LifeVantage
Final Report
September 1, 2018

The Ability of a Hair Care Regimen to Improve Hair Health and Appearance

DCS STUDY NUMBER: DCS-41-18

INVESTIGATOR: ZOE DIANA DRAELOS, M.D.

STUDY SITE: DERMATOLOGY CONSULTING SERVICES
2444 NORTH MAIN STREET
HIGH POINT, NC 27262

SPONSOR: LifeVantage

PRODUCTS: Scalp Treatment, Shampoo, Conditioning Treatment

EDITION NUMBER: 1

PROTOCOL NUMBER: DCS-41-18

SYNOPSIS DATE: June 2, 2018

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PROTOCOL DATE: July 21, 2018

REPORT DATE: September 1, 2018

STUDY TITLE: The Ability of a Hair Care Regimen to Improve Hair Health and Appearance

All designated persons have agreed this version of the report is accepted and final.

_____ _____

Representative
LifeVantage

Date

_____ _____

Zoe Diana Draelos, MD
Primary Investigator
Dermatology Consulting Services

Date

1. PROTOCOL SYNOPSIS

Title of Study:	The Ability of a Hair Care Regimen to Improve Hair Health and Appearance
Study Period:	1 week
Test Product, Dose and Mode of Administration:	Scalp Treatment Apply every night to scalp Shampoo Shampoo Wednesday, Friday, and the following Monday Conditioning Treatment Condition after shampooing, leave it on for at least one minute or longer and rinse thoroughly in shower.
Comparative therapy:	None
Objective:	To evaluate the ability of a hair 3 step care regimen to improve hair health and appearance.
Design:	This was a single site dermatologist investigator evaluated study to evaluate the effect of a 3-step hair care regimen on hair health and appearance. Qualified subjects who met all in the inclusion criteria and none of the exclusion criteria were enrolled in this 1-week study. Subjects presented to the research facility on a Monday evening, after having used their own self-selected hair care products, to sign consent and receive their hair care products. Subjects were instructed to shampoo on Wednesday, Friday, and the following Monday morning. Following shampooing, the subjects applied the conditioning treatment followed by rinsing. The scalp treatment was applied each evening prior to bedtime. All applications were recorded in a diary along with any subject comments. The following assessments were performed at baseline and week 1: 1. Investigator Hair Assessment 2. Subject Hair Assessment 3. Photography Assessment 4. Hair Tensile Strength Assessment Tolerability and adverse events were assessed as needed during the course of the 1-week study by the subjects and the investigator. Subjects were released from their study participation at the end of the 1-

	week study period.
Study Population:	Female subjects 35-65 years of age of all Fitzpatrick skin types I-VI and all hair types (5% African American, 75% Caucasian, 5% Asian, 15% Hispanic)
Number of Subjects:	50 subjects
Inclusion Criteria:	The following represented the inclusion criteria: 1. Female. 2. Age: 35-65 years. 3. All Fitzpatrick skin types I-VI and all hair types. 4. Subjects must be in general good health as determined from a medical history. 5. Subjects must read and sign the informed consent form after the nature of the study has been fully explained. 6. Subjects must be willing to apply the assigned study products as instructed. 7. Subjects must not be allergic to any component of the study products. 8. Subjects must be willing to use only the study shampoo, conditioner, and scalp treatment. No other hair care products can be used. 9. Subjects must be willing to follow the Wednesday, Friday, Monday shampooing and conditioning regimen. 10. Subjects must agree not to undergo any hair treatments, such as permanent waving, straightening, dyeing, etc. 11. Subjects must be willing to return to the research facility at the appointed time.
Exclusion Criteria:	The following represented the exclusion criteria: 1. Subjects with known allergies or sensitivities to ingredients contained in the test products. 2. Subjects who are required to spend excessive time in the sun (i.e. lifeguards, other outdoor workers). 3. Subjects who are pregnant or nursing or planning to become pregnant during the course of the study. 4. Subjects who are currently participating, or have participated within the last 4 weeks, in a clinical testing study. 5. Subjects viewed by the investigator as not being able to complete the study. 6. Subjects who are unwilling or unable to follow the study instructions.
Endpoints:	<u>Primary Efficacy Endpoint:</u> Statistically significant improvement in hair volume, density, strength, shine, body, ease of detangling/combing, resilience and overall hair appearance health after 7 uses of study scalp

	treatment and 3 uses of study shampoo and conditioning treatment as assessed by the investigator. Secondary Efficacy Endpoint: Statistically significant improvement in hair volume, density, strength, shine, body, ease of detangling/combing, resilience and overall hair appearance health after 7 uses of study scalp treatment and 3 uses of study shampoo and conditioning treatment as assessed by the subject. Safety: The safety endpoint was the incidence of all adverse events reported during the study.
Measures:	Investigator Assessments of Product Efficacy: Scalp Treatment Investigator Assessments: The investigator evaluated the following hair parameters: poor hair density, poor hair volume (assessed visually as the distance the hair stands away from the scalp), damaged structure (assessed visually as the presence of broken hairs and split ends), scalp irritation, scalp dryness, and overall poor hair health. All investigator scalp treatment assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments occurred at baseline and week 1. Shampoo Investigator Assessments: The investigator evaluated the following hair parameters: excessive sebum (assessed as the appearance of greasy hair), poorly moisturized hair (assessed as the appearance of hair frizz due to static electricity), poor hair strength. All investigator shampoo assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments occurred at baseline and week 1. Conditioning Treatment Investigator Assessments: poor tensile strength, UV and heat hair damage, poor resilience, poor hair shine (assessed visually as light reflection from the collective hair surface), poor hair body. All investigator conditioner assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments occurred at baseline and week 1. Subject Assessments: Scalp Treatment Subject Assessments: The subjects evaluated the following hair parameters: poor hair density, poor hair volume, damaged structure, scalp irritation, scalp dryness, and overall poor hair health. All subject scalp treatment assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments occurred at baseline and week 1.

