Viviscal™

Viviscal™ Clinical Research Overview and Summary

Summary & Table of Contents

Published and conducted research studies on Viviscal™, confirming significant impact on promoting hair growth* and reducing hair shedding in both men and women.

	WOMEN			
3	**Efficacy assessment of a nutraceutical with a marine protein complex in the reduction of female telogen effluvium.** *J Dermat Cosmetol.* 2017;1(2):1-6	Bloch LD, Escudeiro CC, Sarruf FD.	Controlled Monocentric, 6-mth study	Women (ages 25-50) with severe telogen effluvium. (N=35)
4	**A marine protein-based dietary supplement for subclinical hair thinning / loss.** *J Trichology.* 2015;7(4):156 166.	Rizer RL, Stephens TJ, Herndon JH, Sperber BR, Murphy J, Ablon G.	Multisite, Double-blind, Placebo-controlled, 6-mth study	Women (mean age = 44) with self-perceived, sub-clinical thinning hair. (N=72)
5	**A 3-month, randomized, double-blind, placebo-controlled study evaluating the ability of Viviscal™ Extra Strength formulation to promote hair growth & decrease shedding in women with self-perceived thinning hair.** *Derm Res & Pract.* 2015;ID841570:1 8	Ablon G.	Double blind, Placebo-controlled, 3-mth study	Women (mean age = 48.6) with Fitzpatrick photo skin type I-IV & self-perceived thinning hair associated with poor diet, stress, hormone influences or abnormal menstrual cycle. (N=30)
6	**A randomized, double blind, placebo controlled, multi-center, extension trial evaluating the efficacy of a new oral supplement in women with self perceived thinning hair.** *J Clin Aesthet Dermatol.* 2015;8(12):15 21.	Ablon G, Dayan S.	Multisite, Double-blind, Placebo-controlled, 6-mth study	Women (ages 21-75) with self perceived thinning hair associated with poor diet, stress, hormone influences or abnormal menstrual cycle. (N=20)
7	**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(11):28 34.	Ablon G.	Double-blind, Placebo-controlled, 6-mth study	Women (ages 21-75) with Fitzpatrick I-IV photo skin type & self perceived thinning hair associated with poor diet, stress, hormone influences or abnormal menstrual cycle. (N=15)
8	**A 4-month clinical study evaluating the efficacy and tolerability of an oral supplement for the treatment of thinning hair in African American women.** South Beach Symposium, Clinical + Aesthetic Dermatology, 2011:Poster presentation	Jackson B.	Double-blind, Placebo-controlled, 4-mth study	African American women with scarring alopecia, traction alopecia, or self perceived thinning hair associated with poor diet, stress, abnormal menstrual cycle or hormonal influences. (N=16)
9	**A 6-month, randomized, double-blind, placebo-controlled study evaluating the ability of a marine complex supplement to promote hair growth in men with thinning hair.** *J Cosmetic Dermatol.* 2016;0:1-9	Ablon G.	Double-blind, Placebo-controlled, 6-mth study	Men (mean age = 43 for Viviscal™, 46 for Placebo) with thinning hair, associated with clinically diagnosed male pattern hair loss. (N=60)
	MEN			
10	**Treatment of androgenetic alopecia with a marine based extract of proteins and polysaccharides (Viviscal™).** *Revista Brasileira de Medicina.* 1997;53(3):1 10.	Pereira JM.	Controlled Monocentric, Trichogram confirmed, 6-mth study	Men with androgenic alopecia were enrolled; 34.5% < 26 years old, 28.5% = 26-30 and 37% > 30 years old. (N=178)
11	**Treatment of hereditary androgenic alopecia in middle aged males by combined oral and topical administration of special marine extract compound (Viviscal™).** *J Clin Aesthet Dermatol.* 2015;8(12):15 21.	Lassus A, Santalahti J, Sellmann M.	Controlled Monocentric, 8-mth study	Men (mean age = 40) with androgenic alopecia classified as II-V on Hamilton scale. (N=30)
12	**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.	Lassus A, Eskelinen E.	Double blind, Controlled (fish extract), 6-mth study	Men (mean age = 25) with androgenic alopecia classified as III-V on Hamilton scale - 82.5% treated long-term with topical 1% minoxidil for 1 year prior to the study. (N=40)
	MEN & WOMEN			
13	**Treatment of alopecia areata, alopecia totalis and alopecia universalis with oral Viviscal™ for 12 months.** Swedish Alopecia Assoc. (SAA). *Alopecia.* 1996	Majass M, Puuste O, Prästbacka B, Brorsdotter-Johansson P.	Controlled Monocentric, SAA members, 12-mth study	Healthy men & women with alopecia areata, totalis and universalis - mean ages of 30.9, 26.8, & 40.0 respectively. (N=84)
14	**Efficacy and tolerability of Hairgain® in individuals with hair loss: A placebo controlled, double-blind Study.** *J Int Med Res.* 2001;29:2 6	Thom E.	Double blind, Placebo controlled, Cross over, 12-mth study	Men & women (age ≥ 18) with hair loss 1-yr or longer - 93% androgenic alopecia, 7% alopecia totalis, majority previously tried different approaches to hair loss. (N=60)

*existing hair

CONCLUSIONS

With the use of Viviscal™, 83% saw a significant reduction in telogen hair fibers and experienced significant hair growth by 6-months. The number of patients responding to Viviscal™ at 3-months was high, and responsiveness increased further at 6-months. Viviscal™ was positively evaluated by the vast majority of participants (94% were happy with results at 3-months, and 100% at 6-months), along with positive responses to the QoL questionnaire at the end of the study.

(A) Statistically-significant increase in mean vellus-like hair width was seen at 6-months – Suggesting that they may be transitioning towards terminal hair classification and may continue to transition over time. (B) Statistically-significant reduction in hair shedding was experienced after 3-months of Viviscal™. The total number of shed hairs was consistently lower for the Viviscal™ group vs. placebo. – This observation may have favorably impacted the subjects' perception of fewer hair being shed.

Similar to previous studies, the ingredients in Viviscal™ promote hair growth in women suffering from temporary thinning hair. The current study further demonstrated the ability of this product to increase hair diameter and decrease hair loss. A 32.2% increase in terminal hair growth, 39.1% reduction in hair shedding and increased terminal hair diameter was shown. Viviscal™ continues to demonstrate an excellent safety profile.

The daily administration of Viviscal™ Oral Tablets was associated with a significant increase in the number of terminal hairs (mean change of 80% at 6-months in growth of terminal hairs), and a significant increase in hair thickness (12% increase in terminal hair diameter at 6-months) . The majority of study participants believed the use of Viviscal™ produced significant improvements in skin and hair quality. The majority believed that their quality of life was improved. Viviscal™ exhibited an excellent safety profile.

Viviscal™ significantly increased terminal hair growth at 90 days (111%) and at 180 days (125%). Self-perceived improvements at 90 days improved further after 180 days, 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.

After only 2 months of daily Viviscal™ use, the African-American women participants (with self-perceived thinning hair) reported seeing a significant increase in overall hair volume, scalp coverage and thickness of hair. The majority of study participants also reported that Viviscal™ produced significant improvements in skin and hair quality. Further, there was significant improvements in QoL questionnaire scores. Throughout the study, Viviscal™ exhibited an excellent safety profile.

"The results of this placebo-controlled study show... that Viviscal™, a nutritional supplement containing a marine complex and other ingredients decreases hair shedding and promotes hair growth in men with thinning hair, specifically those with androgenic alopecia. In this era, patients are looking for simple drug-free options, avoiding the risk factors involved with prescription medications. This marine complex supplement provides this optimal opportunity."

