

A 4-Month Study Evaluating the Efficacy and Tolerability of an Oral Supplement for the Treatment of Thinning Hair in African American Women

Brooke Jackson, MD, Skin Wellness Center of Chicago, Chicago, IL, USA.

Background

Some women experience self-perceived hair thinning associated with poor diet, stress, or abnormal menstrual cycles. An oral food supplement has been developed to promote existing hair growth for women suffering from temporary thinning hair (Viviscal® Hair Nourishment System; Lifes2good, Inc., Chicago, IL). The following study was designed to assess the ability of Viviscal to improve hair thickness when administered daily to African-American women.

Subjects

The study enrolled 16 adult African-American women. All subjects were in generally good health but had scarring alopecia, traction alopecia, or self-perceived thinning hair associated with poor diet, stress, abnormal menstrual cycle or other hormonal influences.

Procedures

Prospective subjects were evaluated during an initial baseline visit and those who were free of unacceptable scalp disorders were enrolled. Subjects undergoing any diagnostic procedure or treatment for hair loss or thinning hair during the previous 30 days were excluded. Each subject completed a Quality of Life Questionnaire during their baseline visit.

All subjects agreed to maintain their present lifestyle including their current diet, medications, and exercise routines during the study and expressed their willingness to maintain a consistent hair cut, hair color and hair shampooing frequency throughout the study period. The use of tight-fitting hats or hair restraints such as rubber bands was not permitted. Women of child-bearing potential agreed to use a medically approved form of birth control during the study.

Subjects were instructed to take one tablet each morning and evening with water following a meal. The subjects were re-evaluated after 2 and 4 months of treatment. The primary measure of efficacy was changes in a Subject Self-Assessment Questionnaire. Other assessments included a physical examination, scalp examination, and vital signs.

Safety Measures

At each clinic visit, subjects underwent a brief physical exam including vital signs and were questioned about any possible adverse events.

Ethics

Each subject provided signed informed consent and photographic release forms prior to participating in any study-related activities. This study was performed in accordance with the guidelines for the protection of human research subjects.

Results

The Quality of Life Questionnaire revealed thinning hair results in embarrassment, affects self-esteem and causes most subjects to try to hide their thinning hair. Following treatment with Viviscal, the greatest change in hair growth and hair quality occurred during the initial 2 months of treatment (Table 1, Figure 1). Increased changes continued to occur after that time except there was a very slight decrease in the number of hairs lost on an average day. For other self-assessment parameters, increased changes also occurred throughout the study period but the greatest changes occurred between 2 and 4 months (Table 1, Figure 2). There were no reports of adverse events.

Conclusion

These results indicate that African-American women with thinning hair suffer diminished confidence and self-esteem and they often take steps to hide their condition. The twice-daily administration of Viviscal is associated with rapid improvements in hair growth and appearance. Subjects also experienced ongoing improvements in the quality and appearance of their skin, nails, eyelashes and eye brows. Viviscal is safe and well-tolerated when used as directed.

Acknowledgment

This study was sponsored by Lifes2good, Inc., Chicago, IL, USA.

Figure 1. Effects of Viviscal Treatment on Hair Growth After 2 and 4 Months of Treatment

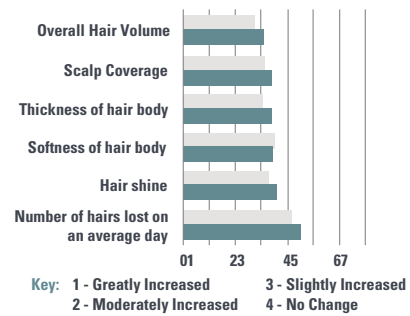


Figure 2. Other Beneficial Effects of Viviscal After 2 and 4 Months of Treatment

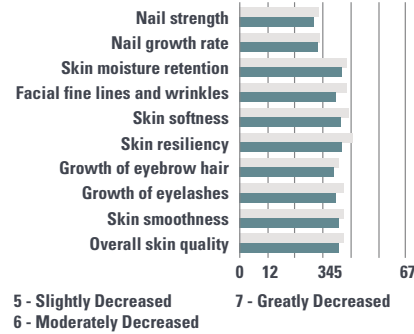


Table 1. Subject Self-Assessment Questionnaire Responses after 2 and 4 Months of Treatment

Please review each of the parameters below and check the most appropriate answer:

Patient	Overall hair volume	Scalp coverage	Thickness of hair body	Softness of hair body	Hair shine	Number of hairs lost on ave. day	Nail strength	Nail growth rate	Skin moisture retention	Facial fine lines and wrinkles	Skin softness	Skin resiliency	Growth of eyebrow hair	Growth of eyelashes	Skin smoothness	Overall skin quality
1	3/3	3/3	2/3	4/3	4/2	5/5	2/2	2/2	4/3	4/3	4/3	4/3	4/3	4/4	4/3	3/3
2	1/1	2/3	4/2	0/4	0/0	7/0	1/1	2/2	0/3	0/4	0/4	4/4	4/4	4/4	4/0	4/0
3	2/1	4/2	4/2	4/5	4/5	4/6	3/3	4/3	4/5	4/3	4/4	4/4	4/4	4/0	4/4	4/4
4	4/4	4/4	5/6	1/1	4/4	0/3	1/1	1/1	4/4	4/4	4/4	4/4	3/2	4/4	4/4	4/3
5	2/2	2/3	1/2	1/4	2/4	4/4	4/4	3/4	4/4	4/4	4/4	4/4	4/4	3/3	4/4	4/3
6	3/4	2/5	3/4	3/4	4/2	4/4	3/2	2/1	3/4	4/4	3/4	4/4	4/2	2/1	2/2	2/3
7	2/0	2/0	3/0	3/0	2/0	7/0	2/0	2/0	3/0	4/0	4/0	4/0	2/0	3/0	4/0	4/0
8	3/2	3/3	3/2	4/1	4/1	4/4	4/5	4/5	4/4	4/4	4/3	4/4	2/3	4/4	4/4	4/4
9	4/4	5/5	3/4	3/4	3/4	3/4	3/4	3/4	3/4	3/4	3/4	4/4	4/4	4/3	4/4	4/4
10	2/4	2/3	2/4	4/4	2/4	5/4	2/4	2/4	4/4	4/4	4/4	4/4	4/4	5/4	4/4	4/4
11	2/3	2/3	1/2	4/3	4/4	6/6	5/5	5/5	4/4	4/4	4/4	4/4	5/6	4/5	4/4	4/4
12	3/3	6/3	6/4	6/3	4/3	2/4	4/1	5/2	4/2	6/2	4/6	4/1	3/1	3/2	3/3	4/3
13	4/6	4/7	4/6	3/6	4/7	4/0	5/4	5/4	4/6	4/4	4/6	4/6	5/6	4/5	4/5	4/5
14	4/0	3/0	4/3	4/4	4/4	3/1	4/3	4/4	4/4	4/4	4/4	5/4	4/4	4/4	4/4	4/3
15	2/3	2/2	2/4	4/4	1/3	1/5	1/1	1/1	4/4	4/4	4/4	4/4	1/1	4/4	3/4	3/4
16	0/3	0/2	0/3	5/1	4/4	0/7	2/1	2/1	4/1	4/1	4/1	4/1	4/3	4/2	4/2	4/2
MEAN	2.7/3.1	3.1/3.4	3.1/3.4	3.5/3.4	3.3/3.6	4.2/4.5	2.9/2.7	2.9/2.8	3.9/3.7	3.9/3.5	4.0/3.7	4.1/3.7	3.6/3.4	3.8/3.5	3.8/3.6	3.8/3.6