Viviscal®
professional

Hair Growth Program

Clinical Trials and Conducted Research

Viviscal®
professional

Hair Growth Program

At Viviscal, we understand hair.

We have combined over 20 years of research and expertise to create the complete Viviscal Hair Growth and Hair Care Program.

Viviscal was originally developed in the late 1980s in Scandinavia with the first clinical trial proving its efficacy being published in 1992 in ***The Journal for International Medical Research***. Since then, we have conducted numerous trials internationally to prove the efficacy and safety of Viviscal supplements to nourish thinning hair and promote existing hair growth from within.

Viviscal contains the exclusive marine complex AminoMar® which is unique to Viviscal supplements.

SCIENTIFICALLY FORMULATED

AminoMar®

MARINE COMPLEX

Today, Viviscal supplements are the number 1 hair growth supplement for women in the US* with over 3.5 million units sold globally since the products inception and during 2013, one box of supplements was sold every minute**.

At Viviscal, we are continually investing in further clinically trials globally combined with an intensive R&D program to ensure product efficacy and advancements for our consumers.

*US IRI Sales Data 52 weeks ending 14th June 2014.

**Viviscal supplements sales globally during 2013

Published and Conducted Research on Viviscal® with Exclusive Key Active AminoMar® Marine Complex to Reduce Hair Shedding and Promoting Hair Growth

Viviscal®
Hair Growth Program

YEAR	NAME OF CLINICAL STUDY	STATUS	DOUBLE BLINDED	PLACEBO CONTROLLED	PARTICIPANTS*	KEY RESULTS	CONCLUSIONS
2014	**A 3-Month Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy of a New Oral Supplement in Women with Self-perceived Thinning Hair.** *By Glynis Ablon, MD, Ablon Skin Institute Research Center, Manhattan Beach, CA.*	Submitted for publication in 2014	Yes	Yes	60 females	Statistically-significant results were observed in the active group versus the placebo group with respect to: • **32% increase** in terminal hairs after **3 months** • After 3 months there was a significant self-perceived improvements in overall **hair volume, scalp coverage and hair strength.**	The results of this study demonstrate that the twice daily administration of Viviscal for 90 days increased the number of terminal hairs and decreased hair shedding in Caucasian, Hispanic and Asian women with self-perceived thinning hair. These changes were associated with improved hair quality including overall hair growth, increased hair diameter and increased hair strength. There were no reports of adverse events.
2014	**A 6-Month Randomized, Double-blind, Placebo-controlled Multi-Center Study Evaluating the Efficacy of a New Oral Supplement in Women with Self-perceived Thinning Hair.** *By Glynis Ablon, MD, Ablon Skin Institute Research Center, Manhattan Beach, CA, Steven Dayan, MD, DeNova Research, Chicago, IL*	Submitted for publication in 2014	Yes	Yes	40 females (3 withdrew from the Viviscal group and 1 from the placebo group before study completed)	Statistically-significant results were observed in the active group versus the placebo group with respect to: • **57% increase** in terminal hairs after **3 months** • **80% increase** in terminal hairs after **6 months** • **12% increase** in hair diameter after **6 months** • After 3 and 6 months there was a significant self-perceived improvements in overall **hair volume, scalp coverage, hair and nail strength**	The daily administration of Viviscal was associated with a **statistically significant increase in the number of terminal and vellus hairs** and also a statistically significant **increase in hair thickness** among women with self-perceived thinning hair. The majority of study participants in the Viviscal group perceived significant improvements in their skin and hair quality and quality of life. Viviscal exhibited an excellent safety profile.
2014	**A 6-month clinical trial to determine, whether Viviscal® dietary/food supplement containing marine proteins shows statistically-significant benefits in reducing hair shedding and increasing hair diameter in females with sub-clinical hair thinning/loss.** *By Stephers & Associates. Thomas J. Stephers & Associates, Inc. Dallas Research Center, 3210 Keller Springs Road, Suite 130, Carrollton, Texas 75006, USA.*	Submitted for publication to **The Journal of Dermatological Treatment** in 2014. Abstract presented at the **World Congress for Hair Research 2013**.	Yes	Yes	72 females	Statistically-significant results were observed in the active group versus the placebo group with respect to: • a **7.4% increase in hair diameter** after 6 months • an **18% reduction in hair shedding** after 3 months.	This study concludes that Viviscal® dietary/food supplement containing marine proteins shows statistically-significant benefits in **reducing hair shedding and increasing hair diameter** in females with sub-clinical hair thinning/loss.
2014	**A 6-month clinical trial demonstrating the Efficacy of a Nutriceutical for Promoting Hair Growth using Digital Photography Technique with Posterior Image Analysis.** *By Medical Dermatologist Leila Bloch, Clinica Bloch, Sao Paulo, Brazil.*	Submitted for publication in 2014	No	No	52 females	The self-assessment questionnaires observed improvements after 6 months of • **94% in hair volume** • **92% hair thickness** • **91% in nail growth rate** and • **92% in nail strength.** Quality of Life Questionnaire showed the greatest improvements were related to **self-esteem** and **self-confidence**.	The use of Viviscal was associated with a **significant increase in the total number of hair strands** and a **decreased in the number of telogen hairs**. A high proportion of treated subjects reported favorable outcomes to various attributes of hair quality overall Quality of Life improvements.
2012	**A 6-month randomized, double-blind, placebo controlled study evaluating the efficacy of an oral supplement Viviscal in women with self-perceived thinning hair.** *By Glynis Ablon, MD, FAAD, of the Ablon Skin Institute Research Center, University of California, Los Angeles, California.*	Published in **The Journal of Clinical and Aesthetic Dermatology**, November 2012	Yes	Yes	15 females	• **111% increase in terminal hairs after 3 months** versus no change amongst the placebo subjects. • **125% increase in terminal hairs after 6 months** versus no change amongst the placebo subjects. • After 3 and 6 months there was a significant self-perceived improvements in **overall hair volume, thickness and scalp coverage.**	The study concludes that Viviscal® safely and effectively promotes significant **hair growth in women with temporary hair thinning.**
2011	**A 4-Month Study Evaluating the Efficacy and Tolerability of an Oral Supplement for the Treatment of Thinning Hair in African American women.** *By Brooke Jackson, MD, Skin Wellness Center of Chicago, Chicago,IL, USA.*	Conducted in 2011	No	No	16 African American females	Following treatment with Viviscal, the greatest **change in hair growth and hair quality occurred during the initial 2 months of treatment.** 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.	The study concludes that the twice daily administration of Viviscal® is associated with **rapid improvements in hair growth and appearance in African-American women.** Subjects also experienced ongoing improvements in the quality and appearance of **their skin, nails, eyelashes and eye brows.**
2010	**A pilot consumer research study to evaluate the overall acceptability of a Viviscal supplement in females with self perceived thinning hair associated with poor diet, stress, hormonal influences, or abnormal menstrual cycles.** *By Thomas J. Stephers & Associates, Inc. on behalf of Lifes2good Inc.*	Conducted in 2010	No	No	16 females	Analysis of hair counts showed a directional reduction in hair shedding. After a 10 week period, there was an average **46% reduction in hair loss** reported. **75% saw an increased thickness** in the body of their hair and **75% saw an increase in overall hair volume**.	Viviscal works well for all ethnic backgrounds, including Caucasian, Asian, African American and Hispanic. **It works well for women and for various reasons/causes of hair loss such as poor diet, everyday stress, and hormonal influences.**
1997	**Treatment of Androgenic Alopecia* with a marine-based (Viviscal) Extract of proteins and polysaccharides for 6 months.** *By Jose Marcos Pereira.*	Published in **Revista Brasileira de Medicina**, March 1997. Vol 53; No. 3; p. 1-5	No	No	200 males (178 completed the study)	• **75.3%** of patients observed a significant **decrease in hair loss** • **14.6%** of patients showed **partial regrowth**	Results suggest the use of marine-based polysaccharides are beneficial for treatment of Androgenetic alopecia in order to **stabilise hair loss**. Also, the earlier Androgenetic alopecia is treated the greater the likelihood of positive results.
1996	**Treatment of Alopecia Areata, Alopecia Totalis and Alopecia Universalis with oral Viviscal for 12 months.** *By M. Majas and O. Puurste.*	Published by **Swedish Alopecia Society** in 1996	No	No	55 females 23 males	After six months of treatment: • **92% of areata group** showed **regrowth** of permanent hair. After four months of treatment: • **83.3% of totalis group** showed **regrowth** of permanent hair and • **31.8% of universalis group** showed regrowth of permanent hair after five months. • **complete cure was observed in 14% of areata, 25% of totalis and 5% of universalis.**	**Long-term use of Viviscal effectively induces regrowth of hair in patients with alopecia areata and alopecia totalis.** Oral use of the treatment for 8-12 months is recommended.
1994	**Treatment of hereditary Androgenic Alopecia* in middle aged males by combined oral and topical administration of special marine extract-compound (Viviscal) for 8 months.** *By A. Lassus, J. Santalahti and M. Sellmann.*	Published in **Les Nouvelles Dermatologiques, Anglo-French International Dermatology**. 1994. No. 13 p. 254-255	No	No	30 males	**Hair loss stopped for 100%** of subjects after two months treatment. **43% showed total regrowth. 23%** showed **three quarter regrowth. 13%** showed **half regrowth** & **13%** showed **30-50% regrowth.**	**Viviscal is effective in the treatment of Androgenic alopecia in both young & middle aged males.** Weight dependant dosage of the oral treatment combined with topical treatment is the most effective mode of using Viviscal.
1992	**A comparative study of a new food Supplement, Viviscal, with fish extract for the treatment of Hereditary Androgenic Alopecia in young males.** *By Lassus & E Eskelinen. Department for Dermatological Research, ARS-Medicina, Helsinki, Finland*	Published in **The Journal of International Medical Research**. Nov. 1992. 20: p. 445-453	Yes	Yes	40 males (3 withdrew from placebo group before study completed)	**100%** of treated subjects reported that **hair loss had stopped after 2 months** of treatment. **Mean increase in non-vellus hair of 36%** was recorded in patients after 6 months treatment. **95% of subjects showed both clinical and histological cure.**	Viviscal appears to be the first highly active treatment for **androgenic alopecia in young males.**
1992	**Treatment of Alopecia Areata and Alopecia Totalis with Viviscal.** *By Prof. Dr. A. Lassus, J. Santalahti.*	Conducted in 1992. Submitted for publication in **The Journal of American Academy of Dermatology**	No	No	40 (20 male) (20 female)	**85% of subjects with Alopecia Areata were completely cured** & 10% showed significant improvement. **25% of subjects with Alopecia Totalis were completely cured** & 20% showed significant improvement.	**Considering severe nature of treated subjects, results are definitely impressive & support conception that Viviscal seems an excellent method for inducing hair growth.** Viviscal might be a new alternative that alters the clinical course of Alopecia Areata & Alopecia Totalis.

