

SUMMARY REPORT
SINGLE BLIND CLINICAL TRIAL FOR THE EVALUATION OF A
FOOD SUPPLEMENT ACTIVITY ON HAIR AND NAILS
VERSUS REFERENCE PRODUCT

Test code: E0106

Study product: PROGLYME[®] FOOD SUPPLEMENT
OF AMINO ACIDS: prot 1120

Reference product: INNEOV TRICO-MASSE: prot 1131

Study Objective: Aim of this study was to evaluate clinically and by non-invasive instrumental evaluations the activity on hair and nails of an amino acids food supplement versus reference product.

It was also aim of this study to evaluate the efficacy of the treatment judged by the volunteers and the product tolerability.

Duration of the test : 90 days

Products arrival: Inneov trico-masse: 26/01/06

Proglyme[®] Food Supplement of Amino Acids I arrival: 9/11/05

II arrival:

10/02/06

Start date: 06/02/06

Method:

3 visits were performed during the trial: a basal visit (T0), an intermediate visit after 30 days (T30) and a final visit after 90 days.

The evaluation of the products activity on hair was performed by:

- *Evaluation of hair regrowth*

Parting test and photographic documentation of the interested area.

- *Measurement by optical microscope of hair shaft thickness*

This measure was executed in the proximity of the bulb on a minimal of 3 anagen. Anagen identification was executed by the bulb morphological examination with the optical microscope.

- *Evaluation of hair resistance to traction*

Thanks to a dedicated device studied and planned by DermIng (the methodology is inspired to the norm UNI EN ISO2062:1997), the value of hair resistance to traction (weight force expressed in grams) was calculated. This measurement was performed for each volunteer on a minimum of 3 anagen hairs.

The product activity on nails was performed by the measurement of the *nail layer hardness*. The methodology was inspired to the norm UNI EN ISO2062:1997 and assumed the perforation of a 2-3 mm of nail fragment by a sthenometric screwdriver connected with a steel penetrometer (force expressed in cN.m). The force value necessary to determine the sample perforation represented the measure of nail hardness.

Moreover at the end of the trial the volunteers gave a self evaluation on tested products efficacy and tolerability.

Frequency of assumption: according to a randomisation list, each volunteer took 1 ampule/day of Proglyme[®] Food supplement of Amino Acids (group I) or 2 tablets/day (single administration) of Inneov trico-masse (group II).

Number of subjects: 24 subjects

Panel description: Healthy subjects of both sexes (22 female and 2 male) were included in the study. Age range 23 – 45 years (mean = 37).

2 drop-out occurred during the test; in fact because of personal problems volunteers n° 9 and 23 interrupted in advance the study.

Statistical analysis:

Because of technical problems it was not possible to measure nails hardness of volunteers n° 5, 21 and 24; therefore these subjects were excluded from the statistical analysis.

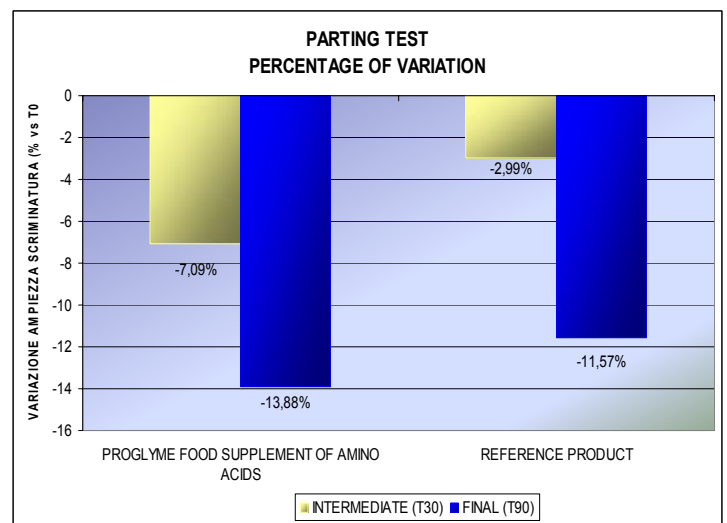
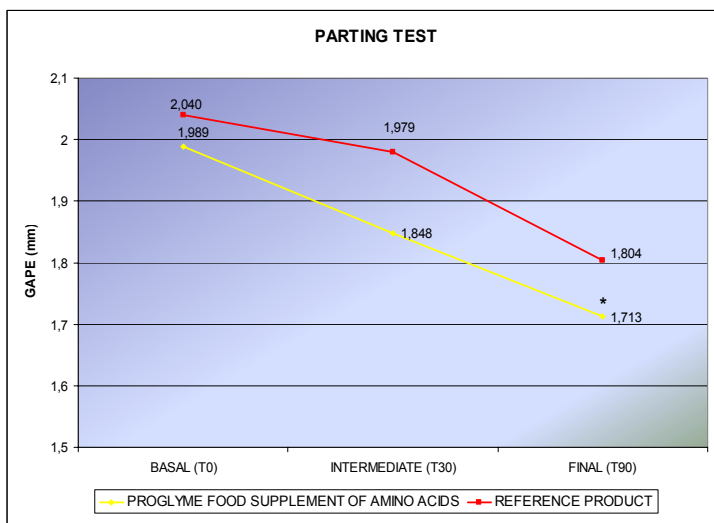
Statistical analysis considered:

- the comparison between the different study times towards basal conditions (Anova test for repeated measures followed when significative by Dunnet test for multiple comparisons).
- comparison between the 2 products under study at the same evaluation time (Student t test).

Efficacy results:

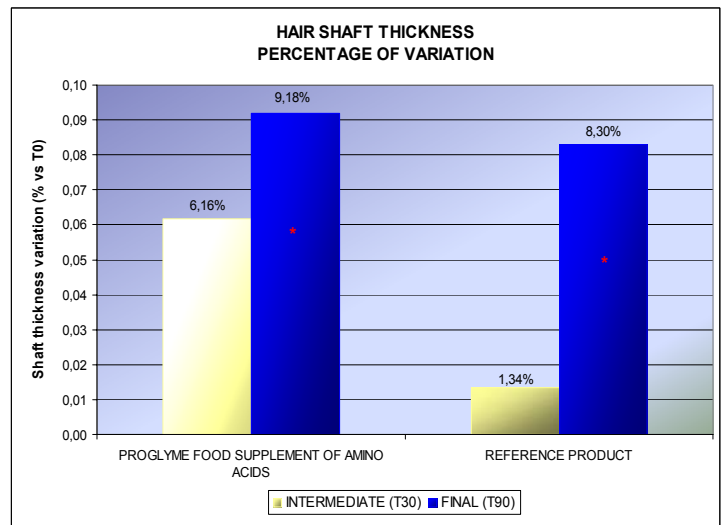
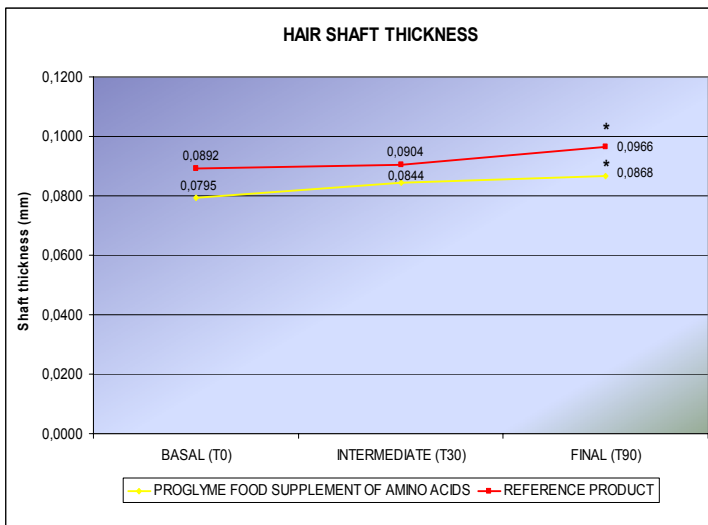
- PARTING TEST

Both food supplements determined after 3 month treatment a statistically significant hair thickening and a consequent decrease of the parting amplitude (Dunnet test $p < 0.05$ T90 vs T0 with a variation percentage versus T0 equal to 13.88% for the study product and to 11.57% for the reference product).



