

# 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.

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## 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 cm<sup>2</sup>.
- Hair type was following by caliber i.e., vellus  $\leq 40 \mu\text{m}$  and terminal hair  $>40 \mu\text{m}$ .
- 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 cm<sup>2</sup>. Under the conditions of the digital analysis, 1Pixel = 5.411  $\mu\text{m}$ . Vellus is defined as hairs with diameters in the range of  $\leq 40 \mu\text{m}$ . Terminal hair is defined as hairs with diameter  $>40 \mu\text{m}$ .

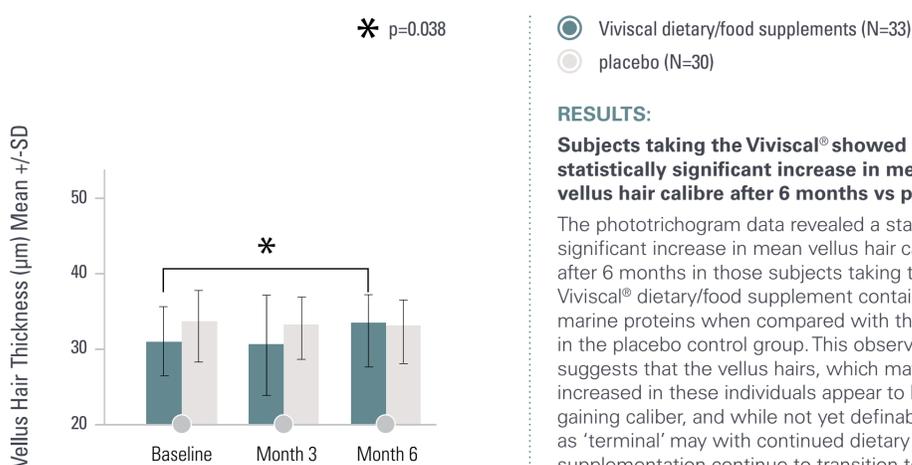
\*Green lines indicate terminal hair. Red lines indicate the vellus hairs.

### 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.



### RESULTS:

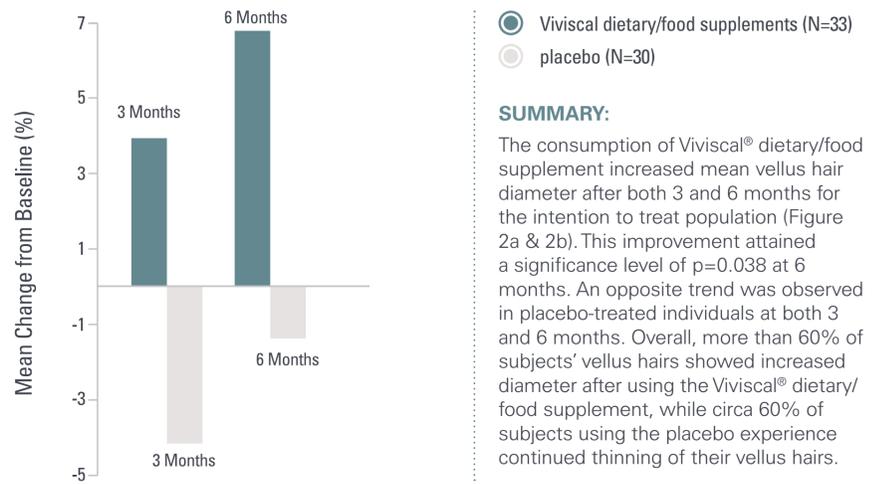
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## REFERENCE:

<sup>1</sup> 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.

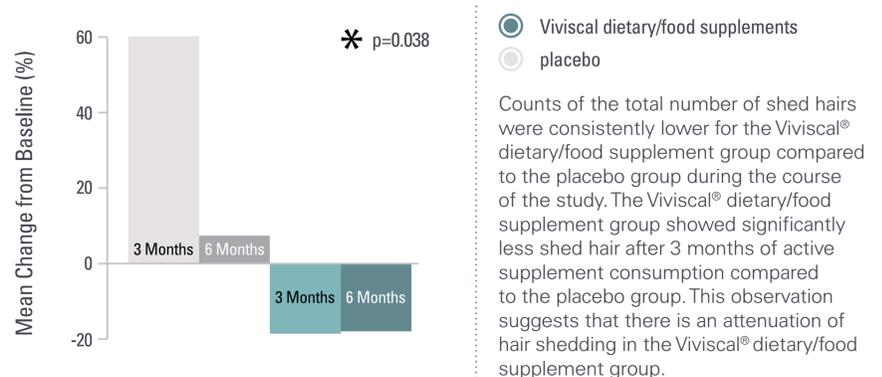
Figure 2b. Changes from Baseline in Vellus Hair Thickness at 3 and 6 months



### SUMMARY:

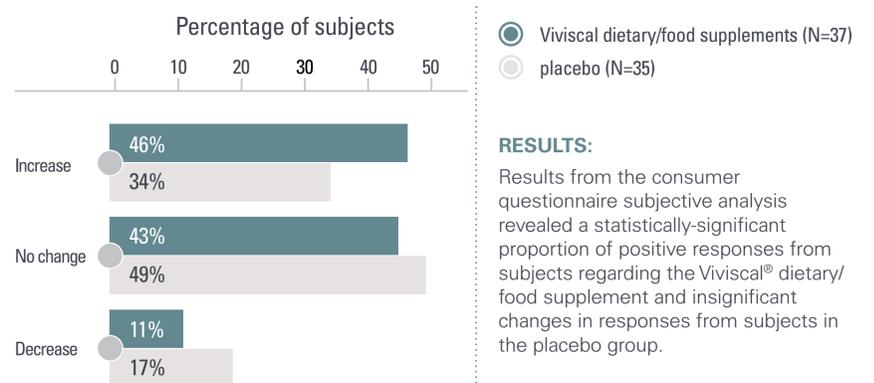
The consumption of Viviscal® dietary/food supplement increased mean vellus hair diameter after both 3 and 6 months for the intention to treat population (Figure 2a & 2b). This improvement attained a significance level of  $p=0.038$  at 6 months. An opposite trend was observed in placebo-treated individuals 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 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.