STUDY REPORT

Male Pattern Hair Loss

Sponsor	Caregen Co. Ltd. 690-3Caregen Bldg Geumjeong-Dong, Gunpo-Si Gyeonggi-Do, Korea Tel : 82-31-452-3867 Fax : 82-31-452-3869
Sponsor Contact	Sophia Ra
proDERM Study-No.	10.0294-57
Report Date	June 24, 2011
Report Status	Final
Test Dates	Screening October 26, 2010 November 02 to April 21, 2011
Study Site	proDERM Institute for Applied Dermatological Research Kiebitzweg 2, 22869 Schenefeld/Hamburg, Germany Tel: +49 (0)40 839 358-52 Fax: +49 (0)40 839 358-
President/CEO	Prof. Dr. med. Klaus-Peter Wilhelm, Dermatologist
Director Cosmetic Research/ Principal Investigator	Dipl. Bio-Ing. Stephan Bielfeldt
Project Manager/Investigator	Dr. rer. nat. Gunja Springmann

Authentication

The signatories confirm that this study was conducted, the analysis performed and the report prepared taking the principles of Good Clinical Practice (GCP) as a guide of reference for this study, and in accordance with the approved protocol(s). The principle requirements of the Declaration of Helsinki were taken into account to protect the rights, safety and well-being of subjects participating in the study. They further confirm that the reported results are a complete and accurate reflection of the clinical research data obtained in this study and based on the statistical analysis to the best of the undersigned's knowledge.

Prof. Dr. med. Klaus-Peter Wilhelm
Dermatologist
- President/CEO -

August 01, 2011
Date / Signature

Dipl. Bio-Ing. Stephan Bielfeldt
- Director Cosmetic Research/Principal Investigator -

July 20, 2011
Date / Signature

Dr. rer. nat. Gunja Springmann
- Project Manager/Investigator -

July 20, 2011
Date / Signature

Dipl-Stat. Agnes Himmelmann
- Statistics -

July 28, 2011
Date / Signature

This report has been audited by an independent quality assurance unit. It gives a faithful description of the study conduct. Quality control measures for completeness and accuracy of the clinical research data obtained in this study and for data analysis have been performed by responsible personnel. The reported results fully and accurately reflect the clinical research data obtained in this study to the best of the undersigned's knowledge. For this type of study in-life audits have been performed at regular intervals to verify adherence to applicable protocol(s) and compliance with the quality system of proDERM.

Dipl. -Ing Benjamin Saddig
- Quality Assurance -

July 29, 2011
Date / Signature

Personnel Involved

Director Cosmetic Research/ Principal Investigator	Dipl. Bio-Ing. Stephan Bielfeldt
Project Manager/Investigator	Dr. rer. nat. Gunja Springmann
Dermatologist/Sub-Investigator	Dr. med. Ulla Theissen
Lead Technician	Renate Barre
Data Management	Dipl.-Chem. Claudia Lippek
Statistics	Dipl.-Stat. Agnes Himmelmann
Report	Jennifer Klein, M.Sc. Biology
Quality Assurance	Dipl. Ing. Benjamin Saddig
Analysis of TrichoScan Data	Prof. Dr. med. Rolf Hoffmann (Tricholog)

Table of Contents

1 Objective

The purpose of this study was to assess the efficacy of a cosmetic product and a placebo against hair loss in male subjects with hair loss after a use period of 6 months regarding hair density and rates of anagen and telogen hairs by TrichoScan. Subjects with a Norwood/Hamilton score 3 to 4 were included.

The primary objective of this study was to demonstrate the efficacy of the cosmetic product on total hair density on day 171 compared to day 3.

Secondary objectives were to assess anagen hair density, telogen hair density, rate of anagen and telogen hair, anagen/telogen ratio, cumulative hair thickness, and hair growth rate for the comparisons of day 3, day 87 and 171 for two test products. Additionally a subjective and objective dermatological evaluation was performed and overall efficacy was evaluated.

A self-evaluation questionnaire was filled in by the subjects at the start and the end of the study.

2 Study Design

- Randomized
- Double blind
- Intra-individual comparison
- Placebo-controlled

3 Test Materials

The test products were cosmetic products, and were used as supplied by the Sponsor. It was the responsibility of the Sponsor to determine, for each batch of product, the identity, strength, purity, composition and other characteristics that appropriately define the test substances before their use in the study, and to identify potential hazard of the test products associated with this study. The determination of the stability of the test products and documentation of methods of synthesis or derivation were also the Sponsor's responsibility. The test products were stored at room temperature and -humidity in the containers in which they were received at proDERM.

Code/proDERM	Product/Code/Sponsor
A	A Concentration
B	B Concentration
Data Samples Received	October 28, 2010
Storage Conditions	Room Temperature

3.1 Application Mode

The subject was instructed to use the test product (hair toner) every day in the morning and evening. The test product should were used as follows:

- Apply the solution 2 times a day, morning and night
- Completely dry your scalp and hair before applying
- Fill the dropper with solution by squeezing the rubber part of the cap
- Using the dropper, apply the solution to the scalp in the hair loss area
- Thoroughly massage into the scalp with fingers while applying
- Repeat this process 3 times
- Do not wash off the solution for 3 – 4 hours

- The product should be shaken well before use and kept closed after use.

3.2 Dispensing, Accountability and Destruction

The responsibility for the test products accountability at the study site rests with proDERM. Records of the test product's receipt, dispensing, retraction, storage, and disposition of unused products or alternative return to the sponsor were maintained. proDERM ensures that the test products were used as directed by this protocol. If the test products were used by the subjects themselves appropriate instructions were given to the subjects either orally or in writing as deemed necessary by proDERM.