Lifes2good

*Androgenetic Alopecia is the same disease in both genders – only difference being area of head affected. Treatment is the same.

Note: AminoMar® is the key active of the oral supplement Viviscal which was assessed in the study.
Only Viviscal supplements contain AminoMar®

A Randomized, Double-blind, Placebo-controlled Multi-Center Study Evaluating the Efficacy of a New Oral Supplement in Women with Self-perceived Thinning Hair

Glynis Ablon, MD, Ablon Skin Institute Research Center, Manhattan Beach, CA, U.S.A.;
Steven Dayan, MD, DeNova Research, Chicago, IL, U.S.A.

Introduction

Viviscal has been designed to promote hair growth in women suffering from temporary thinning hair (Viviscal® Oral Tablets; Lifes2good, Inc., Chicago, IL). The key ingredients in this product are AminoMar®, a proprietary blend of shark powder and mollusk powder which are derived from sustainable marine sources and undergo specific refining processes.

A previous study demonstrated the ability of Viviscal Oral Tablets to increase the number of terminal and vellus hairs when administered for 180 days (1). Using a larger number of subjects and a second clinical facility, the purpose of this 180-day, randomized, double-blind, placebo-controlled study was to assess the ability of Viviscal Tablets to promote the growth of terminal hairs and show an increase in hair diameter in adult women with self-perceived thinning hair associated with conditions such as ageing, diet, stress, hormonal influences or other lifestyle related conditions.

Methods

Study Subjects

Women 21-75 years of age with self-perceived thinning hair associated with aging, poor diet, stress, hormonal influences or abnormal menstrual cycles.

Study Procedures

An approximately 2 cm x 2 cm (4 cm^2) target area was selected for each subject where the frontal hairline and lateral hairline meet (hairline junction). Digital images and macrophotographs of the target areas were obtained at the beginning of the study and at each clinic visit. Subjects were randomized in double-blind fashion to receive the oral supplement or placebo and instructed to take one tablet twice daily, once in the morning and once in the evening following a meal, and to maintain their normal hair care routine for the study duration.

Results

Subject Enrollment

Twenty adult female subjects were randomized to receive Viviscal or placebo of which 17 and 19 completed the study, respectively.

Primary Endpoint

The primary endpoint was change in hair counts using phototrichogram analysis after 180 days. Among the Viviscal-treated subjects, there was a significant increase in the number of terminal hairs between baseline and 90 and 180 days ($p<0.0001$). The number of vellus hairs was also significantly increased but only at 180 days ($p=0.0001$) (Table 1). There was no significant change in terminal or vellus hairs among placebo-treated subjects. The change in hair thickness are apparent in the patient shown in Figure 1.

Secondary Endpoint

There was a significant increase in the diameter of terminal hairs among Viviscal-treated subjects ($p=0.001$) (Table 1) but not placebo-treated subjects. Smaller improvements in eyelashes, eyebrows and nails did not achieve significance. Responses to the Self-Assessment Questionnaire at 90 and 180 days are summarized in Table 2. There was also a significant improvement in the response to eight of the 13 Quality of Life Questionnaire questions (61.5%).The greatest reported improvements were less embarrassment ($p<0.001$) and self-consciousness ($p=0.001$), greater self-esteem ($p<0.001$), and feeling more attractive ($p=0.001$).

Safety Endpoints

There were no reported adverse events.

Discussion

These results are in agreement with a previous study demonstrating Viviscal-treated subjects increased the number of terminal and vellus hairs after 180 days (1). In addition, the current study showed that the use of Viviscal-treated subjects resulted in a significant increase in hair thickness. These objective improvements were associated with subjective improvements in overall hair and skin quality and most quality of life measures in women with thinning hair.

Conclusion

The daily administration of Viviscal Oral Tablets was associated with a significant increase in the number of terminal and vellus hairs and also a significant increase in hair thickness among women with self-perceived thinning hair. The majority of study participants believed the use of Viviscal produced significant improvements in skin and hair quality and quality of life. Viviscal exhibited an excellent safety profile.

Reference
1. Ablon G. A double-blind, placebo-controlled study evaluating the efficacy of an oral supplement in women with self-perceived thinning hair. *J Clin Aesthet Dermatol.* 2012;5:28.

Acknowledgements
This study was sponsored by Lifes2good Inc., Chicago, IL, U.S.A.

Figure 1.
Changes in Hair Growth

Top Row. Macrophotographs of the target area at baseline (left), 90 days (center) and 180 days (right). Bottom row. Digital images of the target area at baseline (left), 90 days (center) and 180 days (right).

Table 1.
Changes in Hair Growth and Hair Diameter

Viviscal	Baseline	Day 90	Day 180	Significance*
Terminal Hairs, N=17	189.88 (15.24)	297.35 (96.09)	341.00 (60.92)	p<.0001
Vellus Hairs, N=17	19.94 (1.71)	20.18 (5.40)	22.82 (2.29)	p=.0001**
Hair Diameter (mm), N=17	0.060 (0.0070)	0.066 (0.0085)	0.067 (0.0085)	p=.006

Placebo	Baseline	Day 90	Day 180	Significance*
Terminal Hairs, N=19	190.26 (20.69)	189.21 (19.89)	192.68 (24.11)	p=NS
Vellus Hairs, N=19	21.79 (5.37)	22.21 (6.71)	22.47 (6.42)	p=NS
Hair Diameter (mm), N=19	0.061 (0.0092)	0.060 (0.0092)	0.061 (0.0114)	p=NS

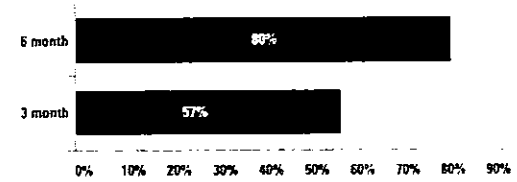
**Repeated measures ANOVA across study days contrasts per treatment group; NS, not significant.*
***Baseline vs. 180 days only*

Table 2.
Self-Assessment Questionnaire Results

Quality	Day 90	Day 180	Day 90	Day 180	Signif.*
1. Overall hair volume	4.76 (0.75)	6.12 (0.99)	4.11 (0.57) 4	.84 (0.90)	p=.056
2. Scalp coverage	4.76 (1.03)	6.12 (0.99)	4.21 (0.79)	4.74 (0.93)	p=.008
3. Thickness of hair body	4.84 (0.81)	5.35 (1.06)	4.37 (0.68)	4.95 (0.91)	p=NS
4. Softness of hair body	4.29 (0.59)	4.94 (1.03)	4.42 (0.61)	4.63 (0.96)	p=NS
5. Hair shine	4.94 (1.03)	5.47 (1.13)	4.21 (0.79)	4.53 (0.77)	p=NS
6. Hair Strength	5.00 (0.87)	5.88 (1.11)	4.68 (0.95)	4.95 (0.91)	p=.019
7. Nail Strength	5.12 (1.05)	5.88 (1.11)	4.89 (1.05)	4.79 (1.03)	p=.030
8. Nail growth rate	5.47 (1.07)	5.94 (1.14)	5.00 (1.00)	4.95 (1.08)	p=NS
9. Growth of eyebrow hair	5.00 (0.87)	5.18 (1.13)	4.32 (0.67)	4.58 (0.90)	p=NS
10. Growth of eyelashes	4.47 (1.28)	5.24 (1.03)	4.42 (0.77)	4.42 (0.90)	p=.086
11. Skin smoothness	4.65 (0.79)	5.24 (1.15)	4.42 (0.77)	4.58 (0.84)	p=.074
12. Overall skin health	4.76 (0.83)	5.29 (1.11)	4.47 (0.91)	4.47 (0.84)	p=.069

**Repeated measures ANOVA; Two-way Interaction of Group by Days. NS, not significant.*

Figure 2.
Change from Baseline in Terminal Hairs Amongst Viviscal Subjects



A Randomized, Double-blind, Placebo-controlled Multi-Center Study Evaluating the Efficacy of a New Oral Supplement in Women with Self-perceived Thinning Hair

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Methods

Study Subjects

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These results are in agreement with a previous study demonstrating Viviscal-treated subjects increased the number of terminal and vellus hairs after 180 days (1). In addition, the current study showed that the use of Viviscal-treated subjects resulted in a significant increase in hair thickness. These objective improvements were associated with subjective improvements in overall hair and skin quality and most quality of life measures in women with thinning hair.

