

Case Report

Malays. j. med. biol. res.



Clinical Study to Assess the Efficacy of a Novel Hair Loss Treatment

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ABSTRACT

Background: Hair loss affects men and women around the world.

Objective: This study analyzed the efficacy of a hair formula named Lotus 39 by Valentino De Salva (Lotus 39) on hair loss.

Methods: Men and women between ages 42 and 72 applied Lotus 39 to their scalp every day for 8 weeks. For ethical reasons, a nonrandomized controlled study protocol was selected

Results: According to the data, Lotus 39 stops hair loss, causes an increase in vellus hair, and an increase total hair count.

Limitations: No control was assigned due to funding, baseline pictures were taken at the onset of the study, during, and at the end of the study to draw a depiction of hair improvement over time.

Conclusion: This study suggests that Lotus 39 improves the health of the scalp and hair.

Keywords: hair, hair loss, vellus hair, scalp health, human hair regrowth, human hair

IRB Approval Status: Reviewed and approved by IntegReview IRB; approval #CRLNJ2019-0198.

Manuscript Received: 11 January 2022

Revised: 12 February 2022

Accepted: 20 February 2022

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INTRODUCTION

Hair loss and thinning are typical disorders in clinical dermatology (Gordon, 2011). Some potential reasons for hair loss include androgenetic alopecia, alopecia areata, telogen effluvium, and chemotherapy-induced alopecia (Otberg et al., 2007; Ghanaat, 2010; Wasserman et al., 2007; Trueb, 2009). Many communities place a large importance on hair. Males and females alike are under constant societal pressure to maintain their physical appearance as it relates to body image, hair, cosmetics and apparel (Helfert and Waschburger, 2013; Dohnt and Tiggemann, 2006; Chen and Jackson, 2012; Andersson, 1979; Jones et al., 2004). Hair loss studies have shown the importance of hair during social and sexual interactions (Randall, 2001), as well as it being a contributing factor to the outlook of the human body (Randall, 2007; Shorter et al., 2008).

Numerous studies conducted internationally have been directed toward determining the best route to regrow hair on humans. Some researchers have attempted to use mammals like rats, hamsters, rabbits and sheep to understand the hair regrowth process in laboratory conditions (Hamilton, 1958; Hamilton, 1951; Ludwig, 1977; Chase et al., 1951). Other researchers have studied human hair and the effect of transplanting that patient's hair from one location of their

scalp to another, unfortunately, this option is limited by cost and patient supply of donor hair (Rogers and Avram, 2008). Although everyone is not eligible for hair transplantation, Abaci is studying ways to regrow human hair in a petri dish first, to open hair restoration surgery for more individuals (Abaci et al., 2018). Another method that has shown some success for human hair regrowth is light therapy (Metelitsa and Green, 2011; Avci et al., 2014). Currently, there are only two Food and Drug Administration (FDA) approved hair loss drugs available for medical management of hair loss: minoxidil and finasteride (Tsuboi et al., 2007; Price, 1999). Unfortunately the efficacy of Minoxidil ranges from 20-40%, causing discontinuity of treatment in the majority of patients (Tosti, 2009). Studies have shown Finasteride to have an adverse reaction with some individuals causing sexual dysfunction in 4% of cases (Mc Phee et al., 2007; Kondo et al., 1990). According to Orasan et al. (2016a) "finasteride and minoxidil (2% or 5%) have temporary effects and unpredictable efficacy, better pharmacological options are necessary for managing hair loss" (Gordon, 2011). Orasan et al. (2016b) went on to review hair loss techniques and stated "further studies are required not only to compare the efficiency of different therapies, but more importantly to establish their long term safety" (p.327).

There is little data on topical formulations that can naturally stimulate new hair follicles to grow, improve skin health and increase hair count. This research will discuss the effects of a clinical study conducted by Eurofin Scientific whereby participants used Lotus 39 to address their hair loss.

STUDY DESIGN

A total of 11 people (6 men and 5 women) took part in this clinical trial to see how effective a hair treatment regimen was (Supplemental Data). Individuals ranging from white to brown based on the Fitzpatrick skin type participated in this study. Study evaluations included corneometer measurements, transepidermal water loss, ocular acuity evaluations, and hair counting. Two Materials were used in this study: Lotus 39 Enhancer (Enhancer) and Lotus 39 Elixir (Elixir).

A study schedule appears in the Supplemental Data of this clinical study.

Subject Termination and Withdrawal: All subjects were free to withdraw from participation at any time and without prejudice.

Randomization: No randomization was required for this study.

Blinding: Subjects were blinded to the name of the test materials

STUDY EVALUATIONS

Test Site Tattooing

One professional micro tattoo was placed in the center of the 0.5 in.2 test site by a professional tattoo artist. The micro tattoo assisted in referencing the exact test site at subsequent study visits.

Evaluation of Hair Growth

The FotoFinder Medicam 1000 using the D-Scope IV 20x lens captured participant images at Baseline, 48 Hours Post-Application, Week 4, Week 4 + 48 Hours, Week 8, and Week 8 + 48 Hours. The images were captured in the Trichogram mode. The Trichoscale program generated the data for this study. The following parameters were collected for analysis.