Unused test materials remaining at the conclusion of the study were destroyed 6 weeks after issuance of the final report unless requested otherwise.

3.3 Application Area

Two defined sides at the head

3.4 Application Volume

The applicated volume was determined by weighing the test product before and after the use period

3.5 Duration of Treatment

6 months per subject

4 Subjects

According to the Declaration of Helsinki the subjects have given consent to the study in writing. Beforehand they have been informed about the study in both oral and written form by the Investigator/Investigator's designee about the objectives, probable benefits, potential risks, as well as about rights and responsibilities.

4.1 Subject Restrictions

The subjects were instructed to perform the last application of test product on the previous day, at least 10 to 16 hours before the instrumental measurements.

The subjects were asked not to change their hairstyle throughout the course of the study (not in a way that affects the assessments in the test area) and not to have hair dyeing or permanent waves. They were asked not to use hairstyling products (hairspray, gel) prior to their visits in the morning.

4.2 Inclusion Criteria

- Male
- Between 45 and 75 years of age
- Written Informed Consent Form to participate in the study
- Willingness to actively participate in the study and to come to the scheduled visits
- Uniform skin color and no erythema or dark pigmentation in the test area
- Hair length of about 2 cm
- Willingness to have micro-tattoos on the clipped area of the scalp
- Willingness not to change the hair care products (e.g. shampoos, conditioner) throughout the course of the study
- Willingness not to change the hairstyle throughout the course of the study (not in a way that affects the assessments in the test area.

- Willingness to use the test product twice daily in the test area throughout the course of the study
- Willingness not to use cosmetic or medical products against hair loss throughout the course of the study
- Willingness not to use hair styling products (e.g. hairspray, gel) in the mornings prior to their visits at the study site
- Willingness not to dye the hair permanent or have permanent waves throughout the course of the study
- Willingness to wash their hair on the morning of their assessment and style as usual at the visits
- Norwood-Hamilton Score 3 to 4

4.3 Exclusion Criteria

- Drug addicts, alcoholics
- AIDS or infectious hepatitis if known to the subject
- Conditions which exclude a participation or might influence the test reaction/evaluation
- One of the following serious illnesses that might require regular systemic medication: insulin-dependent diabetes, cancer, systemic autoimmune disease
- Active skin disease at test area scalp (like psoriasis, seborrheic dermatitis or contact dermatitis)
- Documented allergies to cosmetic products
- Moles, tattoos, scars, irritated skin etc. at the test area that could influence the investigation
- Alopecia areata, inflammatory scarring or other scarring alopecias
- Sudden hair loss within the last 4 month unrelated to normal seasonal hair shedding
- Subject considering a method of surgical correction of the hair loss in the 6 months following inclusion, or who have already had such a method
- Any medical treatment for hair loss such as Finasteride (Propecia), Minoxidil (Regaine, Alosteril), Acitretin, Dudasteride (Avodart), 17-alphaoestradiol = alfatradiol (Ell Cranell alpha), Pantotin Solution or antiandrogens within the last 3 months prior to the start of the study and/or ongoing
- Nutraceutical(s) against hair loss within the last 3 months prior to the start of the study and/or ongoing
- Cosmetic product(s) against hair loss within the last month prior to the start of the study and/or ongoing
- Long-term systemic therapy with anti-inflammatory drugs (e.g. corticosteroids) within the last 4 month prior to the start of the study and/or ongoing
- Long term use of drugs that may cause hair loss such as Chemotherapy, Aromatase inhibitors, Retinoids, Corticosteroids, Anticonvulsant drugs, Anticoagulants, Antithyroid drugs within the last 6 months prior to the start of the study and/or ongoing
- Participation or being in the waiting period after participation in similar cosmetic and/ or pharmaceutical studies

All inclusion and exclusion criteria were checked by a questionnaire during the screening phase and observed throughout the study.

4.4 Prior and Concomitant Diagnosis and Therapy

Any treatment that is not listed in the exclusion criteria was allowed at the discretion of the Investigator. All study relevant concomitant medication and changes thereof were documented in the CRF (generic name, trade name for combinations, reason, start and end of intake, dosage and route).

All diseases which occurred during the study period were treated according to standard medicinal practice. The study relevant disease and the treatment were documented in the CRF. If the treatment was not allowed during the study, the subject was excluded from further participation.

5 Test Procedures

Before initiating the trial, the Investigator had written and dated full approval from the Freiburg Ethics Commission I nternational f or t he pr otocol, pr otocol amendment(s), i f appl icable, an d t he subject informed consent form.

5.1 Test Schedule

The study has been conducted according to the Study Protocol (see Appendix G) and approximating the main principles of GCP.

Day	Scree-ning	1	3	4 - 28	29	30 - 61	62	63 - 84	85	87	88 - 112	113	114 - 140	141	142 - 168	169	171
Informed Consent	X																
Inclusion / Exclusion Criteria	X																
Inclusion by dermatologist	X																
Prior/Concomitant medication	X																
Determination of test areas		X															
Visual Evaluation (Trained Technician and Subject)		X							X							X	
Questionnaire		X							X								X
Shaving		X			X		X		X			X		X		X	
Compliance Visit					X		X					X		X			
Microtattooing		X	X*		X*		X*		X*			X*		X*		X*	
Macrophotos - Phototrichogram		X	X						X	X						X	X
Documentation of AEs / Changes in Concomitant Medication		X**	X**		X**		X**		X**	X**		X**		X**		X**	X**
Hand out of Test products* and Diary			X		X*		X*			X*		X*		X*			
Application of Test Products (Twice daily)			X+	X	X+	X	X+	X	X+	X+	X	X+	X	X+	X	X+	
Termination Form																	X

* if necessary
** if applicable
+ The first application will be performed at the study site.