These study results suggest that the use of a marine based extract mixture of proteins and polysaccharides (Viviscal™) is beneficial to help stabilize existing hair loss in androgenetic alopecia (80% perceived a significant reduction in hair loss after only 2 months). Efficacy may be higher in the early stages of hair loss, when it is more qualitative in nature. There were no reports of adverse events during the 12-month study period.

The study showed that Viviscal™ had a substantial impact on hair loss (100% reported that hair loss stopped at 2-months); and there was a 77% overall reduction in mean area of scalp baldness. No adverse effects were observed except some drying of the skin of the scalp in all patients. The results are impressive, considering the rather high average age of the test group. Viviscal™ appears to be very effective in middle age men with androgenic alopecia, especially when combined with topical Viviscal™ treatment.

Viviscal™ appears to be the first highly active treatment for androgenic alopecia in young males, including those previously treated with topical 1% minoxidil. Viviscal™ significantly increased the regrowth of non-vellus hair in young men with androgenic alopecia (38.1% change from baseline at 6-months). Although the mechanism by which Viviscal™ increases hair growth has not been elucidated, the silica component may be important. It is probable that several nutritional factors have a synergistic effect and improve the efficacy of the product.

"The results of the present study confirm earlier results, which have shown that long term use of Viviscal™ effectively induces regrowth of hair in patients with alopecia areata and alopecia totalis. The results in treatment of alopecia universalis were less encouraging... the investigation clearly shows how patients experience the effect of Viviscal™ in routine practical use...Viviscal™ orally used for 8-12 months is a recommendable mode of treatment of alopecia areata and alopecia totalis, regardless of the age of the patient or duration of the problem."

The positive effect seen in this study together with the excellent tolerability suggest that Hairgain® may provide a valuable alternative treatment for those with androgenic alopecia. The study results do indicate that long term treatment is needed to obtain significant results. Further, there was a positive correlation between the subjects' self evaluations of treatment and the objective counting of hairs in the photos. The results obtained in the present study compare favorably with the results obtained in studies with drugs such as finasteride. [Viviscal™ was originally marketed under the brand name Hairgain® – Ablon G. *J Clin Aesthetic.* 2012;6(11):28 34]

Efficacy assessment of a nutraceutical with a marine protein complex in the reduction of female telogen effluvium.

Bloch LD. Escudelro CC, et al. *J Dermat Cosmetol.* 2017;1(2):1-6

INTRODUCTION

The aim of this study was to investigate the use of Viviscal™, an oral supplement, in female patients experiencing telogen effluvium by employing a Photo-Trichogram technique to evaluate hair scalp, and by the application of standardized questionnaires to assess participant opinion.

METHODS

STUDY SUBJECTS

Healthy woman 25 to 50 years old with severe telogen effluvium and complaints about hair loss were enrolled. Among the 52 subjects enrolled, 35 completed the full 6-months of the study.

STUDY PROCEDURES

During the baseline visit, a 1 cm x 2 cm area of scalp was shaved and photographed immediately and again after 48 hours. Digital imaging software was used to identify each hair shaft and determine which hairs had not grown after 48 hours. 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.

RESULTS

"By the end of the 6 months treatment, 100% of the assessed participants claimed to be satisfied with [Viviscal's] effects." Seventy-seven percent (77%) of patients had a decrease in the percentage of telogen hair after 90 days, with 83% having a decrease by 180 days (Figure 1). Telogen fiber density reduced from 11.1 to 8.7 fibers/cm^2 (Table 1). **Total hair fibers increased 9.3% and telogen hair fibers reduced 19.6% on average after 180 days; overall percentage of telogen hair fibers reduced 25.6%.**

After 90 days 71% of patients experienced an increase in the total number of hair strands, and this increased to 83% by 180 days (Figure 2). Total hair density increased from 110.1 to 118.0 fibers/cm^2 (Table 1).

The results of the Quality of Life Questionnaire are shown in Figure 3. There was a modest but consistent improvement across all responses. The greatest improvements were related to self-esteem and self-confidence. The response to the Self-Assessment Questionnaire are summarized in Table 2. In addition, the proportion of subjects responding they were happy with their treatment was 94% and 100% at 90 and 180 days, respectively.

CONCLUSION

The use of Viviscal™ was effective in reducing telogen hair fibers and to increase the total number of hair fibers after both 3 & 6 months. The number of patients responding to Viviscal™ at 3 months was high, and responsiveness increased further at 6 months. Viviscal™ was positively evaluated by the vast majority of study participants, along with positive responses to the QoL questionnaire at the end of the study.

TABLE 2.
Attributes with >66% Favourable Response

	DAY 90	DAY 180
Happy with Viviscal	**94%**	**100%**
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%

FIGURE 1. Photo-Trichogram

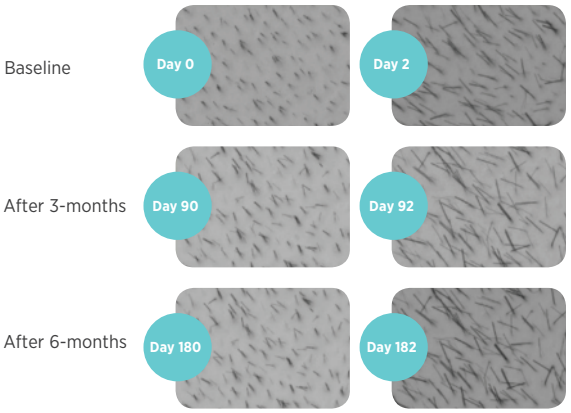


FIGURE 2. Telogen Reduction & Hair Growth

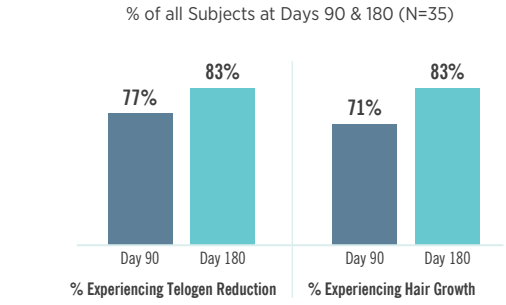
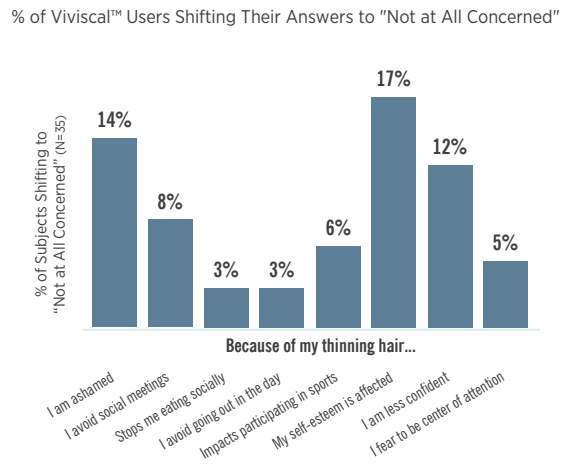


TABLE 1.
Variation of telogen fiber and hair density (fibers/cm^2)

	Baseline	DAY 90	DAY 180
Total Hair Density (p=0.01)	110.1	112.9	118.1
Telogen Density (p=0.00)	11.1	10.1	8.7

FIGURE 3. Improvement in QoL Answers: Baseline Vs. 180 Days



A Marine Protein-based Dietary Supplement for Subclinical Hair Thinning/Loss; Results of a Multisite, Double-blind, Placebo-controlled Clinical Trial.

Rizer RL, Stephens TJ, et al. *J Trichology.* 2015;7(4):156-166.