Conclusion

The daily administration of Viviscal Oral Tablets was associated with a significant increase in the number of terminal and vellus hairs and also a significant increase in hair thickness among women with self-perceived thinning hair. The majority of study participants believed the use of Viviscal produced significant improvements in skin and hair quality and quality of life. Viviscal exhibited an excellent safety profile.

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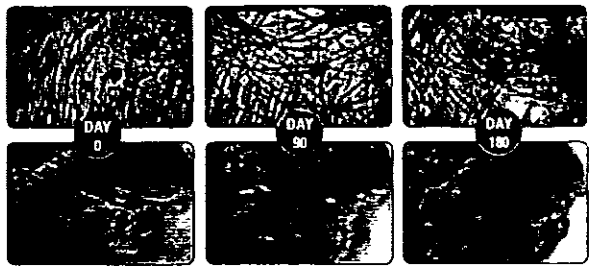

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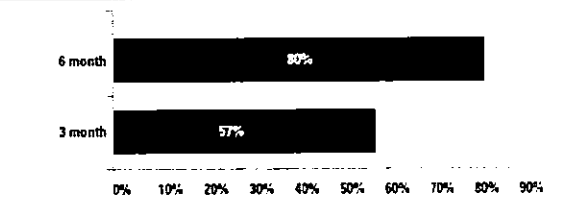
Change from Baseline in Terminal Hairs Amongst Viviscal Subjects



Statistically-significant benefits, in the reduction of hair shedding and increase in diameter of vellus hair, in females with sub-clinical hair thinning/loss, from Viviscal® dietary/food supplement containing marine proteins.

Herndon JH1, Sperber BR2, Stephens TJ1, Rizer RL2, Murphy J3, Ablon G4.
1Thomas J. Stephens & Associates, Inc. Dallas Research Center, 3310 Keller Springs Road, Suite 130, Carrollton, Texas 75006, USA.
2Thomas J. Stephens & Associates, Inc. Colorado Springs Research Center, 5050 Edison Avenue, Suite 202, Colorado Springs, Colorado 80915, USA.
3Lifes2good, 7 Racecourse Business Park Ballybrit, Galway, Ireland.
4Ablon Skin Institute Research Centre, Manhattan Beach, University of California, Los Angeles, California, USA.

INTRODUCTION:

Scalp hair growth is a very powerful social signal in humans. Thus, hair thinning and loss, even at sub-clinical levels, can provoke profound psycho-emotional anxiety. Poor nutrition has been implicated in sub-optimal hair growth, and while drugs are available to treat recognized clinical causes of hair loss, those with sub-clinical hair thinning may seek benefits through nutritional approaches.

AIM:

To determine whether Viviscal® dietary/food supplement containing marine proteins shows statistically-significant benefits in reducing hair shedding and increasing hair diameter in females with sub-clinical hair thinning/loss.

METHODS:

- A multi-site, double-blind placebo controlled clinical study was conducted.
- 96 females with self-perceived thinning hair were enrolled in the study.
- Subjects underwent physical and scalp assessment of their general health status to exclude pre-existing clinically-defined scalp conditions.
- All subjects exhibited skin photo type I-III in the Fitzpatrick skin classification.
- 72 adult females (age range 24-55 years, mean; 44 years) with self-perceived thinning hair were randomly and equally assigned to test and placebo groups and completed a 6-month study involving 6 evaluations.
- Subjects completed a quality of life questionnaire and kept daily diaries.
- Each subject was assigned a unique identity number.
- Hair growth was evaluated using a phototrichogram (Figure 1).
  The tattoo-marked evaluation site was 0.25 cm2.
- Hair type was following by caliber i.e., vellus ≤40 µm and terminal hair >40 µm.
- Hair shedding was assessed using a validated protocol that captured all hairs shed during in-clinic shampooing.

Figure 1. Example of Phototrichogram for Subject 050 (Viviscal® dietary/food supplement)

6 Months

NOTE.

The blue trichogram/count measure 0.5cm X 0.5 cm or 0.25 cm2. Under the conditions of the digital analysis, 1Pixel = 5.411 µm. Vellus is defined as hairs with diameters in the range of ≤40 µm1. Terminal hair is defined as hairs with diameter >40 µm1.

1Green lines indicate terminal hair. Red lines indicate the vellus hairs.

RESULTS.

Subjects taking the Viviscal® showed a statistically significant increase in mean vellus hair calibre after 6 months vs placebo.

The phototrichogram data revealed a statistically-significant increase in mean vellus hair calibre after 6 months in those subjects taking the Viviscal® dietary/food supplement containing marine proteins when compared with those in the placebo control group. This observation suggests that the vellus hairs, which may be increased in these individuals appear to be gaining caliber, and while not yet definable as 'terminal' may with continued dietary supplementation continue to transition towards terminal hair classification.

Figure 2a. Mean Vellus Hair Thickness at Baseline, 3 and 6 months showing a 7.4% increase versus placebo after 6 months.

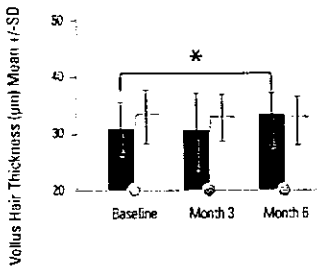


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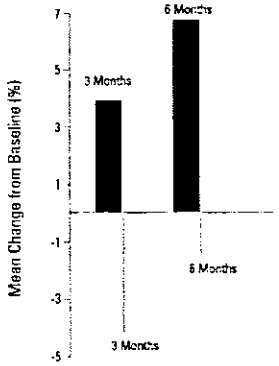
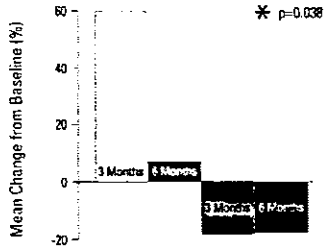
Figure 2b. Changes from Baseline in Vellus Hair Thickness at 3 and 6 months



SUMMARY

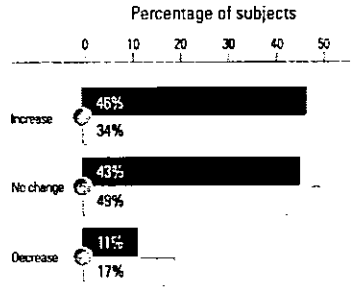
The consumption of Viviscal® dietary/food supplement increased mean vellus hair diameter after both 3 and 6 months for the intention to treat population (Figure 2a & 2b). This improvement attained a significance level of p=0.038 at 6 months. An opposite trend was observed in placebo-treated individuals at both 3 and 6 months. Overall, more than 60% of subjects' vellus hairs showed increased diameter after using the Viviscal® dietary/food supplement, while circa 60% of subjects using the placebo experience continued thinning of their vellus hairs.

Figure 3. Bar Graph of Shed Hair Counts: showing an 18.3% reduction in hair shedding versus placebo after 3 months. Mean Change from Baseline (%)



Counts of the total number of shed hairs were consistently lower for the Viviscal® dietary/food supplement group compared to the placebo group during the course of the study. The Viviscal® dietary/food supplement group showed significantly less shed hair after 3 months of active supplement consumption compared to the placebo group. This observation suggests that there is an attenuation of hair shedding in the Viviscal® dietary/food supplement group.

Figure 4. Bar Graph of of Consumer Questionnaire: Overall Hair Volume - Month 6



RESULTS.

Results from the consumer questionnaire subjective analysis revealed a statistically-significant proportion of positive responses from subjects regarding the Viviscal® dietary/food supplement and insignificant changes in responses from subjects in the placebo group.

OVERALL SUMMARY:

This multi-site, double-blind placebo controlled clinical study conducted in association with an independent contract research organization used a phototrichogram image analysis approach to assess whether daily ingestion of the Viviscal® dietary/food supplement altered hair growth in those with self-perceived hair thinning.

This study revealed:

(A) A clear statistically-significant 7.4% increase (improvement) in the mean vellus hair width after 6 months of Viviscal® dietary/food supplement consumption, when compared to the placebo.

- This observation suggests that the vellus hairs may be transitioning towards terminal hair classification, a process that may continue to develop over treatment time.

(B) A clear statistically-significant 18.3% reduction in hair shedding after just 3 months of Viviscal® dietary/food supplement consumption, when compared to placebo. Counts of the total number of shed hairs were consistently lower for the Viviscal® dietary/food supplement group throughout the trial compared to the placebo group.

- This observation suggests that there is an attenuation of hair shedding in the Viviscal® dietary/food supplement group, which may have favourably impacted the subjects' perception of fewer hair being shed.

REFERENCE

1 Blume-Peytavi U, Hillmann K, Guarrera M. Hair Growth Assessment Techniques. In: Blume-Peytavi U, Tosti A, Whiting D A, Trüeb R, eds. Hair Growth and Disorders. Berlin, Heidelberg, Verlag: Springer; 2008:125-157.

Demonstrating the Efficacy of a Nutriceutical for Promoting Hair Growth using a Digital Photography Technique with Posterior Image Analysis

Medical Dermatologist Leila Bloch,
Clinica Bloch, Sao Paulo, Brazil.