5.2 Description of Test Procedure

Screening: Subjects came to the Study Site. They were informed about the study by a dermatologist and gave their written consent. After the inclusion, dermatological evaluation of hair density regarding Norwood/Hamilton score (male subjects) were performed for suitability of each subject to take part in the study. Only subjects with Norwood/Hamilton 3-4 and fulfilling the inclusion/exclusion criteria were enrolled in the study.

Day 1 : Subjects came to the Study Site. The dermatological assessment was performed by the subjects and the trained technician. A self-evaluation questionnaire was filled in by the subjects.

Two areas of about 1.5 cm x 1.5 cm with the aid of a template were defined on the head (vertex zone) of each subject, which was shaved, until the scalp was almost reached. Retrieval of test areas was optimized by micro-tattoos. The two microtattoos per test area were done manually with color for permanent make up (Cosmetic Color Fire red #8016, Spaulding Color Corp., Voohee Sville, NY, USA) and a tattoo needle (Silver Stylo sterile needles, iMAX Deutschland, Frankfurt, Germany). The color was injected not deeper as the basal layer to avoid permanent tattoos.

Macrophotos were done of the test areas for shaving closeness on the test areas.

Day 3: The subjects returned to the Study Site about 48 hours (± 2 hours) after the shaving procedure. Check for microtattoos were performed and renewed if necessary. For blond or grey hair the contrast was not intense enough for a good photographic discrimination. For that reason the shaved hairs had to be dyed directly before the measurement. This was done with an eyebrow dye (Goldwell Topchic, 2N black, Kao, Darmstadt, Germany). The dye was mixed with the same amount of developer, was then applied with a spatula and was thoroughly removed with an alcoholic solution after 12 minutes.

Macrophotos of the test areas for the phototrichogram were taken and the image stored.

The test product was issued to subjects with instructions to use it twice daily on the assigned test area. The assignment of test areas was done according to a randomization scheme provided by proDERM. The subjects performed the first product application under the guidance of the technical assistant and the correct amount of product was demonstrated. A diary was also given to the subjects.

Day 4 to 84: The subjects used the product and the placebo daily according to sponsor's instructions. In this time frame the subjects came twice for compliance check to the Study Site (approximately **Day 29 and 62**). Check for microtattoos was performed regularly and shaving was performed for retrieval of test areas. Microtattoos were renewed if necessary. New diaries were provided to the subjects on each compliance visit.

Day 85: The subjects came to the Study Site. Procedures of day 1 were repeated. Macrophotos of the test areas for the phototrichogram were taken after shaving. A self-evaluation questionnaire was filled in by the subjects.

Day 87: The subjects came to the Study Site. Procedures of day 3 were repeated. Macrophotos of the test areas for the phototrichogram were taken about 48 hours (± 2 hours) after the shaving procedure. New diaries and test products/placebos were provided to the subjects.

Day 88 to 168: The subjects used the product and the placebo daily according to sponsor's instructions. In this time frame the subjects came twice for compliance check to the Study Site (approximately **Day 113 and 141**). Check for microtattoos was performed regularly and shaving was performed for retrieval of test areas. Microtattoos were renewed if necessary. New diaries were provided to the subjects on each compliance visit.

Day 169: The subjects came to the Study Site. Procedures of day 1 were repeated. Macrophotos of the test areas for the phototrichogram were taken after shaving. The subjects used the product and the placebo daily according to sponsor's instructions.

Day 170: The subjects used the product and the placebo daily according to sponsor's instructions.

Day 171: The subjects came to the Study Site. Procedures of day 3 were repeated. Macrophoto of the test areas for the phototrichogram were taken about 48 hours (± 2 hours) after the shaving procedure. A self-evaluation questionnaire was filled in by the subjects.

Products were collected and reweighed at the end of the study.

A deviation of ± 2 days of the study days were accepted, since no substantial influence on the outcome of the study is expected.

5.3 Objective and Subjective Evaluation

5.3.2 Dermatological Evaluation upon Inclusion

Dermatological Evaluation for Inclusion	Hair Loss evaluation at the scalp according to the classification of Hamilton modified by Norwood (see Appendix 1) upon inclusion

5.3.1 Objective Assessment of Tolerance by Trained Technician

Objective Parameters: Erythema, dryness, scaling, fissures, papules, pustules, edema, vesicles, weeping, other

Scale:

0 = None

0.5 = Very Slight

1 = Slight

2 = Moderate

3 = Strong

Overall Efficacy as rated by trained technician

Scale:

0 = No Anti-Hairloss Efficacy

1 = Low

2 = Moderate

3 = Good

4 = Very Good

5.3.2 Subjective Assessment by Subject

Subjective Parameters: Feeling of itching, burning, tension, tickling, dryness, feeling of pain, other

Scale:

0 = None

0.5 = Very Slight

1 = Slight

2 = Moderate

3 = Strong

Overall Efficacy as rated by the Subjects

Scale:

0 = No Anti-Hairloss Efficacy

1 = Low

2 = Moderate

3 = Good

4 = Very Good

Scores were directly entered into a PC system with an appropriate computer program.