INTRODUCTION

Scalp hair growth is a very powerful social signal in humans. Thus, hair thinning and loss, even at subclinical levels, can provoke profound psycho-emotional anxiety. The aim of this multi-site, double-blind placebo controlled study was to determine whether Viviscal™ dietary supplements shows statistically-significant benefits in reducing hair shedding and increasing hair diameter in females with sub-clinical hair thinning/loss.

METHODS

STUDY SUBJECTS

72 women with self-perceived, sub-clinical thinning hair were selected, enrolled, and completed the 6-month study – mean age of 44 years. All subjects exhibited skin photo type I-III in the Fitzpatrick skin classification.

STUDY PROCEDURES

Each participant had a small tattoo dot applied to target 1 cm^2 area of scalp (ensuring proper alignment of photography equipment) which was shaved to 1 mm in length and dyed black. This area was 1–2 cm lateral to the scalp mid-line half the distance between the forehead hairline and the vertex.

"Vellus-like hair was defined as hair ≤=40 µm and terminal hair defined as >40 µm in diameter... However, in the context of this study, a more accurate definition is "vellus-like fine hair" as these fine scalp hairs were considerably longer than the typically-defined 3 mm of vellus hair fibers."

Photo-Trichogram images were taken to evaluate hair growth on 3 visits: baseline, 3-months, and 6-months (Figure 1). Shed hair was captured using a validated protocol on 3 visits: two days following the baseline visit and the 3- & 6-month visits.

RESULTS

Photo-Trichogram data revealed a statistically significant increase in mean vellus-like hair diameter after 6-months with Viviscal™ (N=30) compared with those in the placebo control group (N=26). This observation suggests that the vellus-like hairs, while not yet definable as 'terminal' may with continued use of Viviscal™ continue to transition towards terminal hair classification.

Viviscal™ increased mean vellus-like hair diameter after both 3- and 6-months, attaining clinical significance at 6-months (p=0.021). An opposite trend was observed with placebo. Overall, more than 60% of subjects' vellus-like hairs showed increased diameter after using Viviscal™ with a mean increase of 7.4% at 6-months (Figure 2). 60% of subjects using placebo, experience continued decrease of vellus hair diameter.

Total number of shed hairs were consistently lower for Viviscal™ (N=37) vs. placebo (N=34) during the study. At 3-months the Viviscal™ group showed significantly less shed hair vs. the placebo group (Figure 3). However, shed hair count remained constant between 3- and 6-months.

The subjective analysis questionnaire revealed patients perceptions of a significant favorable change in overall hair volume at 6 months from those using Viviscal™ (p<0.007).

CONCLUSION

This study revealed:

(A) A statistically-significant increase in mean vellus-like hair width after 6-months
- Observation suggests that vellus-like hairs may be transitioning towards terminal hair classification, and may continue to over time.

(B) A statistically-significant reduction in hair shedding after just 3-months of Viviscal™, with attenuation after 3-months. The total number of shed hairs were consistently lower for the Viviscal™ group vs. placebo.
- This observation may have favorably impacted the subjects' perception of fewer hair being shed.

"In summary, the data suggest that a nutritional approach to improving the hair follicle environment from within can be used to aid hair growth where this is suboptimal due to possible dietary deficiency or insufficiency. A supplement like Viviscal™, containing the marine complex AminoMar® tested here may be a useful dietary adjunct to aid optimal scalp hair growth."

FIGURE 1. Example of Subject Photo-Trichogram

6-Months

The blue trichogram/count measure 0.25 cm^2. Vellus is defined as hairs with diameters ≤40 µm. Terminal hair is defined as hairs with diameter >40 µm. Green lines indicate terminal hair. Red lines indicate the vellus hairs.

FIGURE 2. Vellus-like Hair Diameter: 3-and 6-Months

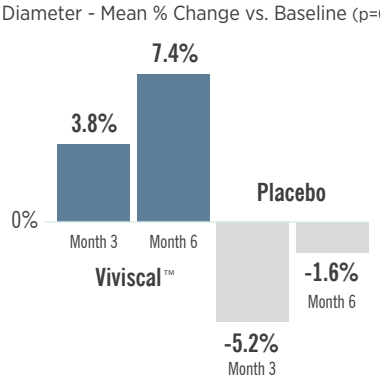
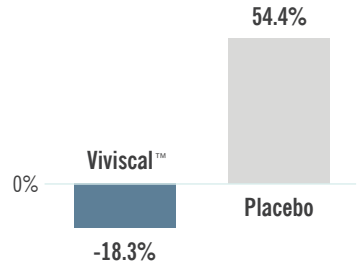


FIGURE 3. Shed Hair Count: 3-Months (N=71)



A 3-Month, randomized, double-blind, placebo-controlled study evaluating the ability of Viviscal™ Extra Strength formulation to promote hair growth and decrease shedding in women with self-perceived thinning hair.

Ablon G. *Derm Res & Pract*. 2015;ID841570:1-8

INTRODUCTION

Female pattern hair loss is a significant problem affecting a large number of women. Viviscal™ is a dietary supplement specifically designed to promote hair growth in patients suffering from temporary thinning hair. The objective of this double-blind, placebo-controlled study was to assess the ability of Viviscal™ to promote the growth of terminal hairs in adult women with self-perceived thinning hair.

METHODS

STUDY SUBJECTS

Women with Fitzpatrick photo skin type I-IV and self-perceived thinning hair associated with poor diet, stress, hormone influences or abnormal menstrual cycle were eligible for enrollment. Sixty women with a mean age of 48.6 years were enrolled and randomized to receive treatment with Viviscal™ (N=30) or placebo (N=30). All subjects completed the study.

STUDY PROCEDURES

Enrolled subjects were seen at a baseline clinic visit and a 90-day follow-up visit. At both visits, each subject had their hair washed with a commercial shampoo (Viviscal™ Gentle Shampoo) over a sink containing a cheesecloth to catch any shed hairs which were collected and counted. During the Baseline visit, a 4 cm^2 area of the scalp was selected along the frontalis bone where frontal hairline and lateral hairline meet and marked with a black marker. Phototrichograms were obtained of the target area at both visits. Ten terminal hairs in the target area were randomly chosen throughout the area and cut at the surface of the scalp. Digital photographs were obtained to measure hair diameter 1 mm from the cut end of the hair and the hair diameter was measured. Subjects also responded to Quality of Life and Self-Assessment Questionnaires at 90 days.

RESULTS

Among the Viviscal™-treated subjects, there was a significant increase in the mean number of terminal hairs from 178.3 (7.8) at baseline to 235.8 (18.4) at day 90 ($p<0.0001$) but not among placebo-treated subjects (Figure 2). There was also a significant increase in the number of vellus hairs in Viviscal™-treated subjects ($p<0.0001$) but not in placebo-treated subjects. The increase in hair regrowth is apparent in the subject shown in Figure 1.

Only the subjects treated with Viviscal™ had a significant decrease in hair shedding $p=0.002$ (Figure 2). There was no significant increase in terminal hair diameter among either groups. Subjects treated with Viviscal™ obtained significantly higher total scores on the Self-Assessment Questionnaire at day 90 ($p=0.006$) with significant differences between the two groups on 7 of 13 items including Overall Hair Growth, Overall Hair Volume, Scalp Coverage, Thickness of Hair Body, Hair Strength, Growth of Eyebrow Hair and Overall Skin Health (Table 1). Both groups achieved significantly higher total scores on the Quality of Life Questionnaire (for each, $p<0.001$); however, the total score was higher for Viviscal™-treated subjects ($p=0.035$) and individual question scores for Viviscal™ subjects showed significant improvement on all 15 QoL questionnaire items.

There were no reported adverse events.

