	60%
AGE (YEARS)	
Mean	46.4
Range	35–62
AGA DURATION (YEARS)	
Mean	9.2
Range	1–35
PRIOR AGA TREATMENT (% OF	
No prior treatment	80%
Minoxidil or finasteride	10%
Biotin	10%

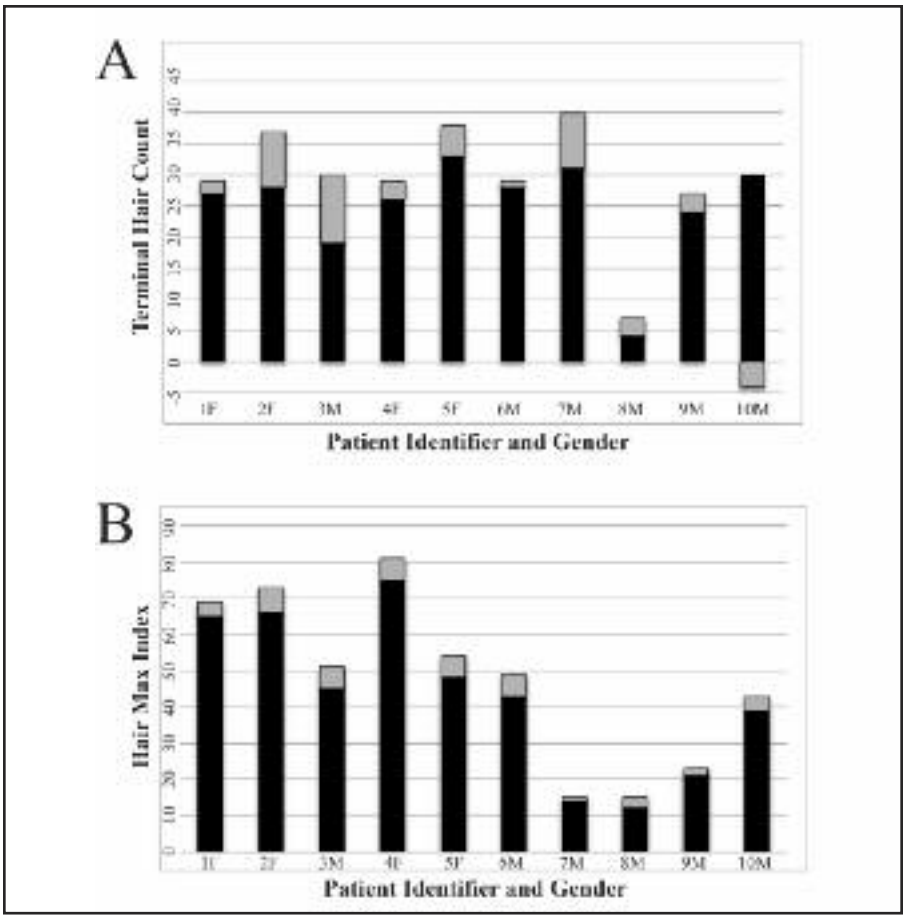

Figure 1. Efficacy of Forti5®. Improvement in both terminal hair count (A) and hair mass (B). Baseline (black bars) and 24 weeks after supplementation (grey bars) for each individual patient. F= Female, M=Male

Figure 2. Clinical photos. Baseline (A, C) and 24 weeks after Forti5@ supplementation (B, D)

decreased, -2=moderately decreased, -1=slightly decreased, 0=no change, +1=slightly increased, +2=moderately increased, +3=greatly increased).

Study endpoints. Primary endpoints were HMI-measured using a cross section trichometer, terminal hair count, and Investigator Global Photography Assessment. Each endpoint was recorded at baseline and after 24 weeks of supplementation. The secondary endpoint was safety and tolerability of the nutritional supplement.

Statistical analysis. The Wilcoxon signed-rank test was used to determine if there was a statistically significant difference in HMI, terminal hair count, and Investigator Global Photography Assessment before and after 24 weeks of supplementation.

RESULTS

Baseline characteristics for the 10 patients who completed the study are shown in Table 1. This small pilot study showed a modest clinically and statistically significant response after 24 weeks of supplementation with Forti5®. Eighty percent of subjects (8/10) were rated as improved after 24 weeks of supplementation (mean change of +1.4 correlating to slightly-to-moderately increased). Forty percent of subjects (4/10) were rated as moderately increased (2+) and 10 percent (1/10) were rated as greatly increased (3+) after 24 weeks (Table 2). The average duration of AGA was 9.2 years with a range of 1 to 35 years; however, the average duration of

hair loss for the five subjects that were rated as moderately or greatly increased was only 3.8 years (data not shown). Overall there was a significant improvement in terminal hair count (mean increase of 5.9% or 4.2 more terminal hairs in the area examined, p=0.014) and in HMI (mean increase of 9.5% or 4.5 higher HMI, p=0.003 [Figures 1 and 2]).

Table 2. Change in hair density after 24 weeks of Forti5® supplementation based on global assessment performed by a single-blinded evaluator

	SUBJECTS (%, N=10)
-3: greatly decreased	0
-2: moderately decreased	0
-1: slightly decreased	0
0: no change	20
1: slightly increased	30
2: moderately increased	40
3: greatly increased	10

DISCUSSION

AGA is characterized by gradual reduction in hair shaft diameter, length and pigmentation. The testosterone metabolite dihydrotestosterone (DHT) acts on androgen-sensitive hair follicles, and DHT is at least partially responsible for AGA. Androgen sensitivity is genetically determined and depends on 5-alpha reductase activity, which regulates the production of DHT. When DHT binds to androgen-sensitive hair follicles, it causes activation of the genes responsible for the transformation of large, terminal hair follicles to smaller follicles with a shorter anagen phase, producing the clinical picture of AGA.[6–12]

Currently, only topical minoxidil and systemic finasteride are United States Food and Drug Administration (FDA)-approved for the treatment of AGA. Given their partial efficacy and potential adverse events many patients use alternative and complementary treatments. A vast array of adjuncts have been purported to be beneficial, including biotin, cholecalciferol, melatonin, omega 3 fatty acids, low level laser therapy, microneedling, and local injections of autologous platelet-rich plasma.[15–26, 28–31]

CONCLUSION

Forti5® is a nutritional supplement combining green tea extract, omega 3 and 6 fatty acids, melatonin, cholecalciferol, beta-sitosterol, and soy isoflavones that was designed to improve thinning caused by AGA. This small proof-of-concept pilot study of men and women with AGA showed a modest, statistically significant improvement in several efficacy measures of hair regrowth after 24 weeks of supplementation. Future studies should determine which patients are likely to benefit most from this nutritional supplement and examine its clinical efficacy when used in combination with standard medical therapy for AGA. The supplement was well tolerated by study subjects without major side effects. In conclusion, Forti5® is a novel nutritional supplement that may be a useful adjunct in the treatment of AGA in both men and women.

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