5.4 Instrumental Measurements

5.4.1 Images of the tested areas (Phototrichogramm), 1-fold

The designated areas were shaved and the template was placed on the areas to enable the precise shaving of the hair of the areas. The two microtattoos per test area were done manually with color for permanent make up (Cosmetic Color Fire red #8016, Spaulding Color Corp., Voohee Sville, NY, USA) and a tattoo needle (Silver Stylo sterile needles, iMAX Deutschland, Frankfurt, Germany). Then, an image of the area was taken using the TrichoScan system. It was set up with a funnel-shaped measuring head that had a glass plate at one side. The technician gently placed the measuring head in a straight angle on the areas, so that all hairs were equally pressed flat for the best analysis. After taking images on one subject, the glass of the camera was cleaned by the technical assistant, using tissues and alcohol, before the next subject was measured. 2 days after this procedure, the image-taking was repeated.

- Template with a hole of about 15 x 15 mm
- Tissues and alcohol/Cutasept (or something similar) for cleaning the measuring head
- Tattoo needle (Silver Stylo sterile needles, iMAX Deutschland, Frankfurt, Germany)

5.4.2 Image Analysis

Images were taken with the TrichoScan system. Analysis of taken images was performed by Tricholog GmbH, Freiburg, Germany. Provided parameters was hair density (hairs/cm²), rate of anagen hairs, rate of telogen hairs and ratio of anagen, telogen hair, cumulative hair thickness, and hair growth rate.This software was especially adapted for this trial. All relevant patient data and image codes were managed in this software. Once a subject had been randomised it was entered into the software data base with the respective randomisation code. The digital images from the subjects were allotted to the chosen subject by a use of a drop down list. Images then got their final codes.

6 Safety Criteria and Adverse Event Reporting

6.1 Recording and Reporting of Adverse Events

All study relevant adverse events (excluding those parameters being scored as part of the protocol) were documented in the study records.

Subjects were questioned for AEs at visit days 1, 3, 29, 62, 85, 87, 113, 141, 169 and 171 using non leading questions. The obligation to document AEs started with enrolment of the subject in a study.

Details recorded included the nature of the adverse event, onset date/time, duration, severity, outcome and relationship to test product. Any adverse event requiring medical attention was referred to the appropriate proDERM medical personnel.

The **PM/**Investigator reported immediately all serious adverse events which occur during the study by telephone or fax Caregen Co. Ltd (Phone: +82-31-452-3867; Fax: +82-31-452-3869). The Investigator ensured that appropriate therapeutic and follow-up measures were instituted in accordance with good medical practice and should notify the Sponsor of such actions. A full written report of the serious adverse events had to be forwarded to the Sponsor by fax or the next available post.

7 Archiving

All raw data pertaining to the study are available for inspection by the Sponsor for compliance monitoring. In addition, specified scientists designated by the Sponsor may, upon appointment, examine any set of data. The study report, and informed consents of the subjects related to the study are stored for at least 10 years. All other study related data are stored for at least 3 years.

8 Statistical Considerations/Evaluation

8.1 Randomization

Random, balanced assignment of cosmetic product and placebo to left and right side of head

8.2 Unblinding and Derandomization

The study was a double-blind study. The subjects were blinded to the test article identification. All data generated were sent to the Sponsor study manager. The Sponsor study manager unblinded the study. In case, unblinded data was needed for statistical analyses due to derandomization, the analyses were finalized after unblinding. Otherwise, statistical analysis was finished before unblinding.

8.3 Methods of Analysis

Efficacy analysis is based on the Per Protocol Population.

No replacement of missing data was performed and the affected measurements were not included in final statistical analysis.

All raw data of subjects as well as calculated values (differences to day 3) were listed. N, means, standard deviations and 95% confidence limits of PP population was calculated for all assessment times as well as for calculated parameters. Counts and percentages of scores were given subjective and objective evaluations as well as for questionnaire.

Primary analysis

Primary statistical analysis of this study was based on total hair density of cosmetic product on day 171 and day 3 (baseline). The following Hypothesis was assessed:

H_0: No change in total hair density between day 3 and day 171 on product treated area vs,

H_1: Hair density is different between day 3 and day 171 on product treated area

For statistical analysis, a paired t-test will be performed at a significance level of α=0.05.

Secondary analyses

The following analyses were performed for the parameters total hair density, anagen hair density, telogen hair density, rate of anagen and telogen hair, anagen/telogen ratio, cumulative hair thickness and hair growth rate separately.

- Repeated measures ANOVA on all subjects including within-subject factor treatment (2 levels: product, placebo) and within-subject factor time (3 levels: day 3, day 87 and day 171)
- Pairwise comparison of treatments (product vs placebo) on differences to day 3 using paired t-tests on day 87 and day 171
- Pairwise comparison of all assessment times (day 3, day 87 and day 171) by treatments using paired t-tests

Furthermore pairwise comparison of all assessment times (day 1, day 85 and day 169) by treatments and comparisons of treatments (product vs placebo) on day 85 and day 169 using Wilcoxon-Signed Ranks Test were performed for subjective and objective evaluations as well as for questionnaire items.

A significance level of 0.05 (alpha) was chosen for all secondary analyses; no adjustment for multiplicity was done.

The mean values of raw data and differences to baseline for phototrichogram data was presented in figures with 95%-confidence intervals.

Demographic variables (age, gender) were based on the Per Protocol Population. Data were summarized using frequency distributions (number and percentage) for categorical/ordinal variables and mean, standard deviation and range for continuous variables.

Safety Analysis (AEs, concomitant medication) was based on the Safety Population. Data was summarized using frequency distributions (number and percentage) for categorical/ordinal variables and mean, standard deviation and range for continuous variables.

Computation of the statistical data was carried out with a commercially available statistics program (SPSS for Windows).