INTRODUCTION:

Healthy-looking hair is a highly desirable aesthetic quality. Numerous hair products have been developed to enhance the overall appearance of hair by increasing shine and volume. Another important attribute is increased hair growth to counteract the effects of normal hair loss. The objective of this study was to test the ability of an oral nutriceutical product (Viviscal® Oral Supplement; Lifes2good, Inc., Chicago, IL) to decrease hair loss and promote hair growth using digital image analysis, and also to assess its ability to enhance overall hair appearance.

METHODS:

Healthy women 25 to 50 years old with severe telogen effluvium and complaints about hair loss were enrolled. Subjects with androgenetic alopecia were excluded. During the baseline visit, a 1 cm x 2 cm area of scalp was shaved and photographed immediately and again after 48 hours (Figures 1 and 2). Digital imaging software was used to identify each hair shaft (Figure 3) and determine which hairs had not grown after 48 hours (Figure 4). Each subject was instructed to take one tablet of Viviscal twice daily after meals and return to the clinic after 90 and 180 days for repeat scalp imaging. At each visit, subjects also completed Self-Assessment and Quality of Life Questionnaires.

Figure 1.
Newly Shaved Scalp

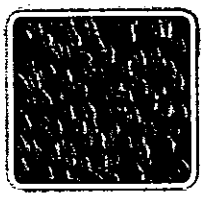


Figure 2.
Scalp after 24 Hours

Figure 3.
Digitally Detected Hairs

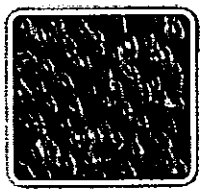
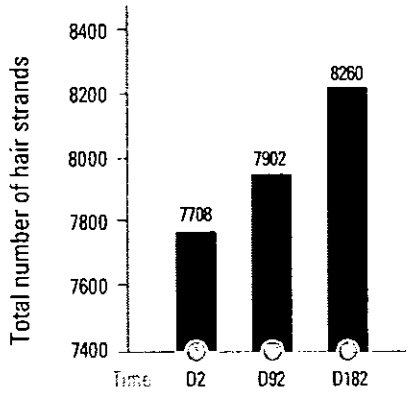


Figure 4.
Non-growing Hairs

RESULTS:

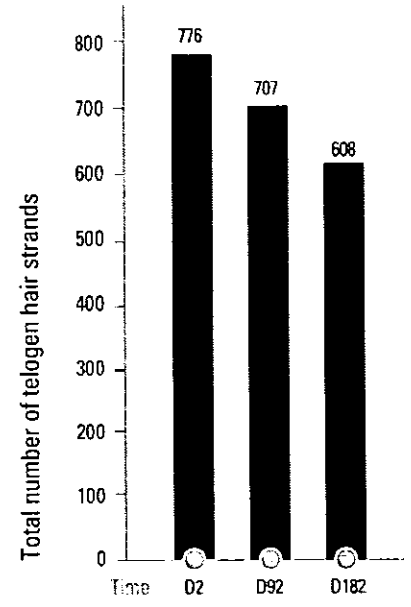
Fifty-two subjects were enrolled. Among the 35 subjects completing the study, 27 (77%) achieved a decrease in the percentage of telogen hair after 90 days and 29 (83%) had a decrease at 180 days. After 90 and 180 days, 25 (71%) and 29 (83%) subjects achieved an increase in the total number of hair strands, respectively. The total number of hair strands for all subjects increased from 7708 at baseline to 7902 at 90 days and 8260 at 180 days. The total number of telogen hairs decreased from 776 at baseline to 707 at 90 days and 608 at 180 days.

Figure 5. Total number of hair strands



Total sum of the number of the subjects' hair strands in D2, D92 and D182

Figure 6. Number of telogen hair strands



Total sum of the number of the subjects' telogen hair strands in D2, D92 and D182

RESULTS CONTINUED:

The response to the Self-Assessment Questionnaire are summarized in Table 1. In addition, the proportion of subjects responding they were happy with their treatment was 94% and 100% at 90 and 180 days, respectively. The results of the Quality of Life Questionnaire are shown in Table 2. There was a modest but consistent improvement across all responses. The greatest improvements were related to self-esteem and self-confidence.

Table 1. Hair Attributes with >60% Favourable Response

	DAY 90	DAY 180
General volume of the hair	-	94%
Coverage of the scalp	-	81%
Thickness of the hair	75%	92%
Smoothness of the hair	86%	97%
Shine of the hair	86%	100%
Nail strength	78%	92%
Nail growth rate	69%	91%
Hydration of the skin	-	86%
Fine lines and wrinkles on the face	-	74%
Softness of the skin	69%	92%
Elasticity of the skin	-	69%
Smoothness of the skin	75%	92%
Health of the skin	81%	94%

Table 2. Mean Quality of Life Questionnaire Responses

	DAY 0	DAY 180
I'm embarrassed by my thinning hair	-	94%
Because of my thinning hair I avoid social gatherings	-	81%
I avoid going out during the day because of my hair loss	86%	97%
My condition affects my self-esteem	78%	92%
Because of my thinning hair, I have problems in my intimate life	69%	92%

CONCLUSION:

The use of Viviscal was associated with a significant increase in the total number of hair strands and a decreased in the number of telogen hairs. A high proportion of treated subjects reported favorable outcomes to various attributes of hair quality overall Quality of Life improvements.

KEY: 1, Very much; 2, A lot; 3, A little bit; 4, Not at all; 5, Irrelevant.

Efficacy of an Oral Supplement in Women with Self-Perceived Thinning Hair: Results from a 6-Month Double-Blind, Placebo-Controlled Clinical Study

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Ablon Skin Institute Research Center, Manhattan Beach, CA, USA.

Published in *The Journal of Clinical and Aesthetic Dermatology*, November 2012.

Background
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 double-blind, placebo controlled study was designed to assess the ability of Viviscal to promote hair growth when administered daily to women with self-perceived thinning hair over a 6-month period.

Subjects
The study enrolled 15 women that were 21-75 years old with Fitzpatrick I-IV photo skin types. All subjects were in generally good health but had self-perceived thinning hair associated with poor diet, stress, abnormal menstrual cycle or other hormonal influences. The enrolled 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 6-month study period. Women of child-bearing potential agreed to use a medically approved form of birth control during the study.

Procedures
Enrolled subjects were evaluated at baseline and after 90 ±7 days and 180 ±7 days of treatment. The investigator selected an approximately 4 cm2 area of scalp at the junction of the frontal and lateral hairlines for assessment. This area was identified using a 3-point system of measurements from the medial canthus, lateral canthus, and preauricular skin pit. This area of scalp was photographed using a digital camera.

Other assessments included a physical examination, scalp examination, and vital signs. Women of childbearing potential were required to provide a negative urine pregnancy test. Enrolled subjects were then randomized to undergo treatment with Viviscal (N=10) or placebo (N=5) in double-blind fashion. Subjects were instructed to take one tablet each morning and evening with water following a meal.

Efficacy Measures
Hair counts in the target area were performed at each clinic visit. The primary measure of efficacy was the change in the number of terminal and vellus hairs in each target area. A secondary measure of efficacy was the change in responses to a subject Self-Assessment Questionnaire.

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

Statistical Analysis
The primary endpoint measures obtained at each evaluation were compared to baseline using a paired t-test. Comparisons between Viviscal and placebo treatments were made using ANOVA. Secondary endpoint parameters were compared using top-box analysis. Differences were considered significant at the level of $p \leq 0.05$.

Ethics
This protocol was approved by a local Institutional Review Board and each subject provided signed informed consent and photographic release forms prior to participating in study-related activities. This study was performed in accordance with the guidelines for the protection of human research subjects as described in 21 CFR Part 50 and according to the standards for Good Clinical Practices and the practice standards of Ablon Skin Institute Research Center.

Results
The mean (SD) age of the women in the Viviscal and placebo treatment groups were 49.9 (8.5) and 47.6 (17.0) years, respectively, and were not significantly different. All subjects were Caucasian and one subject claimed Hispanic ethnicity.

At baseline, the mean number of terminal hairs among placebo-treated subjects was 256.0 (24.1) and remained at 245.0 (22.4) and 242.2 (26.9) after 90 and 180 days, respectively (Table 1). In contrast, the mean number of terminal hairs in the Viviscal-treated subjects was 271.0 (24.2) at baseline, increasing to 571 (65.7) and 609.6 (66.6) after 90 and 180 days, respectively (for each, $p < 0.001$ vs. placebo) (Figure 1). The mean number of vellus hairs among placebo-treated subjects was 57.0 (32.1) at baseline and 68.0 (21.4) and 65.8 (16.6) after 90 and 180 days, respectively. The mean number of vellus hairs among Viviscal-treated subjects was 46.5 (17.7) at baseline and 48.0 (16.2) and 46.5 (14.4) after 90 and 180 days, respectively. The change in hair growth following 180 days of treatment is evident in two patients shown in Figures 2 and 3.

Compared to placebo, the subjects treated with Viviscal for 90 days reported significant improvements in several parameters in the Self-Assessment Questionnaire including Overall Hair Volume ($p=0.007$), Scalp Coverage ($p=0.002$) and Thickness of Hair Body ($p=0.003$) (Table 2). After 180 days of treatment, Viviscal-treated subjects also reported significant improvements in Hair Shine ($p<0.05$), Skin Moisture Retention ($p<0.05$) and Skin Smoothness ($p<0.05$).