CONCLUSION

Similar to previous studies, the ingredients in Viviscal™ promote hair growth in women suffering from temporary thinning hair. The current study further demonstrated the ability of this product to increase hair diameter and decrease hair loss. Viviscal™ continues to demonstrate an excellent safety profile.

FIGURE 1. Images from a Viviscal™-Treated Subject

FIGURE 2. Changes in Growth & Shedding

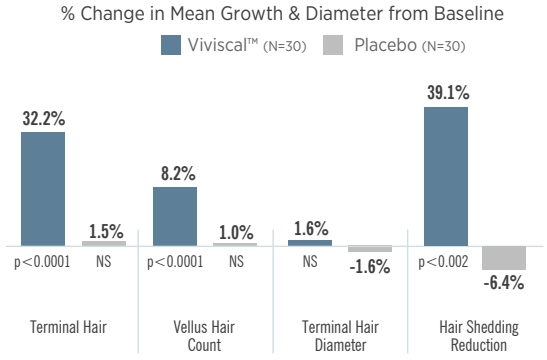


TABLE 1.
Self-Assessment Questionnaire Results @ Day 90

Quality	Viviscal™, *N=17*	Placebo, *N=19*	Significance*
1. Overall Hair Growth	5.03	4.53	*p=0.015*
2. Overall hair volume	4.97	4.17	*p<0.0001*
3. Scalp coverage	4.70	4.23	*p=0.042*
4. Thickness of hair body	4.77	4.20	*p=0.013*
5. Hair Strength	4.97	4.33	*p=0.013*
6. Growth of eyebrow hair	4.40	4.00	*p=0.033*
7. Overall skin health	4.63	4.17	*p=0.045*

*One-Way Analysis of Variance

A randomized, double-blind, placebo-controlled, multi-center, extension trial evaluating the efficacy of a new oral supplement in women with self-perceived thinning hair.

Ablon G, Dayan S. *J Clin Aesthet Dermatol* 2015;8(12):15-21.

INTRODUCTION

Viviscal™ has been designed to promote hair growth in women suffering from temporarythinning hair (Viviscal™ Oral Tablets). 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. 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 aging, 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. Twenty adult female subjects were randomized to receive Viviscal™ or placebo of which 17 and 19 completed the study, respectively.

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

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.

There was a significant increase in the diameter of terminal hairs among Viviscal™-treated subjects (Figure 2) 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 1. 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 ($p=0.001$).

There were no reported adverse events.

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.

FIGURE 1.
Changes in Hair Growth

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

FIGURE 2.
Changes in Hair Growth and DIAMETER

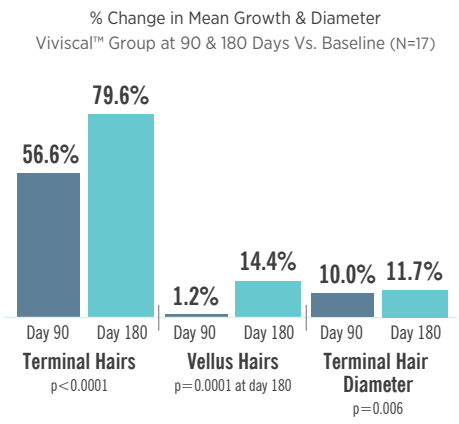


TABLE 1.
Self-Assessment Questionnaire Results

Quality	Viviscal™ Day 90	Viviscal™ Day 180	Placebo Day 90	Placebo Day 180	Signif.*
1. Overall hair volume	4.76	6.12	4.11	4 .84	p=.056
2. Scalp coverage	4.76	6.12	4.21	4.74	p=.008
3. Thickness of hair body	4.84	5.35	4.37	4.95	p=NS
4. Softness of hair body	4.29	4.94	4.42	4.63	p=NS
5. Hair shine	4.94	5.47	4.21	4.53	p=NS
6. Hair Strength	5.00	5.88	4.68	4.95	p=.019
7. Nail Strength	5.12	5.88	4.89	4.79	p=.030
8. Nail growth rate	5.47	5.94	5.00	4.95	p=NS
9. Growth of eyebrow hair	5.00	5.18	4.32	4.58	p=NS
10. Growth of eyelashes	4.47	5.24	4.42	4.42	p=.086
11. Skin smoothness	4.65	5.24	4.42	4.58	p=.074
12. Overall skin health	4.76	5.29	4.47	4.47	p=.069

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

A Double-blind, Placebo-controlled Study Evaluating the Efficacy of an Oral Supplement in Women with Self-perceived Thinning Hair.

Ablon G. *J Clin Aesthet Dermatol* 2012;5(11):28-34.

INTRODUCTION

An oral food supplement has been developed to promote existing hair growth for women suffering from temporary thinning hair (Viviscal™ Dietary Supplement). 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.

METHODS

STUDY 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 mean age of the women in the Viviscal™ and placebo treatment groups were 49.9 and 47.6 years, respectively, and were not significantly different. All subjects were Caucasian and one subject claimed Hispanic ethnicity.

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 cm^2 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. 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.

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.

RESULTS

At baseline, the mean number of terminal hairs among placebo-treated subjects was 256.0 and remained at 245.0 and 242.2 after 90 and 180 days, respectively. In contrast, the mean number of terminal hairs in the Viviscal™-treated subjects was 271.0 at baseline, increasing to 571 and 609.6 after 90 and 180 days respectively (Figure 1 shows % change). The mean number of vellus hairs among placebo-treated subjects was 57.0 at baseline and 68.0 and 65.8 after 90 and 180 days respectively. The mean number of vellus hairs among Viviscal™-treated subjects was 46.5 at baseline and 48.0 and 46.5 after 90 and 180 days respectively. The change in hair growth following 180 days of treatment is evident in the two patients shown in Figures 2 and 3.

Significantly more subjects treated with Viviscal™ perceived improvements in overall hair volume, thickness, and scalp coverage. Compared to placebo, the subjects treated with Viviscal™ for 180 days reported significant improvements in several parameters in the Self-Assessment Questionnaire including Overall Hair Volume, Scalp Coverage and Thickness of Hair Body ($p<0.0001$) (Figure 4).

CONCLUSION

The daily administration of Viviscal™ nutritional supplement significantly increased hair growth after 90 and 180 days. Self-perceived improvements at 90 days improved after 180 days, 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.

FIGURE 1. Mean Change in Terminal Hair

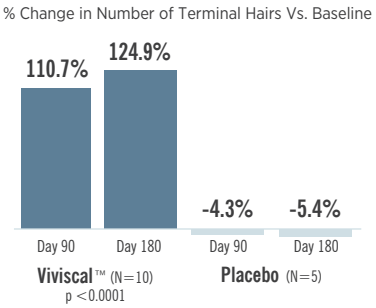


FIGURE 2.
Images of Patient Scalp at Baseline, 90 and 180 Days of Treatment

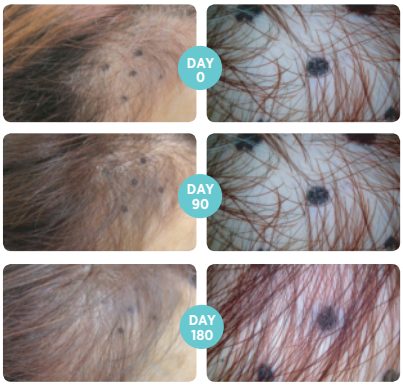


FIGURE 3.
Images of Patient Scalp at Baseline, 90 and 180 Days of Treatment

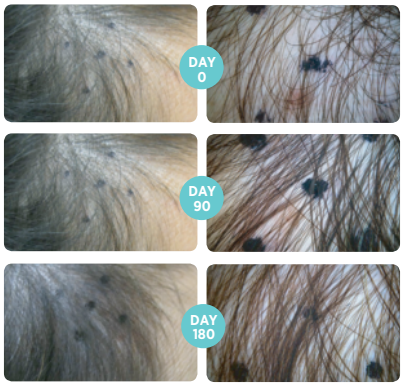
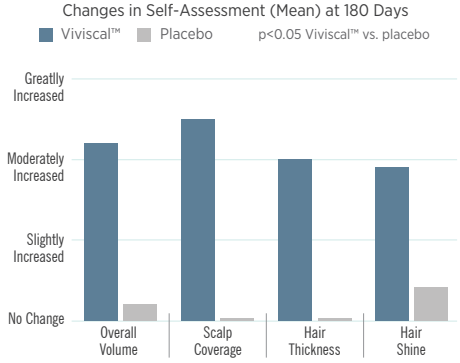


FIGURE 4. Patient Self-Assessment



A 4-month clinical study evaluating the efficacy and tolerability of an oral supplement for the treatment of thinning hair in African American women.