- **Relevant Hair:** Hair Count, Hair Density
- **Length:** Hair Count Anagen, Hair Count Telogen, Hair density Anagen, Hair density Telogen, Mean Length
- **Thickness/Diameter:** Cumulative Thickness

Corneometer

The general appearance of a soft, smooth skin depends on the presence of an adequate amount of water in the stratum corneum. The Corneometer is an instrument designed to measure changes in the capacitance of the skin resulting from changes in the degree of hydration. It is sensitive to low hydration levels. Triplicate Corneometer measurements were obtained at Baseline and Week 8.

Transepidermal Water Loss (TEWL)

The VapoMeter is the only fully portable instrument available for the measurement of TEWL values and evaporation rates. TEWL is an indicator of the skin's barrier function. One TEWL measurement was obtained at Baseline and Week 8.

Ocular Acuity

All subjects were tested for visual acuity using a Snellen Eye Chart. Ocular acuity evaluations were performed at Baseline and Week 8.

Hair Count after Combing

Each subject's hair was divided into four quadrants; front left, front right, back left, and back right. If hair length was not sufficient enough to be parted in order to be divided, the hair was combed from the four quadrants without being divided. The subjects combed the hair onto a white paper, applying two strokes to each quadrant, for a total of eight strokes. Hairs that fell onto the white surface were counted. The paper was folded and collected by the technician. Hair count was performed at Baseline, Week 4, and Week 8.

TEST METHOD

Screening: Participants reported to the testing facility with clean hair, having styled as normal without using any hair products (every subsequent visit). Informed consent was obtained. A trained technician conducted an initial examination of the scalp for signs of hair loss as it was part of the inclusion/exclusion. Participants who met all the study requirements were enrolled into the study.

A patch test of the test materials was performed on the right volar forearm of each subject. A patch test was performed for the hair dye (Just for MEN) and the test products. A trained technician selected a test area on the scalp, located closest to the greatest amount of hair loss. A 0.5in.² template was placed over the test area, and the exposed hair was snipped (Hairliner HL 1 – Wella Professionals) for the tattoo.

One professional micro tattoo (Ink - Company: SOLIDINK; Color-Red and Needle: White Rose tight 3) was placed in the center of the 0.5 in.² test site. The micro tattoo assisted in referencing the exact test site at subsequent study visits.

A patch test was dispersed to participants to test for any irritation

Baseline: Participants acclimated to ambient laboratory conditions for approximately 15 minutes (and every subsequent visit). Hair clips were used to keep the template in place. Using an 8" pin tail comb, the hair was pulled through the holes of the template. First the hair was shortened with a pair of scissors to make the shaving easier. Using the comb, the hair was cut close to the scalp. The shorter the hair, the easier it was to shave with the electric razor to 0.2-0.7mm in length (enough to leave short hair shafts visible). After shaving, the template was removed to enable subsequent and even shortening of marginal hair. The results were checked with images. The shaved hair stubbles were removed completely with paper towels and isopropyl alcohol (clipping process was completed the same way each time).

The clipped hair was no longer than 0.5mm after clipping/shaving. Corneometer and TEWL measurements were obtained from the shaved site. Ocular acuity was assessed. Hair count after combing was performed. Subjects applied the test material for the first time in the testing facility under the supervision of study staff.

48 Hours Post-clipping: Participants returned to the testing facility, the 0.5in.² test site was dyed and images were captured.

Week 4: A trained technician located and identified the test area utilizing the micro tattoos as a reference. The hair was clipped. Hair count after combing was performed. Images were captured.

Week 4 + 48 Hours: Participants returned to the testing facility, the 0.5in.² test site was dyed and images were captured.

Week 8: The hair was clipped and a trained technician made sure the hair was even using images. Corneometer and TEWL measurements were obtained. Ocular acuity was assessed. Hair count after combing was performed.

Week 8 + 48 Hours: Participants returned to the testing facility, the 0.5in.² test site was dyed and images were captured.

DATA TABULATION

Ocular acuity was listed for each subject at each time interval.

Analysis of variance followed by Dunnett's test was applied to determine the differences between baseline and each post-treatment interval for the following parameters: evaluation of hair growth and hair counts.

A paired Student t-test or Wilcoxon signed ranks test depending on the normality of the data (checked by Shapiro-Wilk test at 0.01% significance level) was performed to determine the difference between baseline and week 8 for Corneometer and Vapometer measurements.

Change from baseline and % of subjects improved was calculated at each post-treatment interval for the above mentioned parameter.

RESULTS

Completed and Discontinued Participants

A total of 10 participants completed the study ranging in age from 44 to 75. One subject (#08) was lost to follow up (Supplemental Data).

Evaluation of Hair Growth: Fotofinder Medicam 1000 and D-Scope IV – 20x

Statistical summary tables for hair growth evaluations appear below along with a baseline photo and Week 8 + 48 hours photo of subject 2 (randomly selected). Individual hair growth evaluations and % of subjects showing improvement can be found in **Appendix Table 1** of the supplemental data.