Table 1.
Changes in the Number of Terminal and Vellus Hairs, Mean (SD)

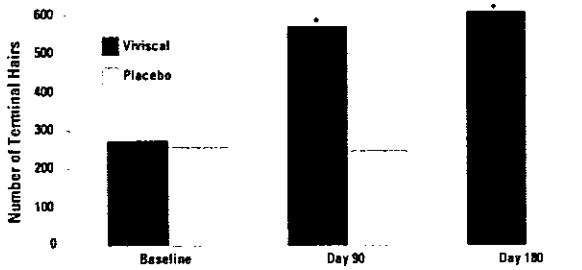
	Viviscal (N=10)			Placebo (N=5)		
	Day 0	Day 90	Day 180	Day 0	Day 90	Day 180
Terminal Hairs	271.0 (24.2)	571.0 (65.7)*	609.5 (66.6)*	256.0 (24.1)	245.0 (22.4)	242.2 (26.9)
Vellus Hairs	46.5 (17.7)	48.0 (16.2)	46.5 (14.4)	57.0 (32.1)	68.0 (21.4)	65.8 (16.6)

*p<0.0001, each vs. placebo, repeated measures ANOVA

Conclusion
The daily administration of a proprietary nutritional supplement significantly increased hair growth after 90 and 180 days. Self-perceived improvements after 90 days were increased after 180 days of additional treatment, suggesting continued improvements may occur with ongoing treatment. No adverse events were reported. These results may represent the first description of increased hair growth in women associated with the use of a nutritional supplement. Based on these promising results, additional studies designed to further assess the use of Viviscal to increase hair thickness and hair counts in larger patient populations are currently under way.

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

Figure 1.
Change in the Number of Terminal Hairs



* = $p < 0.001$ vs. placebo; ANOVA

Figure 2.
Images of Patient Scalp at Baseline, 90 and 180 Days of Treatment

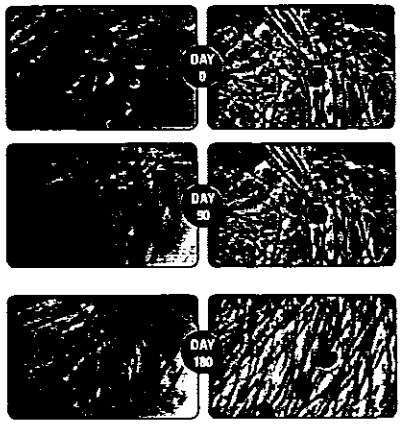


Figure 3.
Images of Patient Scalp at Baseline, 90 and 180 Days of Treatment

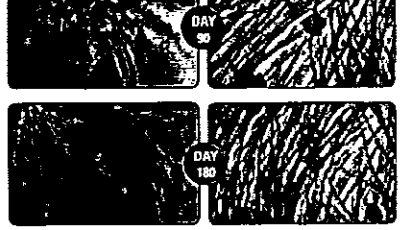


Table 2.
Changes in Self-Assessment Questionnaire, Mean (SD)

	Viviscal (N=10)		Placebo (N=5)	
	90 Days	180 Days	90 Days	180 Days
Overall Hair Volume	2.8 (0.9)*	1.8 (0.8)‡	4.2 (0.4)	3.8 (0.4)
Scalp Coverage	2.6 (0.8)†	1.5 (0.9)*	4.2 (0.4)	4.0 (0.0)
Thickness of Hair Body	2.9 (0.7)‡	2.0 (0.9)*	4.2 (0.4)	4.0 (0.0)
Hair Shine	2.9 (1.1)	2.1 (1.3)†	3.6 (0.9)	3.6 (0.9)
Skin Moisture Retention	3.5 (0.8)	3.0 (0.8)†	4.0 (0.0)	4.0 (0.0)
Skin Smoothness	3.5 (0.7)	3.0 (0.8)†	4.0 (0.0)	4.0 (0.0)

a $p = 0.007$, b $p = 0.002$, c $p = 0.003$, d $p < 0.0001$, e $p < 0.05$, each vs. placebo; ANOVA

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.

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

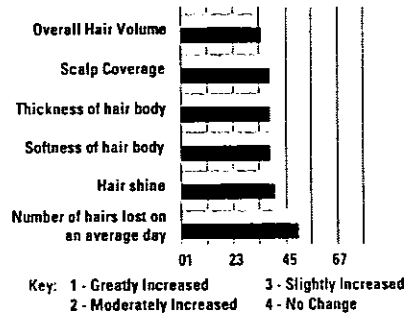
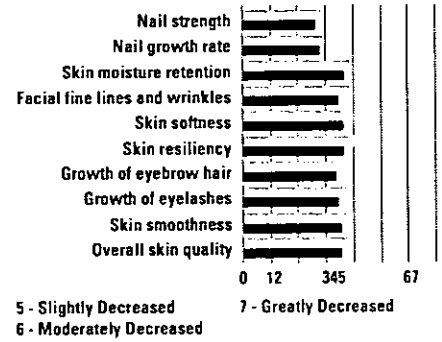


Figure 2.
Other Beneficial Effects of Viviscal After 2 and 4 Months of Treatment



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.

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	0/4	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
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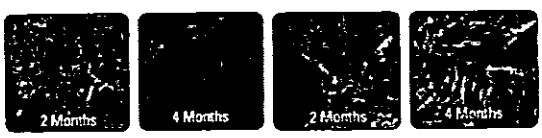
16	0/3	0/2	0/3	5/1	4/4	0/7	2/1	2/1	4/1	4/1	4/1	4/1	4/3	4/2	4/2	4/2
MEAN	2.7/3.1	3.1/3.4	3.1/3.4	3.5/3.4	3.3/3.6	4.2/4.5	2.9/2.7	2.9/2.8	3.9/3.7	3.9/3.5	4.0/3.7	4.1/3.7	3.6/3.4	3.8/3.5	3.8/3.6	3.8/3.6



Treatment of Androgenetic Alopecia with a Marine-Based Extract of Proteins and Polysaccharides.

Pereira JM. Faculty of Medicine, Santa Casa, Sao Pardo, Brazil.
Published in Revista Brasileira de Medicina, March 1997. Vol 53; No. 3: p. 1-5.

INTRODUCTION:

The objective of this study was to assess the effect of a recently discovered oral proteinpolysaccharide mixture obtained from cartilaginous fish in men with androgenetic alopecia (1).

METHODS:

Healthy men with androgenetic alopecia were enrolled. Men with patchy non-telogenic baldness were excluded. Each patient was treated twice daily with a tablet containing 300 mg of a marinebased extract of proteins and polysaccharides for 180 days.

Two areas of the scalp were used to evaluate changes in hair growth using a 5-point baldness severity scale (0, normal hair growth; 1, mild thinning; 2, moderate thinning; 3, severe thinning; 4, baldness). Changes in hair density were determine by counting the number of hairs in a defined area and a trichogram analysis was performed at baseline and 180 days. Scalp thickness in the trichogram area was measured with a needle biopsy and some hairs were cut to measure the rate of hair growth.

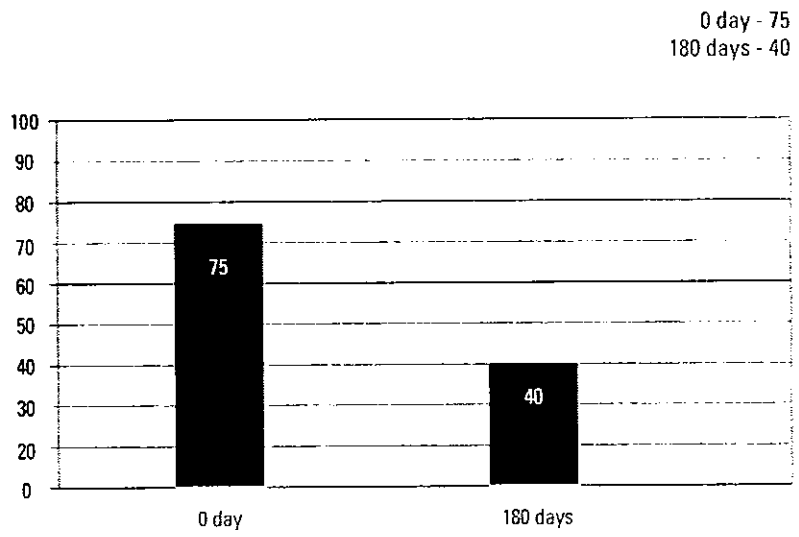
Each subject collected spontaneously lost hair each day for 5 days. Photographs were obtained at baseline and after 180 days. A subgroup of subjects were randomly chosen for safety assessments including complete blood count, serum uric acid, ALT, AST and serum urea.

RESULTS:

A total of 200 men, 17-45 years of age, were enrolled and 178 (89%) completed the study. Sixty-nine patients (34.5%) were <26 years old, 57 (28.5%) were 26-30 years old and 74 patients (37%) were >30 years old.
Thirty subjects were chosen for safety assessments.

Among the evaluable subjects, 356 areas of scalp were assessed and improvement was noted in 21.25%. After 2 months of treatment, 131 subjects (73.5%) had reduced hair loss and 65 subjects (36.5%) noted thickening of their hair; however, 15 patients (8.4%) claimed their bald area had increased in size.The mean baseline hair density was 210 hairs/cm^2 increasing to 218 hairs/cm^2 after 180 days. A comparison of pre and post-treatment photographs clearly showed that clinical cure was achieved in many subjects.