- HAIR SHAFT THICKNESS

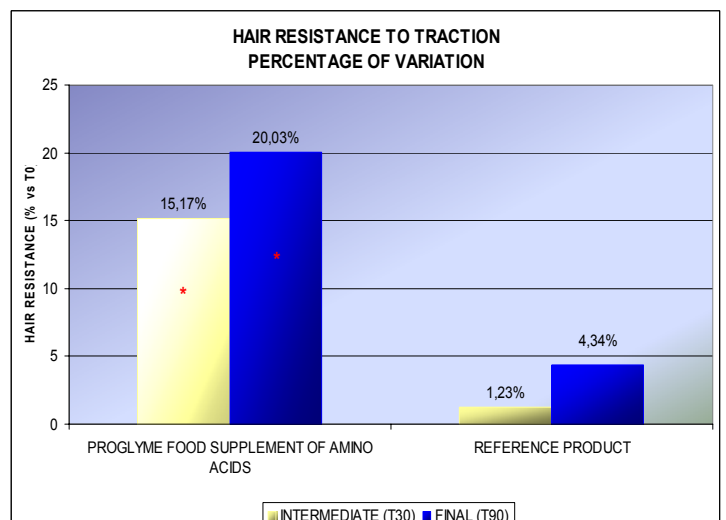
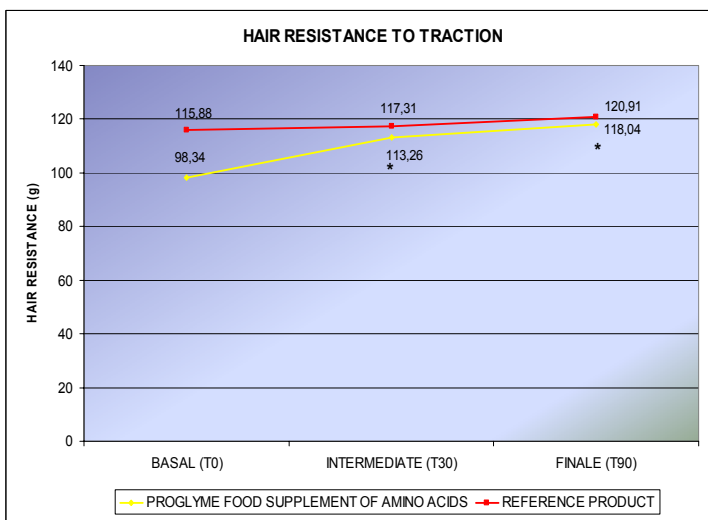
Both tested products determined at the end of the study period a statistically significant increase of shaft thickness (Dunnet test $p < 0.05$ T90 vs T0), with a diameter measurement increase of 9.18% for the product under study and 8.30% for the reference product. In particular concerning Proglyme® Food Supplement of Amino Acids this increase was still evident (but not statistically significant) after 1 month treatment (6.16% versus T0).



- HAIR RESISTANCE TO TRACTION

Still after 1 month treatment with Proglyme®, hair resistance to traction resulted significantly increased (Dunnet test $p < 0.05$ T30 vs T0 with an increase of 15.17%). This increase was yet more consistent at the end of the test (Dunnet test $p < 0.05$ T90 vs T0 with a percentage of increase equal to 20.03%).

No statistically significant variation of the considered parameter was observed due to the assumption of the reference product.



- NAILS HARDNESS

No one of the tested products determined a statistically significant variation of nails hardness.

- VOLUNTEERS' JUDGEMENT

Concerning the study product the volunteers appreciated: the increase of hair brightness (42%), the increase of regrowth speed (34%), and the fact that hairs appeared more thick (34%), and more strong (58%). Moreover they underlined the improvement of nails general aspect (75%), improvement of nails resistance (75%), reduction of nails chipping (75%), improvement of nails regrowth speed (50%).

Tolerability results:

Both the products were well tolerated and no adverse event related to the study products occurred. The optimal tolerability was also confirmed by the volunteers.

Conclusion:

The product Proglyme[®] food supplement of amino acids determined after 3 month treatment a statistically significant general hair thickening (parting amplitude reduction) and a significant thickening of hair shaft (diameter increase). These results were comparable with the ones obtained for the reference product. Moreover, compared to Inneov Trico Mousse, Proglyme Food Supplement of Amino Acids determined a significant increase of hair resistance to traction yet 1 month after trial starting.

Signature:

Date: 10nd July 2006

Adele Sparavigna
Dermatologist
Clinical Research Director
Dermlng