Table 1a: Mean Evaluation of Hair Growth

Mean Evaluation of hair growth-Trichoscale							Mean Change from Baseline + 48 Hours	
Parameter	Baseline	Baseline +48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
Relevant Hair-Hair Count	66.0	114.2	61.0	108.8	78.4	122.9	-5.4 (p=0.4683)	8.7 (p=0.173)
Relevant Hair-Hair Density	73.1	126.4	67.5	120.5	86.8	136.1	-6.0 (p=0.4676)	9.6 (p=0.1747)
Length-Hair Count Anagen	4.0	80.7	5.7	71.9	10.7	80.8	-8.8 (p=0.1166)	0.1 (p=0.9996)
Length-Hair Count Telogen	62.0	33.5	55.3	36.9	67.7	42.1	3.4 (p=0.5105)	8.6 (p=0.037)
Length-Hair density Anagen	4.4	89.4	6.3	79.6	11.8	89.4	-9.8 (p=0.1164)	0.1 (p=0.9998)
Length-Hair density Telogen	68.6	37.1	61.2	40.9	75.0	46.6	3.8 (p=0.5060)	9.5 (p=0.0368)
Length-Mean Length	0.50	0.91	0.51	0.86	0.54	0.88	<i>-0.06</i> (p=0.0348)	-0.03 (p=0.2657)
Thickness/Diameter-Cumulative Thickness	4.3	7.2	4.1	6.3	5.1	7.2	<i>-0.9</i> (p=0.031)	0.0 (p=0.9893)

Bold/shaded indicates a statistically significant improvement

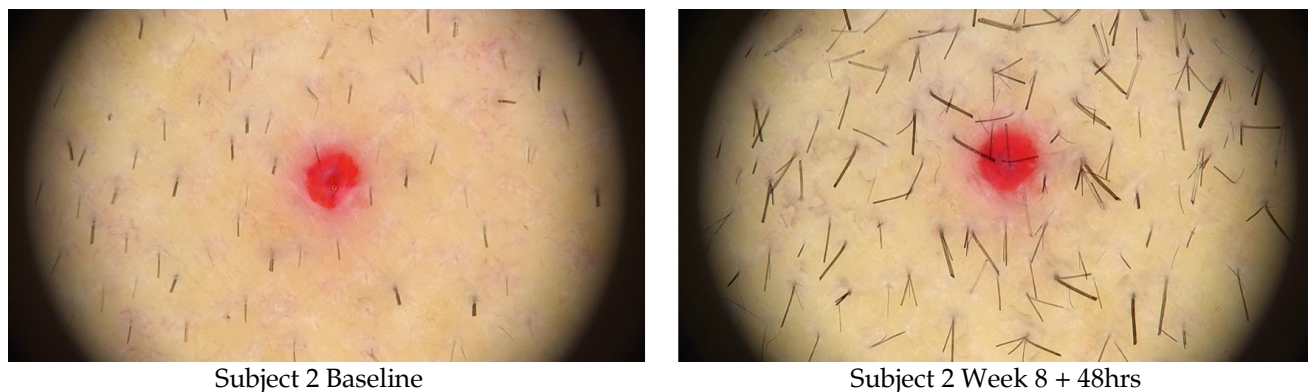
Bold/Italic indicates a statistically significant change but not improvement

Table 1b: Mean Evaluation of Hair Growth

Mean Evaluation of hair growth-Trichoscale -Vellus Hair							Mean Change from Baseline + 48 Hours	
Parameter	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
Hair Rate Vellus (%)	19.1	28.4	21.7	37.6	24.2	35.6	9.2 (p=0.0008)	7.2 (p=0.0063)
Hair Count Vellus	13.0	30.8	12.6	37.5	18.5	42.5	6.7 (p=0.1413)	11.7 (p=0.0087)
Hair Density Vellus (/cm ²)	14.4	34.1	13.9	41.5	20.5	47.0	7.5 (p=0.1393)	13.0 (p=0.0087)

Bold/shaded indicates a statistically significant improvement

Table 1c: Red tattoo was used as a marker for hair count and photo consistency



Corneometer

A statistical summary table for Corneometer measurements appears below. Individual Corneometer measurements and % of subjects showing improvement appear in Table 2 of the supplemental data.

Table 2: Mean Corneometer measurements

Mean Corneometer Measurement		Mean Change from Baseline
Baseline	Week 8	
13.9	20.4	6.5 (p=0.0197)

Bold/shaded indicates a statistically significant improvement

Transepidermal Water Loss

Statistical summary tables for VapoMeter measurements appear below. Individual VapoMeter measurements and % of subjects showing improvement from baseline appear in Table 3 of the supplemental data.

Table 3: VapoMeter measurements

Mean Vapometer Measurement		Mean Change from Baseline
Baseline	Week 8	
16.1	14.9	-1.2 (p=0.2404)

Ocular Acuity

Individual ophthalmic evaluations appear in Table 4 (supplemental data). There were no increases in subjective eye irritation, including stinging, burning, itching, dryness, and/or foreign body sensation. There was no difference in visual acuity at the Week 8 visit, compared to Baseline.

Hair Count after Combing

Statistical summary tables for hair counts after combing appear below. Individual hair counts after combing and % of subjects showing improvement appear in Table 5 of the supplemental data.

Table 4: Bold/shaded indicates a statistically significant improvement

Mean Hair Count After Combing			Mean Change from Baseline	
Baseline	Week 4	Week 8	Week 4	Week 8
33.6	20.9	6.7	-12.7 (p=0.0291)	-26.9 (p<0.0001)

DISCUSSION

Society is shifting toward natural alternatives to everyday problems, hair health is one of those areas. Some not only want their hair healthier, they want their hair regrown as quickly and naturally as possible. Hair loss in humans is

characterized by a progressive alteration in the terminal hair population, typified by an increase in vellus hair and a decline in total hair density (Rushton et al., 1983). Hair follicle restoration has been attributed to the reversal of this process (Whiting et al., 1999, Mirmirani et al., 2015).