Graph 1 Changes from baseline in Hair Shedding



The mean baseline daily hair loss was 75 hairs, decreasing to 40 after 180 days with a slight increase in the size of telogenic hairs. In addition, 160 subjects (89.9%) reported improved beard growth and 49 (27.5%) observed stronger nails and better nail growth. No changes in scalp thickness occurred.The mean rate of hair growth was 0.39 mm per day but increased in 138 subjects (75%) to 0.44 mm per day.

The baseline telogenicity ranged from 30-70% in the trichogram area and corresponded with the clinical alopecia severity; however, the following effects on telogenicity were observed:

50-70% for 45 subjects (25.3%) did not change;

40-50% for 76 subjects (42.7%) decreased by 20% in 28 subjects;

25-40% for 57 subjects (32%) decreased 52.6% in 30 subjects.

One subject showed a small transient rise in ALT and AST. No adverse reactions were reported.

CONCLUSION:

These results suggest that the use of a marine-based extract mixture of proteins and polysaccharides is beneficial for treatment of androgenetic alopecia. In early stages of the disorder when balding is mainly qualitative, this treatment results in clinical cure were no reports of adverse events during the 12-month study period.

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Treatment of Alopecia Areata, Alopecia Totalis and Alopecia Universalis with Oral Viviscal® for 12 Months.

Majass M,[1] Puuste O,[1] Prästbacka B,[2] Brorsdotter-Johansson P.[2]
[1]Department of Dermatology, University Central Hospital, Tallinn, Estonia; [2]Swedish Association for Alopecia, Mölndal, Sweden.
Published by Swedish Alopecia Society in 1996.

INTRODUCTION:

Previous studies have demonstrated excellent regrowth of hair in men with hereditary androgenic alopecia (1) and men and women with alopecia areata and alopecia totalis (2). The present study was performed to evaluate the use of Viviscal for the long-term treatment of men and women with alopecia areata, totalis and universalis (3).

METHODS:

Healthy men and women with alopecia areata, totalis and universalis were enrolled. All subjects had previously used conventional treatment methods without satisfactory results. Each subject was instructed to take two tablets of Viviscal daily for 12 months. All subjects completed a questionnaire regarding the start of regrowth of scalp hair and the estimated area of the scalp with regrowth of permanent hair at baseline and after 6 and 12 months of treatment.

RESULTS:

Ninety-seven (97) subjects were enrolled in the study; however, 13 withdrew after 3-4 months due to lack of efficacy leaving 84 evaluable subjects with alopecia areata (N=50), alopecia totalis (N=12) and alopecia universalis (N=22). Demographic characteristics are shown in Table 1.

Among subjects with alopecia areata, permanent hair started to reappear after approximately 6 months of treatment in 46 subjects (92.0%) After 12 months, seven subjects (14.0%) reported complete regrowth of hair (Table 2). Thirty-four subjects (68.0%) were highly satisfied with their results and 10 (20%) reported their results as good.

Among subjects with alopecia totalis, hair regrowth began after 4 months in 10 subjects (83.3%). After 12 months, three subjects reported complete hair regrowth (25.0%). Six subjects (50%) were highly satisfied with their results and four (33.0%) reported their results as good.

Among subjects with alopecia universalis, new hair growth began after 5 months in seven subjects (31.8%). After 12 months, one subject reported complete hair regrowth (4.5%). Five subjects (23%) were highly satisfied with their results and one (4.5%) reported their results as good.

Improved nail growth was reported by all subjects with weak nails prior to the study. There was no significant correlation between hair growth and gender or age of the subjects or the duration of hair loss. No adverse reactions or unexpected events were reported.

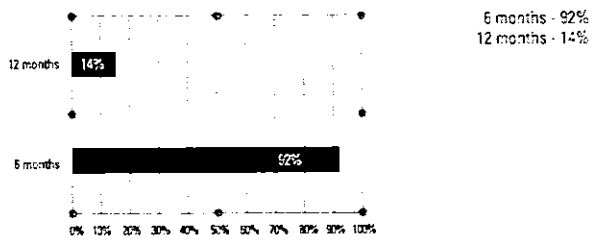
Table 1. Alopecia Type and Demographic Characteristics of Treated Subjects

	Areata N=50	Totalis N=12	Universalis N=22
Male	14	4	5
Female	30	8	17
Mean Age (years)	30.9	26.8	40.0
Mean Duration of Alopecia (years)	6.8	4.9	13.9

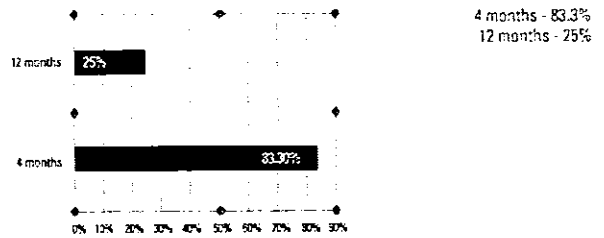
Table 2. Alopecia Type and Demographic Characteristics of Treated Subjects

	Areata N=50	Totalis N=12	Universalis N=22
Mean Time to Hair Regrowth (months)	6.3	4.0	5.4
Percent Regrowth of Scalp Hair, N (%)			
100	7 (14)	3 (35)	1 (5)
90-95	11 (22)	1 (8)	2 (10)
80-85	11 (22)	1 (8)	1 (5)
70-75	5 (10)	1 (8)	1 (5)
60-65	7 (14)	3 (25)	0 (0)
50-55	3 (6)	1 (8)	1 (5)
<50	2 (4)	1 (8)	1 (5)
0	4 (8)	2 (16)	15 (68)

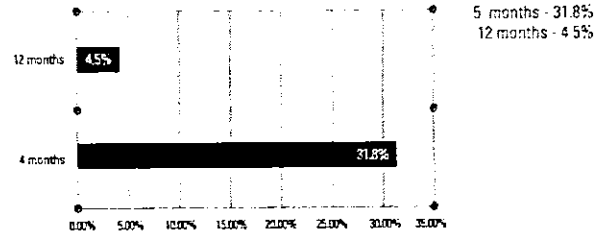
Graph 1 New hair growth reported amongst subjects with Alopecia Areata (N=50)



Graph 2 New hair growth reported amongst subjects with Alopecia Totalis (N=12)



Graph 3 New hair growth reported amongst subjects with Alopecia Universalis (N=22)



CONCLUSION:

Similar to previous studies, the use of Viviscal was associated with substantial hair regrowth in treated subjects including women with alopecia areata, totalis and universalis. Viviscal had its greatest effect in patients with alopecia areata. There were no reports of adverse events during the 12-month study period.

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1. Lassus A, Santalahti 1, Seltmann M. Treatment of hereditary androgenic alopecia in middle-aged males by combined oral and topical administration of special marine extract-compound (Viviscal). Nouv Dermatol 1994;254-255.
2. Lassus A, Santalahti J, Seltmann M. Treatment of alopecia areata and alopecia totalis with ViviScal® (marine derived polysaccharides). Unpublished.
3. Prästbacka B, Brorsdotter-Johansson P. Treatment of alopecia areata, alopecia totalis and alopecia universalis with oral ViviScal® for 12 months. Swedish Association for Alopecia, Mölndal, Sweden, 1996.

Treatment of Hereditary Androgenic Alopecia in Middle-Aged Males by Combined Oral and Topical Administration of Special Marine Extract-Compound (Viviscal).

Lassus A,[1] Santalahti J,[1] Sell mann M[2].
[1]Helsinki Research Centre, Helsinki, Finland; [2]Dermatological Clinic, Leverkusen, Germany.
Published in **Les Nouvelles Dermatologiques, Anglo-French International Dermatology.** 1994. No. 13 p. 254-255.

INTRODUCTION:

The oral administration of a compound derived from marine fish (Viviscal) was shown to be beneficial for treating young men with early male pattern baldness (1). The following 8-month study assessed the effect of oral and topical administration of the same active substance for treating an older population of men with male pattern baldness (2).

METHODS:

Healthy men with hereditary androgenic alopecia (Hamilton scale I-IV) were enrolled. The oral dose of Viviscal was based on body weight: subjects ≤ 80 kg were treated with two tablets daily and subjects > 80 kg received three tablets daily. In addition, Viviscal Lotion was rubbed onto the bald areas of the scalp every evening and the hair was washed with Viviscal Shampoo 2-3 times weekly (both lotion and shampoo contain 1% of the same active ingredients as Viviscal Tablets). Clinical evaluations were carried out at baseline and bimonthly thereafter for 8 months. At each visit the patients were questioned about the severity of hair loss and possible adverse reactions. The total cumulative areas of baldness were measured and epidermal and dermal thickness, elasticity and erythemal index were also assessed.

RESULTS:

Thirty men with a mean age of 40 years (range 34- 48 years) were enrolled. The mean duration of hair loss was 11 years (range 3-20 years and 25 subjects (83.3%) had previously been treated with topical minoxidil and/or photochemotherapy with little or no response. Eleven subjects (36.7%) were smokers. All 30 subjects completed the study.

Hair loss stopped in all subjects after 2 months of treatment. The mean area of total scalp baldness was 39% (11-52%) at baseline, decreasing to 9% (4-25%) after treatment. The extent of hair regrowth is summarized in Table 1. Five of the six subjects with poor results were heavy smokers while 18 subjects (60%) with good response also experienced increased beard growth and two had increased chest hair. The significant increases in epidermal and dermal thickness and elasticity and erythemal indices are shown in Table 1.

All patients experienced mild to moderate drying of the scalp during treatment. No further adverse reactions were reported.