Jackson B. South Beach Symposium, Clinical + Aesthetic Dermatology, 2011:Poster presentation.

INTRODUCTION

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

METHODS

STUDY 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.

STUDY 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.

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.

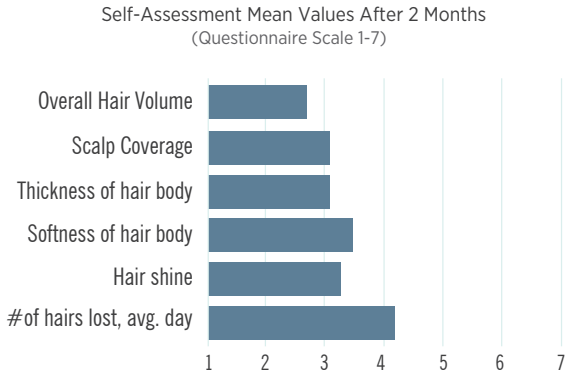
RESULTS

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 (Figure 1). Self-assessment values between months 2 and 4 were similar. For other self-assessment parameters the greatest changes also occurred after 2 months (Figure 2). There were no reports of adverse events.

CONCLUSION

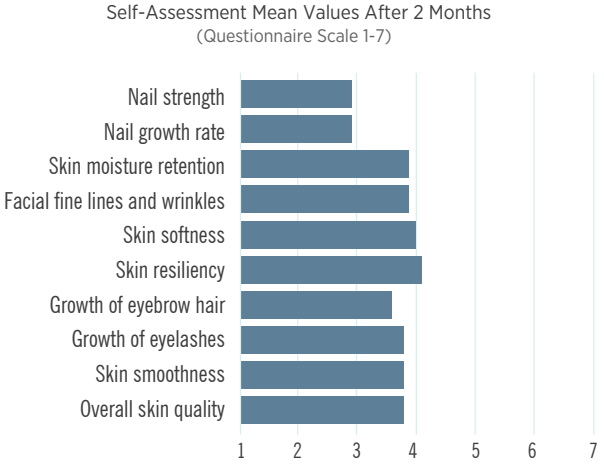
The daily administration of Viviscal™ Oral Tablets was associated with a significant increase in the number of terminal and vellus hairs and also a significant increase in hair thickness among women with self-perceived thinning hair. The majority of study participants believed the use of Viviscal™ produced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

FIGURE 1.
Effects of Viviscal™ on Hair Growth After 2 Months

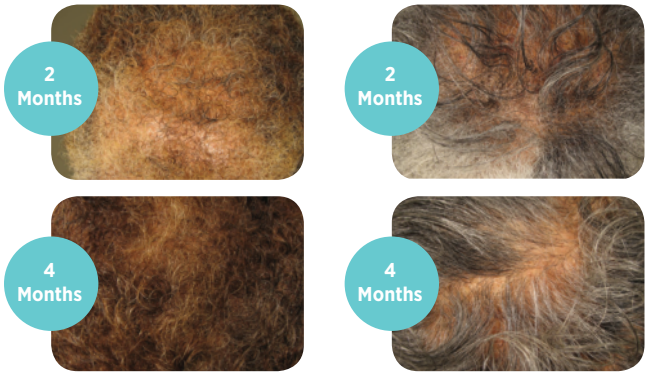


Key: 1 - Greatly Increased; 2=Moderately Increased; 3=Slightly Increased; 4=No Change; 5=Slightly Decreased; 6=Moderately Decreased; 7=Greatly Decreased

FIGURE 2.
Other Effects of Viviscal™ After 2 Months



Key: 1 - Greatly Increased; 2=Moderately Increased; 3=Slightly Increased; 4=No Change; 5=Slightly Decreased; 6=Moderately Decreased; 7=Greatly Decreased



A 6-Month, randomized, double-blind, placebo-controlled study evaluating the ability of a marine complex supplement to promote hair growth in men with thinning hair.

Ablon G. *J Cosmetic Dermatol.* 2016;0:1-9

INTRODUCTION

Male pattern hair loss is a significant problem affecting many men. Viviscal™ Oral Tablets is a dietary supplement specifically designed to promote existing hair growth in those suffering from thinning hair. The objective of this double-blind, placebo-controlled study was to confirm the beneficial effects of Viviscal to promote the hair growth in adult man with thinning hair.

METHODS

STUDY SUBJECTS

60 healthy adult male subjects with thinning hair, associated with clinically diagnosed male pattern hair loss, were enrolled and completed the study. Thirty men with a mean age of 42.8 years received Viviscal™ (N=30). Thirty men enrolled in the placebo arm (N=30) with a mean age of 46.1 years. All subjects completed the study.

STUDY PROCEDURES

Subjects were randomized in double-blind fashion to receive Viviscal™ Tablets or placebo. Subjects were instructed to take one tablet twice daily in the morning and evening following a meal and maintain their normal hair care routine.

Subjects were evaluated at Baseline, Day 90, and Day 180. A physical examination was performed at each visit, including a review of 14 basic body systems, scalp examination, vital signs, and BMI. At Baseline, the scalp was examined by the investigator to rule out any confounding scalp conditions. An approximately 1.5 cm x 1.5 cm (2.35 cm^2) target area was selected for each subject where the midline scalp defined as the half-way point on the coronal band. This area was prepared, and digital images were taken for trichoanalysis. Subjects were required to refrain from hair washing for at least 3 days (72 h) prior to the hair pull test, which was performed on the right and left parietal, frontal, and occipital areas of the scalp during Visits 1 (Baseline) and 3 (Day 180).

RESULTS

Viviscal™ significantly improved hair count, terminal hair density and overall hair density by 90 days, with improvements continuing to increase up to the end of the study at 180 days (Figure 2). Significant changes within the Viviscal™ group could be seen easily in photographs taken (Figure 1). Among the Viviscal™-treated subjects, there was a significant increase in the mean total hair count from 162.20 at baseline to 169.08 at Day 90, and to 174.89 at Day 180. Total hair density increased from 159.71 at baseline to 166.50 at Day 90 and 172.17 at Day 180 p=0.001 (Table 1). In placebo-treated subjects at day 90, a non-significant negative change was reported, becoming more negative by day 180 (Figure 2).

At Day 180, several Self-Assessment questions showed a significant improvement, including overall hair growth, hair volume, nail strength and overall skin health. Additionally, results of the hair pull test were significantly improved in the Viviscal™ group vs placebo at Days 90 ($P < 0.05$) and 180 ($P < 0.01$).

There were no reports of treatment-emergent adverse events at any time during the study.