A hair follicle is capable of producing three different types of hair as follows: lanugo, vellus and terminal hairs. The type of hair originated by an individual follicle can change with age or under the influence of hormones. The initial hair produced is the lanugo hair. Lanugo hair is non pigmented hair which covers the body of newborns (Alves and Grimalt, 2015), sheds within the womb, but can remain 3 to 4 months after birth. The lanugo hairs are replaced by vellus hairs (Alves and Grimalt, 2016).

Vellus hair is short, light-colored, barely noticeable, and covers almost the whole body. Puberty can cause the vellus hair to be converted to terminal hairs due to the increase in androgens which lead to secondary sex characteristics (Moreno-Romero and Grimalt, 2014; Harrison and Sinclair, 2003).

Terminal hair is larger and thicker usually. This type of hair is strongly pigmented and is found on the scalp, eyebrows, axillary and pubic areas, chest and face (Moreno-Romero and Grimalt, 2014). Someone who is losing their hair will begin to have more terminal hair follicles convert to vellus hairs. Uno and Kurata (Uno and Kurata, 1993) studied hair growth promoters, minoxidil, diazoxide, and Cooper peptides, on fuzzy rats. Their results with minoxidil demonstrated a conversion of short vellus hairs to prolonged terminal hairs.

According to the results, individuals who used Lotus 39 for 8 weeks + 48hrs had a statistically significant increase in vellus hair from the baseline. The Hair Rate Vellus (%) increased by 7.2 units ($p = 0.0063$), The Hair Count Vellus increased 11.7 units ($p = 0.0087$), and hair density vellus increased 13.0 units ($p = 0.0087$). This data suggests new hair follicles were formed that were not previously there. Not only did the amount of vellus hairs increase, 90% of the subjects improved both their Relevant Hair Density and Hair Count. This is an indication that the amount of hair on the subjects scalp increased over time. The amount of hair is important for hair to appear healthier, what often gets overlooked is the thickness of each individual hair (Cohen, 2008). 60% of the subjects' follicles hair grew in Thickness/Diameter. Which means that the individual hairs on subjects grew bigger which can give the appearance of healthier hair, decreases in the diameter of hair can be a sign of hair loss (Lacharrière et al., 2001). We believe the key to hair health is scalp health. Lotus 39 contains nutrients that protect the energy of the hypoderm of the skin so they do not degenerate. Corneometer and Transepidermal water loss tests are ideal for examining skin health. Corneometer measurements indicated a significant change from baseline of 6.5 units ($p = 0.0197$) with 80% of the subjects having improvement in skin health. Transepidermal water loss measurements indicated 60% of the subjects had improvement in the hydration of their skin. Since most subjects improved the health of their scalp and most subjects improved their hair, a healthy scalp can assist in the health of an individual's hair (Trüeb et al., 2018).

Not only did the data suggest Lotus 39 can increase the amount of hair on someone's scalp, the data also suggests that individuals reduced or stopped losing their hair. From baseline to 8 weeks +48hrs 100% of subjects showed a statistically significant difference in the amount of hair they lost. Stopping hair shedding is another way to make an individual's hair fuller and thicker. There was no change in ocular acuity and hair length. The ocular acuity of the subjects was not altered because Lotus 39 is not expected to improve or harm the eyes. Hair length did not change because the area of the hair that was used for measuring was shaved prior to taking the length of the hair.

CONCLUSION

Under the conditions of this study, the test material Lotus 39 can stop hair loss, increase the amount of hair on the scalp, significantly improve scalp hydration all while causing no ocular irritation or adverse effects. Future studies include increasing the amount of time subjects use Lotus 39, observing for changes in the restoration of hair color, increasing the age range of the subjects, and incorporating a placebo.

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APPENDICES (SUPPLEMENTAL DATA)

Appendix Table 1: Trichoscale Hair Growth Evaluations

Subject Number	Evaluation of hair growth-Trichoscale (Relevant Hair-Hair Count)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	54.0	99.0	58.0	107.0	61.0	121.0	8.0	22.0
02	44.0	85.0	55.0	74.0	70.0	117.0	-11.0	32.0
03	118.0	122.0	156.0	138.0	176.0	133.0	16.0	11.0
04	74.0	111.0	85.0	116.0	73.0	113.0	5.0	2.0
05	64.0	123.0	9.0	98.0	55.0	106.0	-25.0	-17.0
06	32.0	93.0	18.0	56.0	34.0	98.0	-37.0	5.0
07	14.0	128.0	13.0	118.0	16.0	137.0	-10.0	9.0
09	50.0	112.0	46.0	116.0	92.0	130.0	4.0	18.0
10	120.0	154.0	83.0	142.0	104.0	156.0	-12.0	2.0
11	90.0	115.0	87.0	123.0	103.0	118.0	8.0	3.0
Mean	66.0	114.2	61.0	108.8	78.4	122.9	Mean	8.7
Std.Dev.	35.0	19.6	44.6	26.8	44.5	16.7	Std.Dev.	13.4