Table 1. Results after 8 Months of Treatment

	Baseline N=30	8 Months N=30
Hair Loss Severity		
Severe	12	0
Moderate	5	0
Mild	13	0
Area of Baldness, cm2 (%)	**39 (11-52)**	**9 (4-25)**
Percent Hair Regrowth		
100	0	13
>75	-	7
50-75	-	4
30-50	-	4
0	-	2
Epidermal Thickness (mm)	0.30	0.46
Dermal Thickness (mm)	2.17	2.62
Elasticity Index	64	77
Erythemal Index	0.209	0.306

Figure 1: Image of scalp of a 40 year old male with androgentic alopecia before treatment.

Figure 2: Image of scalp of the same 40 year old male with androgentic alopecia after treatment.

CONCLUSION:

Viviscal appears to be an effective treatment of androgenic alopecia in both young and middle-aged males.
The increase in erythemal index suggests topical Viviscal may increase capillary circulation. The combination of oral and topical application may be the most effective method of using Viviscal.

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1. Lassus A., Eskelinen E. A comparative study of a new food supplement, Viviscal, with fish extract for the treatment of hereditary androgenic alopecia in young males. *J Int Med. Res.* 1992; 20:445-453.

2. Lassus A, Santalahti J, Sellmann M. Treatment of hereditary androgenic alopecia in middle-aged males by combined oral and topical administration of special marine extract-compound (Viviscal). *Nouv Dermatol.* 1994;254-255.

A Comparative Study of a New Food Supplement, Viviscal, with Fish Extract for the Treatment of Hereditary Androgenic Alopecia in Young Males

Lassus A, Eskelinen E. Department for Dermatological Research, ARS-Medicina, Helsinki. Finland

Published in *The Journal of International Medical Research*. Nov. 1992. 20: p. 445-453

Introduction

Several reports have demonstrated that certain proteins derived from marine fish promote effect on hair growth in women (1,2). The following 6-month, double-blind study was conducted to compare the effects of an extract of marine origin with the same extract containing a silica compound (Viviscal) in men with androgenic alopecia (3).

Methods

Healthy men 20-30 years old with androgenic alopecia classified as III-V on the Hamilton scale were enrolled. The duration of hair loss varied from 2-9 years and most of them had received prior treatments including 2% minoxidil solution (N=33; 82.5%). Subjects were randomized to receive two tablets containing Viviscal (N=20) or fish extract (N=20) daily for 6 months. Patients were seen every 2 months and non-vellus scalp hair counts were performed using a 2.5 cm^2 template. A punch biopsy was obtained within this area at baseline and after 6 months.

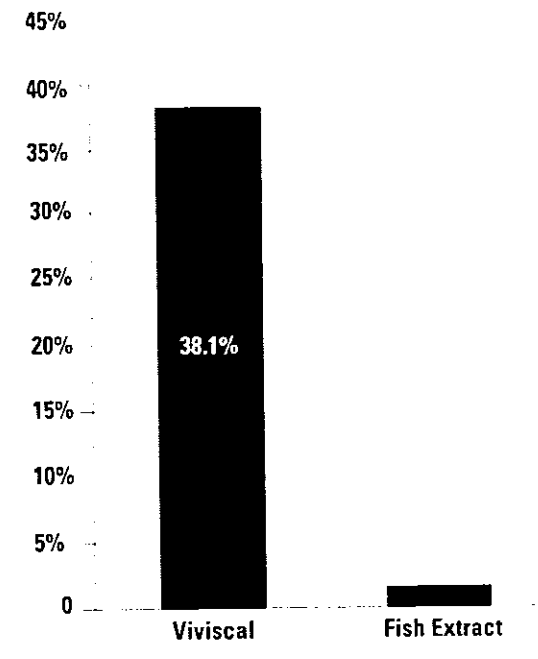
Results

At 6 months, there were 37 evaluable subjects. Three subjects in the fish extract group withdrew due to lack of efficacy or increased hair loss. There was significantly more regrowth of. nonvellus hair throughout the treatment period among Viviscal-treated patients compared to subjects treated with fish extract (Table 1). There was a mean increase of 472 new non-vellus hairs increased in the Viviscal group (38.1%) vs. 26 in the fish extract group (2.1 %; p<0.00011). Hair loss continued during the entire treatment period in the fish extract group. Subjective estimates of new hair growth by were similar to objective measures. At baseline, histological examination showed typical alopecia in all 40 subjects with mild to moderate perifollicular inflammation. After 6 months. alopecia could no longer be diagnosed in 19 of the 20 patients in the Viviscal group. No adverse reactions were observed in eithertreatment group.

Table 1.
Changes in Non-Vellus Hair Counts After 6 Months

	VIVISCAL		FISH EXTRACT	
Time (Months)	***N***	**Non-vellus Hairs (SD)**	***N***	**Non-vellus Hairs (SD)**
0	20	1238 (73.8)	20	1233 (74.6)
2	20	1318 (42.2)	20	1230 (45.2)
4	20	1419 (95.2)	17	1257 (75.4)
6	20	17101 (18.9)	17	1259 (80.6)
Total Increase, N (%)		472 (38.1%)		26 (2.1%)

Figure 1.
Mean Increase in New Non-Vellus Hairs (%)



Conclusion

The combination of fish extract and silica compound significantly increased the regrowth of non-vellus hair in men with androgenic alopecia. Although the mechanism by which Viviscal increases hair growth has not been elucidated, the silica component may also be important. It is probable that several nutritional factors have a synergistic effect and improve the efficacy of the product.

REFERENCES:
1. Van der Donk J, Passchier J, Knegt-Junk C, et al. Psychological characteristics of women with androgenetic alopecia: a controlled study. *Br J Dermatol.* 1991;125:248-252
2. Reid EE, Haley AC, Borovicka JH, et al. Clinical severity does not reliably predict quality of life in women with alopecia areata, telogen effluvium, or androgenic alopecia. *J Am Acad Dermatol.* 2012;66:e97-102
3. Ablon G. A double-blind, placebo-controlled study evaluating the efficacy of an oral supplement in women with self-perceived thinning hair. *J Clin Aesthet Dermatol.* 2012;5:28-34

Patient Satisfaction Following the Use of a Hair Fiber Filler Product to Temporarily Increase the Thickness and Fullness of Thinning Hair

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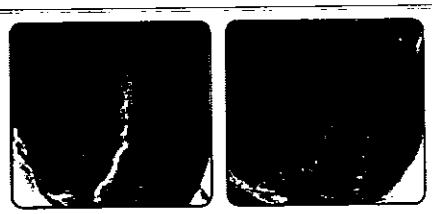
Pinski Dermatology and Cosmetic Surgery, Chicago, IL, USA.

Introduction
Hair loss can have a devastating effect on self-image and self-esteem, especially for women (figure 1, 2). A recent randomized, placebo-controlled, double-blind study demonstrated the ability of a new oral supplement to increase hair growth in women with thinning hair after 90 days (3 months) (Viviscal® Hair Growth Program; Lifes2good, Inc., Chicago, IL). A companion hair filler fiber product has been developed for use with the Viviscal Hair Supplement. The product is designed to be applied to areas of thinning hair and temporarily provide the appearance of fuller, thicker-looking hair instantly until hair growth occurs. A series of questionnaires were developed to measure user satisfaction with the product and assess the effects of thinning hair on their quality of life.

Methods
Subjects were recruited from patients treated at a dermatology and cosmetic surgery clinic. Each subject completed a pre-treatment quality of life questionnaire prior to applying the hair filler fiber under the supervision of the clinic staff. To match hair color as closely as possible, the hair filler fibers are available in six natural-looking colors including black, dark brown, light brown, auburn, blonde and grey (Viviscal® Hair Filler Fibers; Lifes2good, Inc., Chicago, IL). Pre- and post-application photos were obtained and subjects completed post-application satisfaction questionnaires.

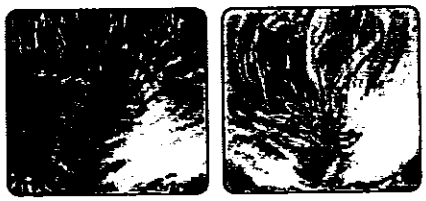
Results
The study subjects included 20 men and 20 women. The pre-treatment Quality of Life Questionnaire showed that thinning hair had the greatest impact on being embarrassed, feeling unattractive and a negative effect on self-esteem. Following the application of the hair fillers, mean scores on the Self-assessment Questionnaire were all very favorable (Table 1). Hair qualities showing the greatest improvement were Scalp Coverage and Hair Fullness while the area showing the least improved change was Softness of Hair. The results of the Product Satisfaction Questionnaire indicate a high level of satisfaction (Table 2). The ability of the hair fiber product to effectively cover the scalp and match hair color is shown in Figures 1-3.