9 Results

9.1 Demographic Data and Drop Outs

Subjects Screened	37
Subjects Enrolled	36
Complete Data Exclusions	1 without relation to test products * Subject #24 further explanation: see List of Subjects, Appendix C
Subjects Analyzed	35
Age (n = 36)	58.4 ± 8.3 years (mean ± standard deviation)
Sex	All males

9.2 Screening

37 subjects were screened for this study, which had a mean dandruff score of 4.3. One of these subjects was not randomized into the study.

9.3 Medical History – Diagnosis, Concomitant Therapies

No diagnosis and therapies were registered in any of the subjects.

9.4 Adverse Reaction and Serious Adverse Event Reporting

No serious adverse event and no adverse reaction were seen during the conduct of the study.

9.5 Protocol Deviations/Additional Remarks

Subject #24 withdrew from the study, therefore all data from this subject was excluded from statistical analysis.

Subject #17 applied the test product in the morning of study day 85. As it did not influence the study procedures, this deviation was expected to be minor and the subject was included into the final analysis.

Subject #6 did not come to the scheduled visit on study day 171. Assessments were performed 24 h later than intended for this subject

Subject #17 applied the test product in the morning of study day 85. Therefore, the last application was performed less than 10 hours before the instrumental measurements.

Subject #19, 20 missed the compliance check on study day 113

Subject #22 applied the test product only once on study day 28. Due to personal reasons, the subject came to the study site 6 hours earlier than intended on study day3.

Phototrichogram evaluations regarding test product A were not available for the following subject: #31, study day 3 (all parameters).

Phototrichogram evaluations regarding test product B were not available for the following subjects: #4 on study day 87 (growth-related parameters), #11 on day 87 (growth-related parameters could not be used due to incomplete hair dye), #32 on study day 3 (all parameters due to hair dye remnants), #33 on study day 3 (all parameters due to hair dye remnants).

Phototrichogram evaluations regarding test products A and B were not available for the following subjects: #17 on study day 3 (growth-related parameters could be used due to incomplete hair dye), #29 on study day 3 (growth-related parameters could not be used due to incomplete hair dye).

9.6 Amount of Test Product Used

The amount of test product test product A used was determined to a mean value of 68.84 g in the first 4 weeks (sequence 1 - until day 29), 76.93 g in the following 4 weeks (sequence 2 - until day 57), 65.35 g in the following 4 weeks (sequence 3 - until day 87), 67.33 g in the following 4 weeks (sequence 4 - until day 113), 73.69 g in the following 4 weeks (sequence 5 - until day 141), 74.38 g in the last 4 weeks (sequence 6 - until day 171).

The amount of test product B used was determined to a mean value of 67.08 g in the first 4 weeks (sequence 1 - until day 29), 78.05 g in the following 4 weeks (sequence 2 - until day 57), 66.97 g in the following 4 weeks (sequence 3 – until day 87), 68.65 g in the following 4 weeks (sequence 4 – until day 113), 72.89 g in the following 4 weeks (sequence 5 – until day 141) and 74.43 g in the last 4 weeks (sequence 6 – until day 171).

Detailed information about the amount of test product used is provided in Appendix H.

9.7 Results of Phototrichogram

Primary Objective

Table 1 presents the mean values of total hair density for treatments A and B on study days 3 and 171 as well as the differences to day 3 (baseline). Additionally, the results of statistical comparisons of study day 3 vs. day 171 for both treatments are presented.

Table 1: Mean Values of Total Hair Density for Treatments A and B and Results of Comparisons of Day 3 vs. Day 171 (N = 32)

Parameter	Treatment	Day 3 (baseline)	Day 171	Diff. to Day 3	p-Values of t-Test Day 171 vs. Day 3
Total Hair Density [1/cm²]	**A**	213.24	223.68	10.44	**0.001***
	B	204.31	218.69	14.38	**< 0.001***

n.s.: not significant ***: significant p ≤ 0.05**

The evaluation of the total hair density on the areas to be treated with the test product A or B showed a slightly greater total hair density (213.24 1/cm²) on the area to be treated with test product A compared to the area to be treated with test product B (204.31 1/cm²). After 6 months of treatment with test product A or B, the mean of the total hair density increased on both test areas (A = 223.68 1/cm², B = 204.31 1/cm²). The comparison of day 3 (baseline) versus day 171 showed a significant increase of the total hair density on the areas treated with test products A and B.

Secondary Objective:

Hair grows in cycles of various phases: anagen is the growth phase; catagen is the regressing phase and telogen is the resting phase. Tables 2 presents the mean values of Phototrichogram data for treatments A and B on study days 3 and 87.

Table 2: Mean Values of Phototrichogram Raw Data for Day 87 and Differences to Day 3. Comparison of A vs. B on Differences to Day 3 by Paired t-Tests, Comparison of Day 87 vs. Day 3 by Paired t-Tests