Subject Number	Evaluation of hair growth-Trichoscale (Relevant Hair-Hair Density)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	59.8	109.6	64.2	118.5	67.5	134.0	8.9	24.4
02	48.7	94.1	60.9	81.9	77.5	129.5	-12.2	35.4
03	130.6	135.1	172.7	152.8	194.8	147.2	17.7	12.1
04	81.9	122.9	94.1	128.4	80.8	125.1	5.5	2.2
05	70.9	136.2	10.0	108.5	60.9	117.3	-27.7	-18.9
06	35.4	103.0	19.9	62.0	37.6	108.5	-41.0	5.5
07	15.5	141.7	14.4	130.6	17.7	151.7	-11.1	10.0
09	55.4	124.0	50.9	128.4	101.8	143.9	4.4	19.9
10	132.8	170.5	91.9	157.2	115.1	172.7	-13.3	2.2
11	99.6	127.3	96.3	136.2	114.0	130.6	8.9	3.3
Mean	73.1	126.4	67.5	120.5	86.8	136.1	Mean	9.6
Std.Dev.	38.7	21.7	49.4	29.7	49.2	18.5	Std.Dev.	14.8

Subject Number	Evaluation of hair growth-Trichoscale (Length-Hair Count Anagen)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	3.0	72.0	3.0	66.0	6.0	72.0	-6.0	0.0
02	1.0	52.0	2.0	29.0	4.0	75.0	-23.0	23.0
03	3.0	91.0	22.0	94.0	32.0	89.0	3.0	-2.0
04	7.0	95.0	5.0	89.0	3.0	75.0	-6.0	-20.0
05	1.0	74.0	0.0	60.0	2.0	62.0	-14.0	-12.0
06	3.0	44.0	0.0	17.0	8.0	42.0	-27.0	-2.0
07	1.0	94.0	1.0	82.0	3.0	108.0	-12.0	14.0
09	4.0	84.0	2.0	86.0	7.0	76.0	2.0	-8.0
10	5.0	122.0	5.0	114.0	12.0	122.0	-8.0	0.0
11	12.0	79.0	17.0	82.0	30.0	87.0	3.0	8.0
Mean	4.0	80.7	5.7	71.9	10.7	80.8	Mean	0.1
Std.Dev.	3.4	22.4	7.6	29.8	11.1	22.5	Std.Dev.	12.5

Subject Number	Evaluation of hair growth-Trichoscale (Length-Hair Count Telogen)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	51.0	27.0	55.0	41.0	55.0	49.0	14.0	22.0
02	43.0	33.0	53.0	45.0	66.0	42.0	12.0	9.0
03	115.0	31.0	134.0	44.0	144.0	44.0	13.0	13.0
04	67.0	16.0	80.0	27.0	70.0	38.0	11.0	22.0
05	63.0	49.0	9.0	38.0	53.0	44.0	-11.0	-5.0
06	29.0	49.0	18.0	39.0	26.0	56.0	-10.0	7.0
07	13.0	34.0	12.0	36.0	13.0	29.0	2.0	-5.0
09	46.0	28.0	44.0	30.0	85.0	54.0	2.0	26.0
10	115.0	32.0	78.0	28.0	92.0	34.0	-4.0	2.0
11	78.0	36.0	70.0	41.0	73.0	31.0	5.0	-5.0
Mean	62.0	33.5	55.3	36.9	67.7	42.1	Mean	8.6
Std.Dev.	33.5	9.9	38.1	6.5	36.3	9.2	Std.Dev.	11.9

Appendix Table 1: Trichoscale Hair Growth Evaluations (Continued)

Subject Number	Evaluation of hair growth-Trichoscale (Length-Hair density Anagen)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	3.3	79.7	3.3	73.1	6.6	79.7	-6.6	0.0
02	1.1	57.6	2.2	32.1	4.4	83.0	-25.5	25.4
03	3.3	100.7	24.4	104.1	35.4	98.5	3.4	-2.2
04	7.7	105.2	5.5	98.5	3.3	83.0	-6.7	-22.2
05	1.1	81.9	0.0	66.4	2.2	68.6	-15.5	-13.3
06	3.3	48.7	0.0	18.8	8.9	46.5	-29.9	-2.2
07	1.1	104.1	1.1	90.8	3.3	119.6	-13.3	15.5
09	4.4	93.0	2.2	95.2	7.7	84.1	2.2	-8.9
10	5.5	135.1	5.5	126.2	13.3	135.1	-8.9	0.0
11	13.3	87.5	18.8	90.8	33.2	96.3	3.3	8.8
Mean	4.4	89.4	6.3	79.6	11.8	89.4	-9.8	0.1
Std.Dev.	3.8	24.8	8.4	33.0	12.3	25.0	11.6	13.8

Subject Number	Evaluation of hair growth-Trichoscale (Length-Hair density Telogen)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	56.5	29.9	60.9	45.4	60.9	54.2	15.5	24.3
02	47.6	36.5	58.7	49.8	73.1	46.5	13.3	10.0
03	127.3	34.3	148.3	48.7	159.4	48.7	14.4	14.4
04	74.2	17.7	88.6	29.9	77.5	42.1	12.2	24.4
05	69.7	54.2	10.0	42.1	58.7	48.7	-12.1	-5.5
06	32.1	54.2	19.9	43.2	28.8	62.0	-11.0	7.8
07	14.4	37.6	13.3	39.9	14.4	32.1	2.3	-5.5
09	50.9	31.0	48.7	33.2	94.1	59.8	2.2	28.8
10	127.3	35.4	86.4	31.0	101.8	37.6	-4.4	2.2
11	86.4	39.9	77.5	45.4	80.8	34.3	5.5	-5.6
Mean	68.6	37.1	61.2	40.9	75.0	46.6	3.8	9.5
Std.Dev.	37.1	10.9	42.2	7.2	40.2	10.2	10.3	13.2