CONCLUSION

"The results of this placebo-controlled study show... that Viviscal™, a nutritional supplement containing a marine complex and other ingredients decreases hair shedding and promotes hair growth in men with thinning hair, specifically those with androgenic alopecia. In this era, patients are looking for simple drug-free options, avoiding the risk factors involved with prescription medications. This marine complex supplement provides this optimal opportunity."

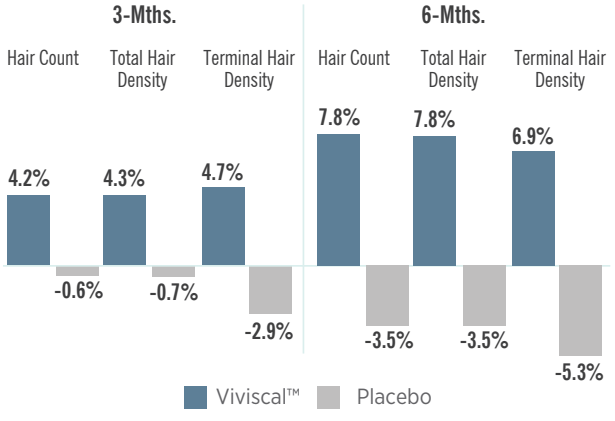
TABLE 1. Changes Vs. Placebo

	Baseline	Day 90	Day 180	Significance (Day 180)
Total Hair Density *(Mean)*				
Viviscal™	159.7	166.5	172.2	p=0.001
Placebo	150.0	149.0	144.7	NS
Terminal Hair Density *(Mean)*				
Viviscal™	122.0	127.7	130.3	p=0.001
Placebo	104.7	101.7	99.2	NS

FIGURE 1. Two Study Patient Image Examples

FIGURE 2. Efficacy Results - Viviscal™ Vs. Placebo

Change from Baseline at 3 & 6 Months



Treatment of androgenetic alopecia with a marine-based extract of proteins and polysaccharides (Viviscal™).

Pereira JM. *Revista Brasileira de Medicina*. 1997;53(3):1-10.

INTRODUCTION

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

METHODS

STUDY SUBJECTS

A total of 200 healthy men with androgenic alopecia were enrolled (34.5% were <26 years old, 28.5% were 26-30, and 37% were >30 years old). 178 (89%) completed the study. Men with patchy non-telogenic baldness were excluded.

STUDY PROCEDURES

Each patient was treated twice daily with a Viviscal™ tablet containing 300 mg of marine-based extract of proteins and polysaccharides for 180 days.

Two areas of the scalp were used to elevate changes in hair growth using a 5-point baldness severity scale (0=normal growth, 1= mild thinning, 2=moderate thinning, 3=severe thinning, 4=baldness). Changes in hair density were determined 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. Next to this area a small number of hairs were cut with a scalpel. After one week the length of regrown hairs was measured and the rate of hair growth (mm/day) could be estimated.

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

Not all subjects (8.4%) had observed hair loss during their balding period. 168 subjects (91.6%) had noticed hair loss. After 2 months of treatment, 80.4% of these patients did perceive a reduction in their hair loss (Figure 1). After treatment (180 days) 36.5% of subjects noticed a thickening of their hair. The mean baseline hair density was 210 hairs/cm^2 increasing to 218 hairs/cm^2 after 180 days.

No changes in scalp thickness occurred. The mean rate of hair growth at baseline was 0.39 mm per day and significantly increased 12.8% in 138 subjects (75%) to 0.44 mm per day (Figure 2).

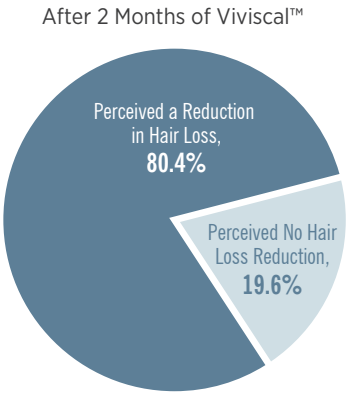
The baseline telogenicity ranged from 30-70% in the trichogram area and severity of telogenisation corresponded with the clinical severity of alopecia. The effects on telogenicity were noted (Table 1).

TABLE 1. Telogenicity

Severity of Telogenisation	# of Subjects	Decrease in Severity
25%-40%	57	52.6% saw a **30% decrease**
40%-50%	76	36.8% saw a **20% decrease**
50%-70%	45	No Changes Observed

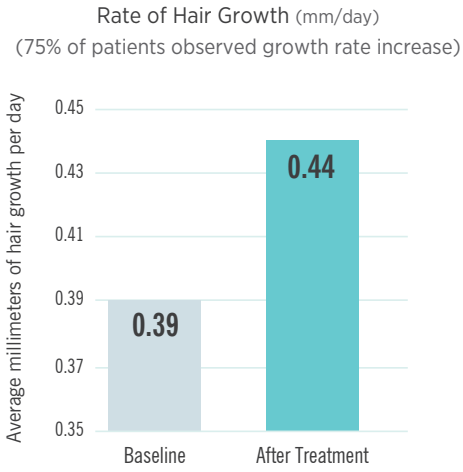
Severity of Telogenisation corresponded to clinical severity of alopecia

FIGURE 1. Hair Loss Perception



Base: Those noticing hair shedding during their balding process

FIGURE 2. Hair Growth Rate



CONCLUSION

These study results suggest that the use of a marine-based extract mixture of proteins and polysaccharides (Viviscal™) is beneficial to help stabilize existing hair loss in androgenetic alopecia. Efficacy may be higher in the early stages of hair loss, when it is more qualitative in nature. There were no reports of adverse events during the 12-month study period.

Treatment of hereditary androgenic alopecia in middle-aged males by combined oral and topical administration of special marine extract-compound (Viviscal™).

Lassus A, Santalahti J, et al. *J Int Derm.* 1994;13:254-255.

INTRODUCTION

The oral administration of a compound derived from marine fish (Viviscal™) has been shown to be beneficial for treating young men with early male pattern baldness. This 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.

METHODS

STUDY SUBJECTS

30 Healthy men with hereditary androgenic alopecia (Hamilton scale II-IV), and a mean age of 40 years (34-48 years) were enrolled. The mean duration of hair loss was 11 years, with a range between 3 and 20 years. Smokers accounted for 36.7% of the subjects (7 heavy smokers, 4 moderate smokers).

STUDY PROCEDURES

All patients were treated for 8 months (240 days) - all completed the study. Each subject took a Viviscal™ Tablet two or three times per day depending on weight (< 80 kg = 2-tablets/day; > 80 kg = 3-tablets/day). 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. Photos were taken at each visit and the total cumulative areas of baldness was measured (cm^2) and expressed as a percentage of total scalp area. In addition, epidermal and dermal thickness was measured, an elasticity index determined, and erythemal index measured.

RESULTS

At baseline the perception of hair loss severity ranged from mild to severe (Table 1). After 2 months, all subjects reported that their hair loss had stopped. After 8 months significant improvement in scalp baldness was reported. The mean area of total scalp baldness was 39% (11-52%) at baseline, decreasing to 9% (4-25%) after treatment (Figure 1). The extent of hair regrowth is summarized in Table 2.

The significant increases in epidermal and dermal thickness and elasticity and erythemal indices are shown in Figure 2.

Five of the six subjects with poor results were heavy smokers. 18 subjects (60%) with good scalp response also experienced increased beard growth and two had increased chest hair. All patients experienced mild to moderate drying of the scalp during treatment. No further adverse reactions were reported.

CONCLUSION

The study showed that Viviscal™ had a substantial effect on hair loss; and with most patients, on regrowth of permanent hair in bald areas. No adverse effects were observed except some drying of the skin of the scalp in all patients. The results are impressive, considering the rather high average age of the test group. Viviscal™ appears to be very effective in middle-age men with androgenic alopecia, especially when combined with topical treatment.