Parameter	Product	N	Day 3	Day 87	Diff. to Day 3	p-Values of t-Test	
						Comparison of Treatments	Comparison D3 vs D87
Total Hair Density [1/cm²]	**A**	32	213.24	223.73	10.49	**0.009 ***	**0.001 ***
	B	32	204.31	224.23	19.92		**<0.001 ***
Cum. Hair Thickness [mm]	**A**	32	22.31	23.98	1.67	0.099 n.s.	**<0.001 ***
	B	32	21.18	23.47	2.29		**<0.001 ***
Anagen Hair Density [1/cm²]	**A**	28	171.35	187.18	15.83	**0.006 ***	**<0.001 ***
	B	28	163.32	187.10	23.78		**<0.001 ***
Telogen Hair Density [1/cm²]	**A**	28	34.23	30.13	-4.10	0.607 n.s.	**0.015 ***
	B	28	35.35	30.08	-5.27		**0.034 ***
Rate of anagen [%]	**A**	28	83.62	86.32	2.70	0.269 n.s.	**0.001 ***
	B	28	82.33	86.13	3.81		**<0.001 ***
Rate of telogen [%]	**A**	28	16.38	13.68	-2.70	0.269 **n.s.**	**0.001 ***
	B	28	17.67	13.87	-3.81		**<0.001 ***
Anagen/telogen Ratio [%]	**A**	28	5.62	7.07	1.44	0.216 n.s.	**0.003 ***
	B	28	5.29	7.61	2.32		**<0.001 ***
Hair Growth Rate [mm/day]	**A**	28	0.34	0.37	0.03	0.923 n.s.	**0.001 ***
	B	28	0.33	0.36	0.03		**0.001 ***

The evaluation of the **total hair density** on the areas to be treated with the test product A and B showed a slightly greater **total hair density** in the mean (213.24 1/cm²) on the area to be treated with test product A compared to the area to be treated with test product B (204.31 1/cm²). The comparison of day 3 vs. day 87 showed a significant increase of the **total hair density** on the areas treated with test products A and B compared to baseline values (day 3). A significantly ($p = 0.009$) greater increase was documented for test product B (Diff. to Day 3 = 19.92) compared to test product A (Diff. to Day 3 = 10.49).

The **cum. hair thickness** on the areas to be treated with the test product A was slightly greater (22.31 mm) than on the area to be treated with the test product B (21.18 mm). The comparison of day 3 versus day 87 showed a significant increase of the **cum. hair thickness** on the areas treated with test products A and B compared to baseline values (day 3). A greater increase was documented for test product B (Diff. to Day 3 = 2.29) compared to test product A (Diff. to Day 3 = 1.67). The comparison of test product A vs. B showed no statistical significant difference between the treatments.

The evaluation of the **anagen hair density** showed a slightly greater value (171.35 1/cm²) on the area to be treated with test product A compared to the area to be treated with test product B (163.321/cm²). The comparison of day 3 versus day 87 showed a significant increase of the the **anagen hair density** on the areas treated with test products A and B compared to baseline values (day 3). A significantly greater increase was documented for test product B (Diff. to Day 3 = 23.78 %) compared to test product A (Diff. to Day 3 = 15.83 %).

The evaluation of the **telogen hair density** on the areas to be treated with the test product A and B was comparable (A = 83.62 % , B = 82.33 %). The comparison of day 3 versus day 87 showed a significant decrease of the telogen hair density on the areas treated with test products A and B compared to baseline values (day 3). A greater decrease was documented for test product B (Diff. to Day 3 = -5.27) compared to test product A (Diff. to Day 3 = -4.10). The comparison of test product A vs. B showed no statistical significant difference between the test products.

The **anagen/telogen ratio** was 5.62 on study day 3 and increased to 7.07 on study day 87 regarding test product A. For test product B, the **anagen/telogen ratio** increased from 5.29 on study day 3 to 7.61 on study day 87. No significant differences were found between the treatments. The comparison of day 3 vs. day 87 showed a significant increase of the anagen/telogen ratio on the areas treated with test products A and B compared to baseline values (day 3).

The evaluation of the **hair growth rate** on the areas to be treated with the test product A and B was comparable (A = 0.34 mm/day, B = 0.33 mm/day. The comparison of day 3 vs. day 87 showed a significant increase of the hair growth rate on the areas treated with test products A and B compared to baseline values (day 3). No statisticalsignificant differences were found between the products.

Tables 3 presents the mean values of Phototrichogram data for treatments A and B on study days 3 and day 171.

Table 3: Mean Values of Phototrichogram Raw Data for Day 171 and Differences to Day 3 . Comparison of A vs. B on Differences to Day 3 by Paired t-Tests, Comparison of Day 171 vs. Day 3 by Paired t-Tests

Parameter	Product	N	Day 3	Day 171	Diff. to Day 3	p-Values of t-Test	
						Comparison of Treatments	Comparison D3 vs D171
Total Hair Density [1/cm²]	**A**	32	213.24	223.73	10.49	0.320 n.s.	**0.001 ***
	B	32	204.31	218.69	14.38		**< 0.001 ***
Cum. Hair Thickness [mm]	**A**	32	22.31	23.70	1.39	0.448 n.s.	**< 0.001 ***
	B	32	21.18	22.88	1.69		**< 0.001 ***
Anagen Hair Density [1/cm²]	**A**	28	171.35	184.82	13.46	0.280 n.s.	**<0.001 ***
	B	28	163.32	180.34	17.01		**<0.001 ***
Telogen Hair Density [1/cm²]	**A**	28	34.23	30.15	-4.07	0.953 n.s.	0.053 n.s.
	B	28	35.35	31.43	-3.92		0.109 n.s.
Rate of anagen [%]	**A**	28	83.62	86.19	2.57	0.670 n.s.	**0.006 ***
	B	28	82.33	85.30	2.97		**0.007 ***
Rate of telogen [%]	**A**	28	16.38	13.81	-2.57	0.670 n.s.	**0.006 ***
	B	28	17.67	14.70	-2.97		**0.007 ***
Anagen/telogen Ratio [%]	**A**	28	5.62	6.89	1.27	0.913 n.s.	**0.005 ***
	B	28	5.29	6.51	1.22		**0.024 ***
Hair Growth Rate [mm/day]	**A**	28	0.34	0.36	0.02	0.506 n.s.	**0.016 ***
	B	28	0.33	0.36	0.03		**0.003 ***