Subject Number	Evaluation of hair growth-Trichoscale (Length-Mean Length)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	0.49	1.02	0.51	0.89	0.52	0.91	-0.13	-0.11
02	0.49	0.81	0.51	0.69	0.55	0.84	-0.12	0.03
03	0.48	0.96	0.53	0.94	0.55	0.94	-0.02	-0.02
04	0.51	1.05	0.52	0.99	0.49	0.87	-0.06	-0.18
05	0.48	0.79	0.44	0.75	0.50	0.77	-0.04	-0.02
06	0.48	0.71	0.52	0.63	0.58	0.71	-0.08	0.00
07	0.48	0.90	0.52	0.81	0.57	0.93	-0.09	0.03
09	0.51	0.92	0.48	0.91	0.54	0.88	-0.01	-0.04
10	0.49	1.06	0.51	1.08	0.53	1.01	0.02	-0.05
11	0.55	0.90	0.56	0.87	0.58	0.94	-0.03	0.04
Mean	0.50	0.91	0.51	0.86	0.54	0.88	-0.06	-0.03
Std.Dev.	0.02	0.12	0.03	0.14	0.03	0.09	0.05	0.07

Subject Number	Evaluation of hair growth-Trichoscale (Thickness/Diameter-Cumulative Thickness)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	3.7	5.7	3.9	6.0	4.3	6.5	0.3	0.8
02	2.5	4.0	2.6	3.4	4.0	5.1	-0.6	1.1
03	6.9	8.2	9.7	9.5	10.1	9.3	1.3	1.1
04	5.5	8.5	6.5	8.7	5.8	9.6	0.2	1.1
05	5.0	8.0	0.5	5.2	3.1	5.4	-2.8	-2.6
06	1.8	4.5	1.1	2.3	1.5	4.3	-2.2	-0.2
07	0.8	7.2	0.8	5.4	2.0	6.7	-1.8	-0.5
09	3.1	7.1	2.8	6.1	5.0	7.2	-1.0	0.1
10	9.0	10.6	7.5	9.7	8.2	10.7	-0.9	0.1
11	5.1	7.8	5.7	6.6	6.7	7.2	-1.2	-0.6
Mean	4.3	7.2	4.1	6.3	5.1	7.2	-0.9	0.0
Std.Dev.	2.5	2.0	3.1	2.5	2.7	2.1	1.2	1.1

Appendix Table 1: Trichoscale Hair Growth Evaluations (Continued)

Subject Number	Evaluation of hair growth-Trichoscale (Hair Rate Vellus (%))						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	27.8	37.4	32.8	51.4	16.4	44.6	14.0	7.2
02	34.1	49.4	50.9	51.4	38.6	58.1	2.0	8.7
03	27.1	17.2	22.4	18.1	28.4	15.8	0.9	-1.4
04	12.2	14.4	12.9	10.3	13.7	11.5	-4.1	-2.9
05	14.1	27.6	33.3	43.9	32.7	38.7	16.3	11.1
06	15.6	46.2	16.7	64.3	52.9	61.2	18.1	15.0
07	7.1	36.7	7.7	54.2	6.2	54.0	17.5	17.3
09	18.0	23.2	21.7	31.9	30.4	33.8	8.7	10.6
10	10.8	14.3	4.8	16.9	6.7	12.8	2.6	-1.5
11	24.4	17.4	13.8	33.3	15.5	25.4	15.9	8.0
Mean	19.1	28.4	21.7	37.6	24.2	35.6	9.2	7.2
Std.Dev.	8.8	13.2	14.0	18.3	15.0	18.8	8.2	7.0

Subject Number	Evaluation of hair growth-Trichoscale (Hair Density Vellus (cm ²))						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	16.6	41.0	21.0	60.9	11.1	59.8	19.9	18.8
02	16.6	46.5	31.0	42.1	29.9	75.3	-4.4	28.8
03	35.4	23.2	38.7	27.7	55.4	23.2	4.5	0.0
04	10.0	17.7	12.2	13.3	11.1	14.4	-4.4	-3.3
05	10.0	37.6	3.3	47.6	19.9	45.4	10.0	7.8
06	5.5	47.6	3.3	39.9	19.9	66.4	-7.7	18.8
07	1.1	52.0	1.1	70.9	1.1	81.9	18.9	29.9
09	10.0	28.8	11.1	41.0	31.0	48.7	12.2	19.9
10	14.4	24.4	4.4	26.6	7.7	22.1	2.2	-2.3
11	24.4	22.1	13.3	45.4	17.7	33.2	23.3	11.1
Mean	14.4	34.1	13.9	41.5	20.5	47.0	7.5	13.0
Std.Dev.	9.8	12.3	12.7	16.7	15.4	23.6	11.1	12.2