TABLE 1. Hair Loss Severity

Perceived Hair Loss Severity	% at Baseline	% at 2 Months
Mild	43.3%	Hair loss reported to have stopped for all 30 participants
Moderate	16.6%	
Severe	40.0%	

FIGURE 1. Improvement in Baldness

Change in Mean Area of Total Scalp Baldness (N=30)

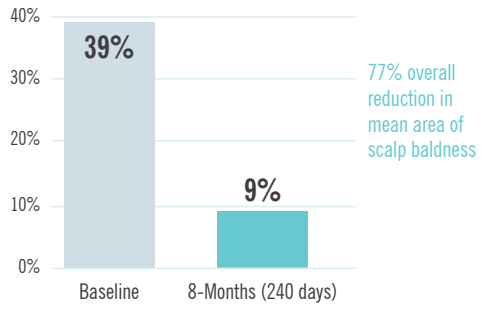
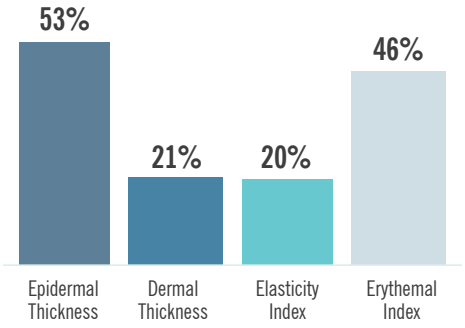


TABLE 2. Hair Regrowth

% of Scalp Hair Regrown	% of Subjects at 8-Months
100%	43%
76%-99%	23%
50%-75%	13%
30%-49%	14%
No Regrowth	7%

FIGURE 2. Perceived Impact on Scalp*

(% Increase at 8 Months from Baseline)



*It is difficult to separate oral vs. topical treatment impact on the scalp. For example, the oral treatment is not known to cause vasodilation, therefore erythemal index may be associated only with topical treatment use. All patients did observe some drying of the scalp.

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. *J Int Med Res*. 1992;20:445-453.

INTRODUCTION

Several reports have demonstrated that certain proteins derived from marine fish promote effect on hair growth in women. The following 6-month, double-blind study was conducted to compare the effects of Viviscal™ (a food supplement incorporating special marine extracts and a silica compound) with those of a fish extract in men with androgenic alopecia.

METHODS

STUDY SUBJECTS

Forty healthy men 20-30 years old (mean age of 25) with androgenic alopecia classified as III-V on the Hamilton scale were enrolled. The duration of hair loss varied from 2-9 years. Most patients (82.5%) had been treated long-term with topical 2% minoxidil for 1 year or more prior to the study.

Subjects were randomized to receive two Viviscal™ tablets (N=20) or fish extract tablets (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.

At 6 months, there were 37 evaluable subjects. All Viviscal™ patients completed the study, but three patients in the fish extract group withdrew due to lack of effect.

RESULTS

There was significantly more regrowth of non-vellus hair throughout the treatment period among Viviscal™ treated patients compared to subjects treated with fish extract (Table 1). Patients in the Viviscal™ group had a 38.1% mean increase in non-vellus hair at 6-months (Figure 1). There was a mean increase of 472 new non-vellus hairs in the Viviscal™ group vs. only 26 in the fish extract group ($p<0.0001$). Patient assessments of new hair growth were similar to investigators.

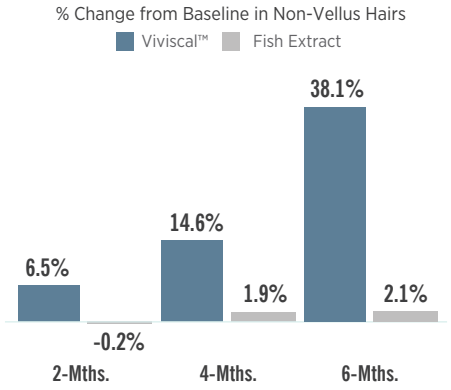
All patients in the Viviscal™ treatment group reported no hair loss after 2 months. In the fish extract group hair loss continued during the entire treatment period.

Histological examination at baseline showed typical alopecia in all 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 either treatment group.

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

	VIVISCAL™		FISH EXTRACT	
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	1710 (18.9)	17	1259 (80.6)

FIGURE 1. Efficacy



"In the Viviscal™ treatment group all patients reported that there was no hair loss after 2 months' treatment..."

"After 6 months, alopecia could no longer be diagnosed in 19 of 20 patients in the Viviscal™ treated group."

CONCLUSION

Viviscal™ appears to be the first highly active treatment for androgenic alopecia in young males. Viviscal™ significantly increased the regrowth of non-vellus hair in young men with androgenic alopecia. Although the mechanism by which Viviscal™ increases hair growth has not been elucidated, the silica component may be important. It is probable that several nutritional factors have a synergistic effect and improve the efficacy of the product.

Treatment of alopecia areata, alopecia totalis and alopecia universalis with oral Viviscal™ for 12 months.

Majass M. Puuste O, et al. *Swedish Assoc.* Alopecia. 1996.

INTRODUCTION

Previous studies have demonstrated excellent regrowth of hair in men with hereditary androgenic alopecia and men and women with alopecia areata and alopecia totalis. 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.

METHODS

STUDY SUBJECTS

Healthy men and women with alopecia areata, totalis and universalis were enrolled. All subjects had previously used conventional treatment methods without satisfactory 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.

STUDY PROCEDURES

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

Among subjects with alopecia areata, permanent hair started to reappear after approximately 6 months of treatment in 92% of subjects (Figure 1). After 12 months, 14.0% reported complete regrowth of hair (Figure 2). 66% of subjects were highly satisfied with their results and 22% reported their results as good.

Among subjects with alopecia totalis, hair regrowth began after 4 months in 83.3% of subjects (Figure 1). After 12 months, 25% of subjects reported complete hair regrowth (Figure 3). 50% were highly satisfied with their results and 33.0% reported their results as good.

Among subjects with alopecia universalis, new hair growth began after 5 months in 31.8% of subjects (Figure 4). After 12 months, one subject reported complete hair regrowth (Figure 4). 23% were highly satisfied with their results and 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.

CONCLUSION

"The results of the present study confirm earlier results, which have shown that long-term use of Viviscal™ effectively induces regrowth of hair in patients with alopecia areata and alopecia totalis. The results in treatment of alopecia universalis were less encouraging... the investigation clearly shows how patients experience the effect of Viviscal™ in routine practical use."

"Viviscal™ orally used for 8 - 12 months is a recommendable mode of treatment of alopecia areata and alopecia totalis, regardless of the age of the patient or duration of the problem."