The comparison of day 3 versus day 171 showed a significant increase of the **Total Hair Density** on the areas treated with test products A and B compared to baseline values (day 3). A slightly greater

increase was documented for test product B (Diff. to Day 3 = 14.38 mm) compared to test product A (Diff. to Day 3 = 10.49 mm). No statistical significant differences were found between the products

The comparison of day 3 versus day 171 showed a significant increase of the **cum. hair thickness** on the areas treated with test products A and B compared to baseline values (day 3). A slightly greater increase was documented for test product B (Diff. to Day 3 = 1.69 mm) compared to test product A (Diff. to Day 3 = 1.39 mm). No statistical significant differences were found between the products

The comparison of day 3 versus day 171 showed a significant increase of the **anagen hair density** treated with test products A and B compared to baseline values (day 3).A slightly greater increase was documented for test product B (Diff. to Day 3 = 17.01) compared to test product A (Diff. to Day 3 = 13.46). No significant differences were found between the products.

The comparison of day 3 vs day 171 showed no significant difference of the **telogen hair density** for test products A and B compared to baseline values (day 3). A slightly lower decrease was documented for test product B (Diff. to Day 3 = -3.92 mm) compared to test product A (Diff. to Day 3 = -4.07 mm) No significant differences were found between the products.

The comparison of day 3 versus day 171 showed a significant increase of the **anagen/telogen** ratio on the areas treated with test products B compared to baseline values (day 3). The **anagen/telogen** ratio was 5.62 on study day 3 (baseline) and increased to 6.89 on study day 171 regarding test product A. For test product B, the **anagen/telogen** ratio increased from 5.29 on study day 3 (baseline) to 6.51on study day 171. No significant differences were found between the products.

After 171 days of treatment with test product A or B the mean of **hair growth rate** values increased to on both test areas. No significant differences were found between the treatments.

10 Conclusions

The purpose of this study was to assess the efficacy of a cosmetic product and a placebo against hair loss in male subjects with hair loss after a use period of 6 months regarding hair density and rates of anagen and telogen hairs by TrichoScan. Subjects with a Norwood/Hamilton score 3 to 4 were included.

The primary objective of this study was to demonstrate the efficacy of the cosmetic product on total hair density on day 171 compared to day 3.

Secondary objectives were to assess **anagen hair density**, **telogen hair density**, **rate of anagen, rate of telogen**, **anagen/telogen ratio**, **cumulative hair thickness** and **hair growth rate** for the comparisons of day 3, day 87 and 171 for placebo and test product. Additionally, subjective and objective dermatological evaluations were performed and overall efficacy was evaluated. A self-evaluation questionnaire was filled in by the subjects at the start of the study and after 3 and 6 months of treatment.

Concerning the primary objective: After 6 months of treatment with test products **A Concentration (A)** or **B Concentration (B)** the **total hair density** improved significantly on both test areas. Regarding test product **B Concentration**, the total hair density improved to a higher degree compared to test product **A Concentration** In the direct statistical comparison between test product **A Concentration** and **B Concentration**, no significant difference was detected.

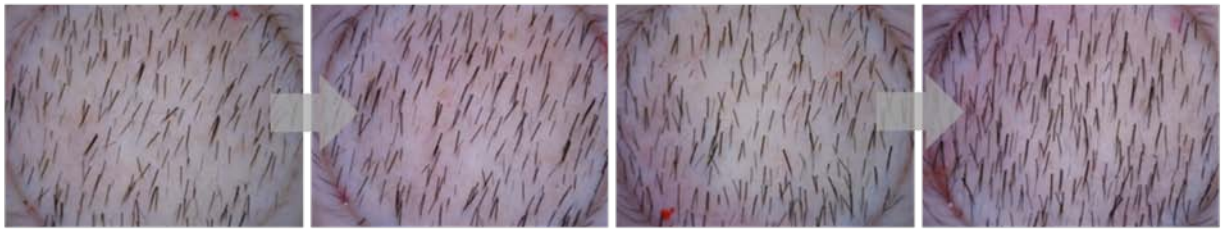
Concerning the secondary objectives: Significant improvement of **total hair density, cumulative hair thickness, anagen hair density, telogen hair density, rate of telogen, rate of anagen, anagen/telogen ratio** and **hair growth rate** were observed for test products **A Concentration** and **B Concentration** after 3 weeks of treatment compared to baseline (day 3). Test product **B Concentration** performed significantly better than test product **A Concentration** concerning following parameters: **total hair density** and **anagen hair density** after 3 months of treatment.

Significant improvement of **total hair density, cumulative hair thickness, anagen hair density, rate of anagen, rate of telogen, anagen/telogen ratio** and **hair growth rate** were observed for test products **A Concentration** and **B Concentration** after 6 months of treatment compared to baseline (day 3). For the **telogen hair density**, no difference to baseline was found. No significant differences between test products **A Concentration** and **B Concentration** were found after 6 months of treatment.

According to the results of this study, test product B Concentration performed significantly better than test product A Concentration concerning the total hair density and anagen hair density after 3 months of treatment. After 6 months, no differences between the test products A Concentration and B were detected.