Subject Number	Evaluation of hair growth-Trichoscale (Hair Count Vellus)						Change from Baseline + 48 hours at week 4 + 48 hours and week 8 + 48 hours	
	Baseline	Baseline+48 Hours	Week 4	Week 4+48 hours	Week 8	Week 8+48 hours	Week 4+48 hours	Week 8+48 hours
01	15.0	37.0	19.0	55.0	10.0	54.0	18.0	17.0
02	15.0	42.0	28.0	38.0	27.0	68.0	-4.0	26.0
03	32.0	21.0	35.0	25.0	50.0	21.0	4.0	0.0
04	9.0	16.0	11.0	12.0	10.0	13.0	-4.0	-3.0
05	9.0	34.0	3.0	43.0	18.0	41.0	9.0	7.0
06	5.0	43.0	3.0	36.0	18.0	60.0	-7.0	17.0
07	1.0	47.0	1.0	64.0	1.0	74.0	17.0	27.0
09	9.0	26.0	10.0	37.0	28.0	44.0	11.0	18.0
10	13.0	22.0	4.0	24.0	7.0	20.0	2.0	-2.0
11	22.0	20.0	12.0	41.0	16.0	30.0	21.0	10.0
Mean	13.0	30.8	12.6	37.5	18.5	42.5	6.7	11.7
Std.Dev.	8.9	11.1	11.5	15.1	13.9	21.3	10.0	11.1

Parameter	Hair Growth Trichoscale	
	Visit	% of Subjects showing improvement
Relevant Hair-Hair Count	Week 4+48 hours vs. Baseline +48 hours	50.0%
	Week 8+48 hours vs. Baseline +48 hours	90.0%
Relevant Hair-Hair Density	Week 4+48 hours vs. Baseline +48 hours	50.0%
	Week 8+48 hours vs. Baseline +48 hours	90.0%
Length-Hair Count Anagen	Week 4+48 hours vs. Baseline +48 hours	30.0%
	Week 8+48 hours vs. Baseline +48 hours	30.0%
Length-Hair Count Telogen	Week 4+48 hours vs. Baseline +48 hours	70.0%
	Week 8+48 hours vs. Baseline +48 hours	70.0%
Length-Hair density Anagen	Week 4+48 hours vs. Baseline +48 hours	30.0%
	Week 8+48 hours vs. Baseline +48 hours	30.0%
Length-Hair density Telogen	Week 4+48 hours vs. Baseline +48 hours	70.0%
	Week 8+48 hours vs. Baseline +48 hours	70.0%
Length-Mean Length	Week 4+48 hours vs. Baseline +48 hours	10.0%
	Week 8+48 hours vs. Baseline +48 hours	30.0%
Thickness/Diameter-Cumulative Thickness	Week 4+48 hours vs. Baseline +48 hours	30.0%
	Week 8+48 hours vs. Baseline +48 hours	60.0%

Appendix Table 1: Trichoscale Hair Growth Evaluations (Continued)

Trichoscale -Vellus Hair		
Parameter	Visit	% of Subjects showing improvement
Hair Rate Vellus (%)	Week 4+48 hours vs. Baseline +48 hours	90.0%
	Week 8+48 hours vs. Baseline +48 hours	70.0%
Hair Count Vellus	Week 4+48 hours vs. Baseline +48 hours	70.0%
	Week 8+48 hours vs. Baseline +48 hours	70.0%
Hair Density Vellus (/cm ²)	Week 4+48 hours vs. Baseline +48 hours	70.0%
	Week 8+48 hours vs. Baseline +48 hours	70.0%

Appendix Table 2: Trichoscale Hair Growth Evaluations

Subject Number	Corneometer Measurements			Change from Baseline
	Baseline	Week 8		Week 8
01	19.6	23.1		3.5
02	21.3	15.8		-5.5
03	27.1	20.8		-6.3
04	5.2	16.7		11.5
05	17.1	31.1		14.0
06	4.6	14.2		9.6
07	7.8	18.1		10.3
09	15.6	23.3		7.7
10	8.8	15.4		6.6
11	11.6	25.0		13.4
Mean	13.9	20.4	Mean	6.5
Std.Dev.	7.5	5.3	Std.Dev.	7.2

Corneometer Measurement		
Parameter	Visit	% of Subjects showing improvement
Corneometer	Week 8	80.0%

Appendix Table 3: VapoMeter Measurements

Subject Number	Vapometer Measurements			Change from Baseline
	Baseline	Week 8		Week 8
01	17.1	13.6		-3.5
02	15.1	16.3		1.2
03	15.0	10.6		-4.4
04	12.8	14.2		1.4
05	19.8	14.0		-5.8
06	13.6	14.0		0.4
07	15.3	14.5		-0.8
09	19.0	15.9		-3.1
10	21.5	25.0		3.5
11	11.8	11.2		-0.6
Mean	16.1	14.9	Mean	-1.2
Std.Dev.	3.2	4.0	Std.Dev.	2.9

Vapometer Measurement		
Parameter	Visit	% of Subjects showing improvement
Vapometer	Week 8	60.0%

Appendix Table 4: Ophthalmic Evaluations

Subject Number	Eye Type	Ophthalmic Examination Results			
		Baseline		Week 8	
		Right	Left	Right	Left
01	N	0	0	0	0
02	N	0	0	0	0
03	N	0	0	0	0
04	N	0	0	0	0
05	C	0	0	0	0
06	N	0	0	0	0
07	N	0	0	0	0
09	N	0	0	0	0
10	N	0	0	0	0
11	N	0	0	0	0
0		10	10	10	10
1		0	0	0	0
2		0	0	0	0
3		0	0	0	0
4		0	0	0	0
Total		10	10	10	10