TABLE 1. Alopecia Type and Demographic Characteristics of Treated Subjects

	Areata N=50	Totalis N=12	Universalis N=22
Male	14	4	5
Female	36	8	17
Mean Age (years)	30.9	26.8	40.0
Mean Duration of Alopecia (years)	6.8	4.9	13.9

FIGURE 1. Time to Hair Regrowth Start

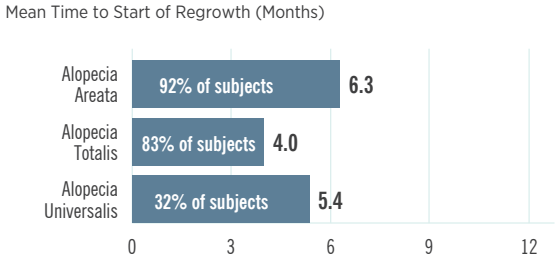


FIGURE 2. Alopecia Areata: 12-Mths

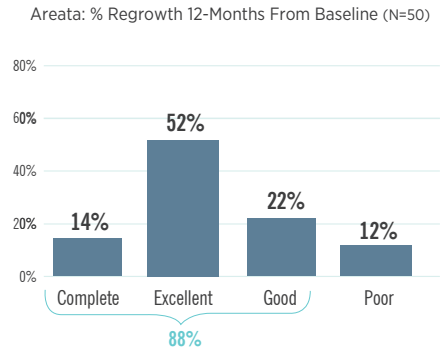


FIGURE 3. Alopecia Totalis: 12-Mths

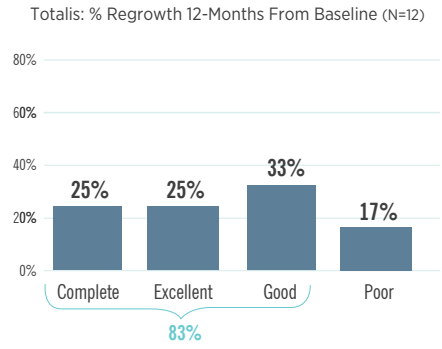
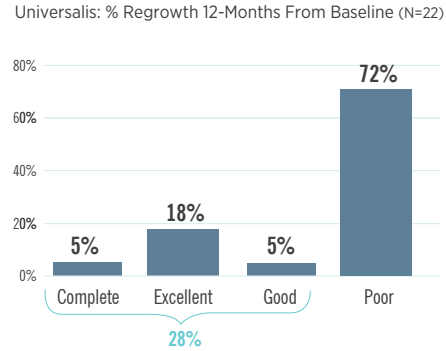


FIGURE 4. Alopecia Universalis: 12-Mths



Efficacy and Tolerability of Hairgain® in individuals with Hair Loss: A Placebo-controlled, Double-blind Study.

Thom E. *J Int Med Res*. 2001;29:2-6

INTRODUCTION

Hair loss can have a considerable psychological and social impact on those affected. Much effort has been put into attempts to develop efficient pharmaceutical and other treatments for hair loss. In most cases, however, the results have been disappointing. Viviscal™ was previously marketed in capsule form as Hairgain® by another company. It contains a marine protein extract and several different vitamins and minerals. Based on favorable effects on hair loss seen in open studies, it was decided to carry out a placebo-controlled double-blind trial in subjects with hair-loss problems.

METHODS

STUDY SUBJECTS

Sixty volunteers of both sexes, aged 18 years or more, were recruited to the study. All had had hair-loss problems for a period of at least 1 year before entering the study, and the majority of the participants had tried different treatment approaches for their hair loss. 93% had androgenic alopecia and 7% had alopecia totalis.

STUDY PROCEDURES

Subjects were randomized into either placebo or active treatment groups. The duration of the blinded phase lasted 6 months. After that time, the subjects in the Hairgain® group were followed for another 6 months in an open study format. The placebo arm group, after the initial 6 months, were then given Hairgain® and followed for an additional 12 months in an open study format. Therefore, all subjects were exposed to Hairgain® for 12 months. At baseline, the two groups were comparable with respect to gender, age, degree and duration of hair loss, body weight, previous treatment, and number of subjects with alopecia totalis.

Dosage was two capsules per day for <80 kg subjects, and 3 per day for those >80 kgs – taken in morning and evening (those taking 3 per day, took two in the evening). The capsules were to be swallowed with 200 ml of water on each occasion.

Global inspection of hair loss was performed at baseline (day 0) and each volunteer's hair loss was graded according to internationally accepted rating scales. The duration of hair loss and previous treatment was recorded. Participants came for a study visit every second month during the blinded phase, and every 6 months during the open part of the study.

Overview photographs were taken at beginning and end of the study. On each occasion the same four pre-defined areas of the scalp were photographed, and the pictures were enlarged (× 80). Photos were assessed blind by a qualified person not involved in the study. Additionally, subjects were asked at each visit to score their satisfaction with the treatment on a 10-cm Visual Analogue Scale (VAS) ranging from 0, not at all satisfied, to 10, very satisfied. Participants also reported any positive reports from close family members or their hairdresser on hair growth.

RESULTS

In the blinded active group, hair counting based on the close-up pictures showed a significant average increase in hair growth of 32.4%. The increase was negligible and insignificant in the placebo group. A further improvement in hair growth with this group took place in the period between 6 and 12 months, resulting in an average improvement in hair growth of 63.9% at the end of the study (Figure 1). The group on the placebo for the first 6 months, after 12 months of active treatment hair growth improved by 60.8% ($p < 0.001$) similar to that in the group who started on active treatment.

The VAS scores for satisfaction in the two groups during the blinded phase differed considerably in the two treatment groups, with significant improvement in satisfaction seen between 6 and 12 months (Figure 2). Satisfaction among the placebo group, up to and including 6 months, was very poor.

Viviscal™ was "...originally marketed under the brand name Hairgain® [Parexel Medstat AS, Lillestrøm, Norway]..."

Ablon G. *J Clin Aesthetic.* 2012;6(11):28-34

FIGURE 1. Hair Growth Increases

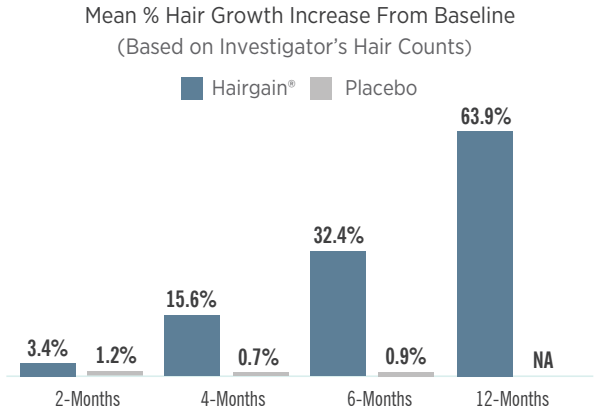
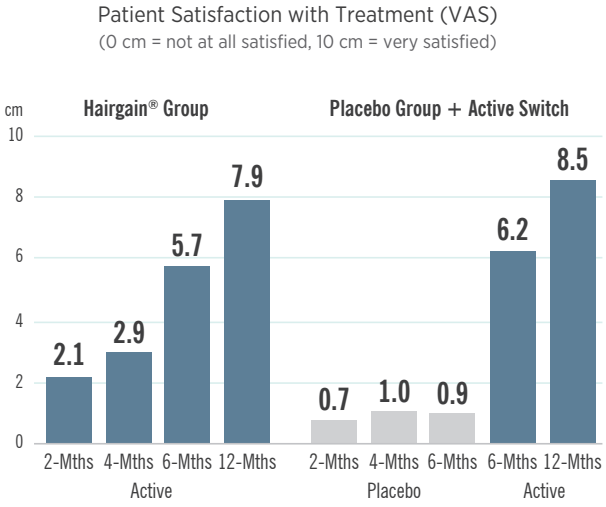


FIGURE 2. Patient Evalution of Treatment



CONCLUSION

The positive effect seen in this study together with the excellent tolerability suggest that Hairgain® may provide a valuable alternative treatment for those with androgenic alopecia. The study results do indicate that long-term treatment is needed to obtain significant results. Further, there was a positive correlation between the subjects' self-evaluations of treatment and the objective counting of hairs in the photos. The results obtained in the present study compare favorably with the results obtained in studies with drugs such as finasteride.

QUESTIONS? CONTACT US.

Customer Service **(800) 277-3316**
INFO@VIVISCALPROFESSIONAL.COM
VIVISCALPROFESSIONAL.COM