Figure 1.
Woman with Dark Brown Hair



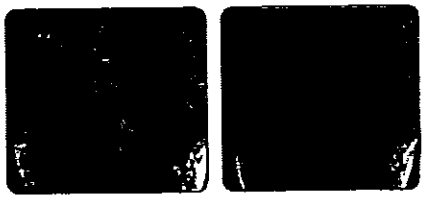
Before Treatment | After Treatment

Figure 2.
Woman with Grey Hair



Before Treatment | After Treatment

Figure 3.
Man with Brown Hair



Before Treatment | After Treatment

Table 1.
Self- Assessment Questionnaire

Please review each of the parameters below and check the most appropriate answer from 1 (Greatly Decreased) to 7 (Greatly Increased):

	Mean	Median (min, max)
1. Overall hair volume	5.7	6 (0, 7)
2. Scalp coverage	6.3	7 (2, 7)
3. Thickness of hair body*	5.6	6 (0, 7)
4. Softness of hair	4.7	4 (0, 7)
5. Hair quality*	5.2	5 (0, 7)
6. Hair Fullness	6.0	6 (0, 7)
7. Personal Attractiveness	5.7	6 (1, 7)
8. Confidence*	5.7	6 (3, 7)

*N=39

Table 2.
Product Satisfaction

Please rank the following questions on a scale of 1 to 5 that matches your opinion for each characteristic with 5 being the highest:

	Mean	Median (min, max)
1. Was this product easy to use?	4.6	5 (4, 5)
2. Would you use it yourself?	4.4	5 (4, 5)
3. Would you recommend it to a friend?	4.4	5 (4, 5)
4. Overall product rating?	4.5	5 (4, 5)

Conclusion
A companion hair filler fiber product temporarily provides the appearance of fuller, thicker-looking hair. Overall consumer satisfaction of the product was high, noting increased scalp coverage and hair fullness with the ability of the product to match hair color.

REFERENCES:
1. Van der Donk J, Passchier J, Knegt-Junk C, et al. Psychological characteristics of women with androgenetic alopecia: a controlled study. *Br J Dermatol.* 1991;125:248-252
2. Reid EE, Haley AC, Borovicka JH, et al. Clinical severity does not reliably predict quality of life in women with alopecia areata, telogen effluvium, or androgenic alopecia. *J Am Acad Dermatol.* 2012;66:e97-102
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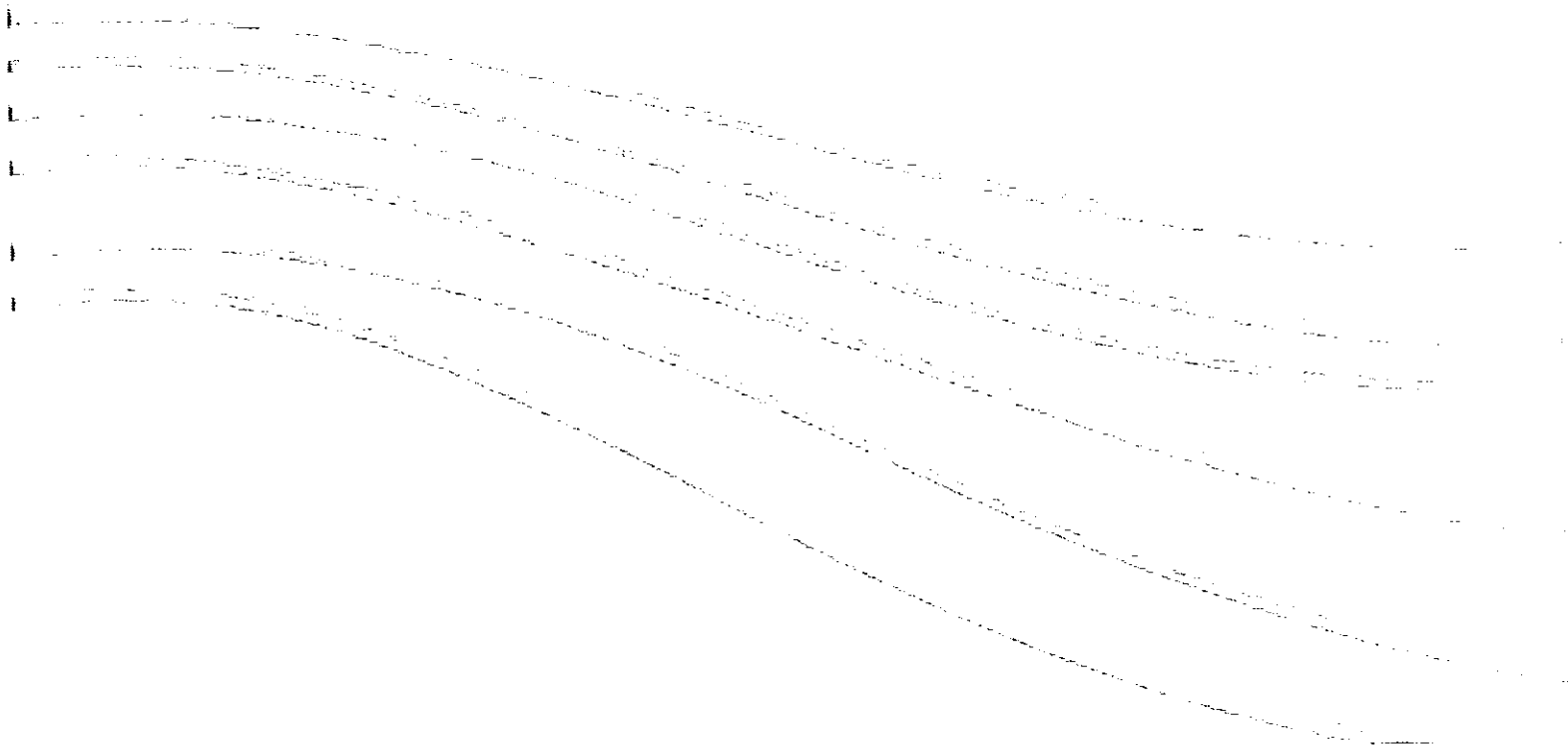

Viviscal©
Hair Growth* Program

Viviscal Supplements Clinical Trials

At Viviscal, we have been researching hair loss for over 20 years and we are very proud to have developed the most researched hair growth* supplement. Viviscal oral supplements have been tested in clinical trials with some of the world's leading dermatologists and physicians.

Viviscal dietary supplements are not treatments for any hair loss caused by the alopecia conditions discussed, or by extreme stress or psychiatric disorders. Consumers must consult medical professionals for the diagnosis and treatment of such conditions.

	2014	2013	2012	1997
	40 females	72 females	15 females	178 males
RESEARCHER	Glynis Ablon, M.D., FAAD, Ablon Skin Institute Research Center, University of California, Los Angeles, California, U.S.A.; and Steven Dayan, M.D., FACS, DeNova Research, Chicago, Illinois, U.S.A.	Thomas J. Stephens & Associates, Inc., Dallas Research Center, Carrollton, Texas, U.S.A.	Glynis Ablon, M.D., FAAD, Ablon Skin Institute Research Center, University of California, Los Angeles, California, U.S.A.	Jose Marcos Pereira, M.D., Sao Paulo, Brazil
RESULTS	(In progress) 6-month, multi-center, randomized, double-blind, placebo-controlled clinical trial Hypothesis: ingestion of oral Viviscal supplement will strengthen and promote terminal hairs in female subjects, ages 21-75, who have self-perceived thinning hair Estimated publication date: summer 2014	6-month double-blind, placebo-controlled clinical trial demonstrated statistically significant results: 18.3% reduction in hair shedding vs. placebo 7.4% increase in hair thickness vs. placebo Abstract presented: 7th World Congress for Hair Research (2013; Edinburgh, Scotland)	6-month double-blind, placebo-controlled clinical trial demonstrated statistically significant results: 125% increase in terminal hairs vs. placebo group Significant, self-perceived improvements in overall hair volume, thickness and scalp coverage Published: *The Journal of Clinical and Aesthetic Dermatology* (Nov. 2012)	Results suggest marine-based polysaccharides are beneficial for treatment of androgenetic alopecia** in order to stabilize hair loss; early treatment increases likelihood of positive results. 75.3% participants observed decrease in hair loss 14.6% participants observed partial regrowth Published: *Revista de Brasileira Medicinas* (March 1997)

	1997	1994	1992
	84 females	30 males	37 males
RESEARCHER	M. Majas and O. Puuste, Department of Dermatology, University Central Hospital, Tallin, Estonia	A. Lassus, J. Santalahti and M. Sellmann	A. Lassus and E. Eskelinen, Department for Dermatological Research, ARS-Medicina, Helsinki, Finland
RESULTS	12-month treatment of alopecia areata, alopecia totalis and alopecia universalis with Viviscal oral supplements demonstrated that Viviscal effectively induces regrowth of hair in patients with alopecia areata and alopecia totalis. Recommend oral use of treatment for 8-12 months. Complete cure was observed in: 25% of participants with alopecia totalis 14% of participants with alopecia areata 5% of participants with alopecia universalis Published: Swedish Alopecia Society (1996)	Viviscal oral supplements are effective in treatment of androgenetic alopecia** in both young and middle-aged males. 100% of participants reported that hair loss had stopped after 2 months of treatment 43% of participants showed total regrowth 23% of participants showed three-quarter regrowth 13% of participants showed half regrowth 13% of participants showed 30-50% regrowth Published: *Les Nouvelles Dermatologiques*, Anglo-French International Dermatology (1994)	6-month double-blind, placebo-controlled trial showed Viviscal oral supplements to be the first highly active treatment for androgenetic alopecia** in young males: 100% of participants reported that hair loss had stopped after 2 months of treatment 38% mean increase in non-vellus hair after 6 months of treatment 95% of participants showed clinical and histological cure Published: *The Journal of International Medical Research* (Nov. 1992)

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

**Androgenetic alopecia is the same disease in both genders – only difference being area of head affected. Note: AminoMar© is the key active ingredient in the oral supplement Viviscal that was assessed in the clinical trials. Only Viviscal dietary supplements contain AminoMar.