N = Non-Contact Lens Wearer
 C = Contact Lens Wearer

Appendix Table 5: Hair Counts after Combing

Subject Number	Hair Count After Combing			Change from Baseline	
	Baseline	Week 4	Week 8	Week 4	Week 8
01	39.0	14.0	13.0	-25.0	-26.0
02	27.0	4.0	4.0	-23.0	-23.0
03	20.0	19.0	8.0	-1.0	-12.0
04	28.0	43.0	11.0	15.0	-17.0
05	36.0	16.0	1.0	-20.0	-35.0
06	30.0	31.0	5.0	1.0	-25.0
07	20.0	39.0	5.0	19.0	-15.0
09	59.0	18.0	14.0	-41.0	-45.0
10	45.0	3.0	3.0	-42.0	-42.0
11	32.0	22.0	3.0	-10.0	-29.0
Mean	33.6	20.9	6.7	Mean	-12.7
Std.Dev.	11.9	13.4	4.5	Std.Dev.	21.3

Parameter	Hair Count After Combing	
	Visit	% of Subjects showing improvement
Hair Count	Week 4	70.0%
	Week 8	100.0%

Appendix Table: Study Schedule

Study Evaluations and Procedures	Screening (Day -7 ± 3 Days)	Baseline	48 Hours	Week 4	Week 4 + 48 Hours	Week 8	Week 8 + 48 Hours
Informed Consent Obtained	X						
Inclusion and Exclusion Criteria Verified	X						
Test Site Location by Tattoo Artist	X						
Hair Clipping		X		X		X	
Hair Dying			X		X		X
Medicam 1000 Digital Imaging and TrichoScan Software		X	X	X	X	X	X
Corneometer Measurements		X				X	
TEWL Measurements		X				X	
Ocular Acuity Evaluations		X				X	
Hair Count After Combing		X		X		X	
Test Material Application in Lab		X					
Test Material, Daily Diary, and Use Instructions Distributed		X					
Test Material Collected							X
Daily Diary Collected and Reviewed for Study Compliance							X

Appendix Table: Balding Scales

Scores of 3 to 7 on the Norwood Scale Required for Male Subject Enrollment

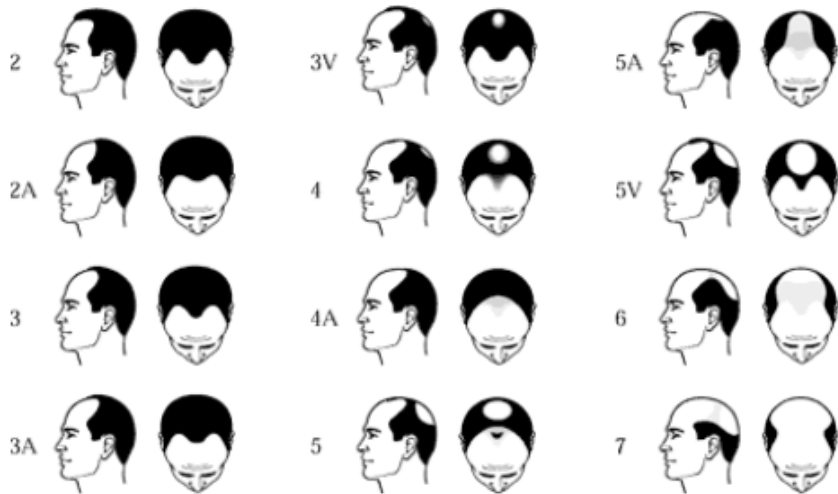


Image Source: American Hair Loss Association

Scores of 1 to 3 or Higher on Ludwig Scale Required for Female Subjects

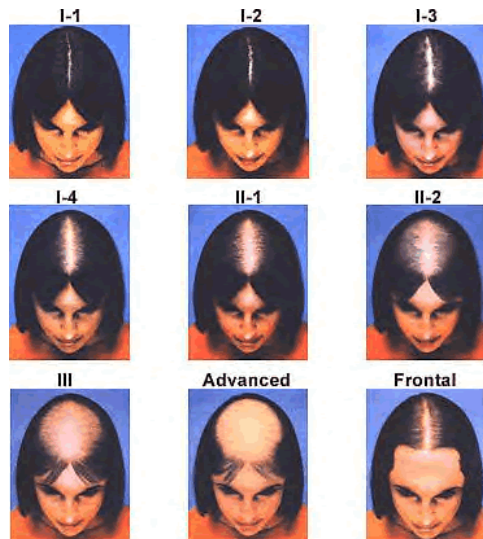


Image Source: American Hair Loss Association

Appendix Table: Participant Demographics

Subject Number	Age	Sex	Skin Type
01	75	F	II
02	75	F	II
03	58	F	IV
04	44	F	IV
05	47	M	II
06	57	M	III
07	66	F	II
08	47	M	IV
09	65	M	II
10	53	M	II
11	69	F	II

Fitzpatrick Skin Type	Color	Reaction to the Sun
II	White	Usually burns, tans with difficulty
III	White	Sometimes burns, but tans easily
IV	Moderate Brown	Rarely burns, tans very easily