Tricoscan analysis

A : A Concentration
B : B Concentration

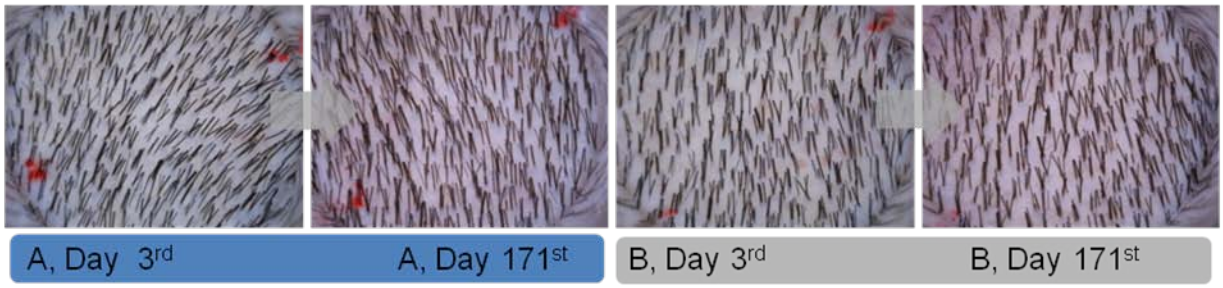


No. 16	Total Hair Density (1/cm²)				Cumulative Hair Thickness (mm)		Anagen Hair Density [1/cm²]	
Age : 49 yr	Day3	Day171	diff. to Day3	% change	diff. to Day 3	% change	diff. to Day3	% change
A	108.50	110.71	2.21	2.04	0.85	8.31	8.93	10.22
B	126.77	153.06	26.29	20.74	2.49	21.10	28.07	26.70

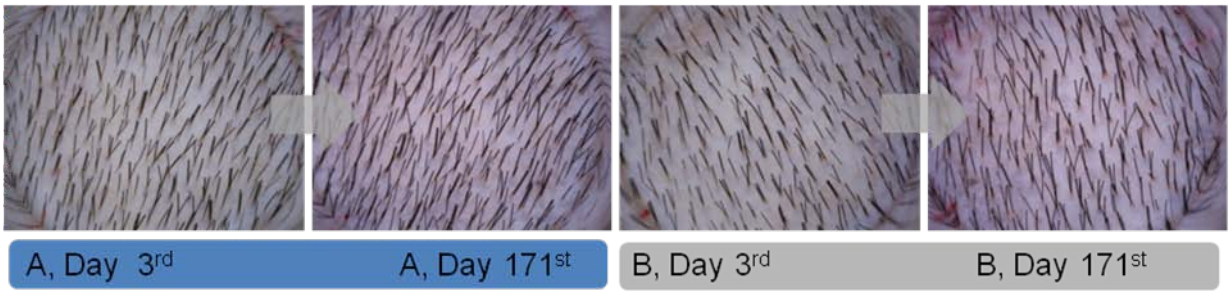
No. 30	Total Hair Density (1/cm²)				Cumulative Hair Thickness (mm)		Anagen Hair Density [1/cm²]	
Age : 52 yr	Day3	Day 171	diff. to Day3	% change	diff. to Day3	% change	diff. to Day3	% change
A	260.17	270.13	9.96	3.83	0.28	1.13	25.5	13.13
B	190.15	236.37	46.22	24.31	2.30	11.50	20.54	12.90

Tricoscan analysis

A : A Concentration
B : B Concentration



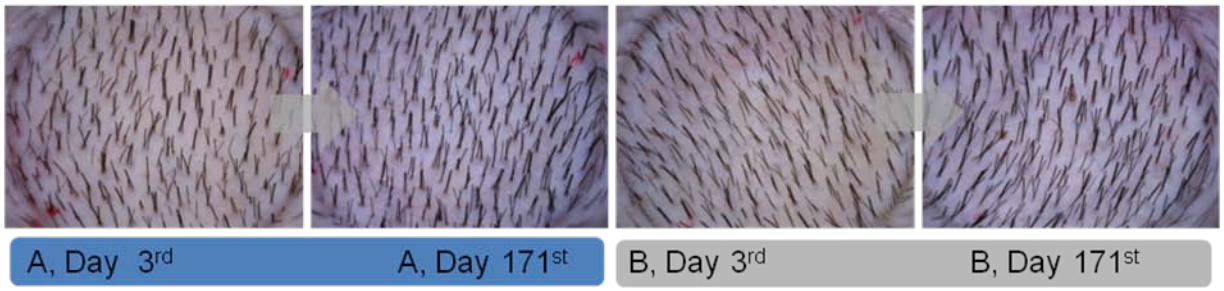
No. 22	Total Hair Density (1/cm²)				Cumulative Hair Thickness (mm)		Anagen Hair Density [1/cm²]	
Age : 52 yr	Day3	Day 171	diff. to Day3	% change	diff. to Day3	% change	diff. to Day3	% change
A	262.39	274.01	11.62	4.43	2.05	7.35	7.39	3.26
B	263.22	317.47	54.25	20.61	6.22	22.40	23.97	10.50



No. 6	Total Hair Density (1/cm²)				Cumulative Hair Thickness (mm)		Anagen Hair Density [1/cm²]	
Age :	Day3	Day171	diff. to Day3	% change	diff. to Day3	% change	diff. to Day3	% change
A	173.54	208.69	35.15	20.25	2.24	13.13	11.21	7.31
B	138.94	163.85	24.91	17.93	1.49	10.10	6.86	5.30

Tricoscan analysis

A : A Concentration
B : B Concentration



No. 27	Total Hair Density (1/cm²)				Cumulative Hair Thickness (mm)		Anagen Hair Density [1/cm²]	
Age :	Day3	Day87	diff. to Day3	% change	diff. to Day3	% change	diff. to Day3	% change
A	180.46	208.69	28.23	15.64	3.22	19.96	18.05	12.00
B	184.06	208.42	24.36	13.23	2.56	15.80	25.30	16.20