	Shampoo Subject Assessments: The subjects evaluated the following hair parameters: excessive sebum, poorly moisturized hair, and poor hair strength. All subject shampoo assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments occurred at baseline and week 1. Conditioning Treatment Subject Assessments: poor tensile strength, UV and heat hair damage, poor resilience, poor hair shine, and poor hair body. All subject conditioner assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments occurred at baseline and week 1. <u>Photography:</u> Photography was conducted of the hair with a Nikon D90 camera with flash by the dermatologist investigator in a manner specified by the sponsor at baseline and week 1. <u>Noninvasive Hair Assessments:</u> Hair tensile strength was assessed by holding 5 hairs between the fingers and exerting pressure to fracture the hair shaft. The number of hairs that broke was recorded. The dermatologist investigator performed all hair tensile strength assessments. Hair tensile strength was assessed at baseline and week 1.
Statistical Methods:	A Mann-Whitney two-tailed t-test was used to analyze the nonparametric investigator and subject efficacy and tolerability data. A t-test was used to analyze the numerical noninvasive hair tensile strength data. Significance was defined as p less than or equal to 0.05.

2. STUDY VISIT SCHEDULE

	Baseline Monday	Week 1 Following Monday
Informed Consent	X	
Medical History	X	
Subject Eligibility and Investigator Lesion Assessment	X	
Photography	X	X
Subject Instructions Reviewed	X	
Investigator Hair Assessment	X	X
Subject Hair Assessment	X	X
Study Product & Subject Diary Dispensed	X	
Noninvasive Hair Tensile Strength Assessment	X	X
Study Product and Study Diary Collected		X
Adverse Event Assessment		X

3. INTRODUCTION

Hair health and appearance can be improved through well-formulated and carefully selected hair care products. These products can clean and condition the hair while preserving the integrity of the cuticle, which is the source of hair health. This research examined the value of a novel 3-step hair care regimen in improving and restoring hair health and consequently hair appearance.

4. STUDY OBJECTIVE

The objective of this study was to evaluate the ability of a hair 3 step care regimen to improve hair health and appearance

5. STUDY DESIGN OVERVIEW

This was a single site dermatologist investigator evaluated study to evaluate the effect of a 3-step hair care regimen on hair health and appearance. Qualified subjects who met all in the inclusion criteria and none of the exclusion criteria were enrolled in this 1-week study. Subjects presented to the research facility on a Monday evening, after having used their own self-selected hair care products, to sign consent and receive their hair care products. Subjects were instructed to shampoo on Wednesday, Friday, and the following Monday morning. Following shampooing, the subjects applied the conditioning treatment followed by rinsing. The scalp treatment was applied each evening prior to bedtime. All applications were recorded in a diary along with any subject comments.

The following assessments were performed at baseline and week 1:

1. Investigator Hair Assessment
2. Subject Hair Assessment
3. Photography Assessment
4. Hair Tensile Strength Assessment

Tolerability and adverse events were assessed as needed during the course of the 1-week study by the subjects and the investigator.

Subjects were released from their study participation at the end of the 1-week study period.

6. STUDY POPULATION

6.1 NUMBER OF SUBJECTS

50 subjects

6.2 SUBJECT CHARACTERISTICS

Female subjects 35-65 years of age of all Fitzpatrick skin types I-VI and all hair types (5% African American, 75% Caucasian, 5% Asian, 15% Hispanic).

6.3 INCLUSION CRITERIA

The following items represented the inclusion criteria:

1. Female
2. Age: 35-65 years.
3. All Fitzpatrick skin types I-VI and all hair types.
4. Subjects must be in general good health as determined from a medical history.
5. Subjects must read and sign the informed consent form after the nature of the study has been fully explained.
6. Subjects must be willing to apply the assigned study products as instructed.
7. Subjects must not be allergic to any component of the study products.
8. Subjects must be willing to use only the study shampoo, conditioner, and scalp treatment. No other hair care products can be used.
9. Subjects must be willing to follow the Wednesday, Friday, Monday shampooing and conditioning regimen.
10. Subjects must agree not to undergo any hair treatments, such as permanent waving, straightening, dyeing, etc.
11. Subjects must be willing to return to the research facility at the appointed time.

6.4 EXCLUSION CRITERIA

The following items represented the exclusion criteria:

1. Subjects with known allergies or sensitivities to ingredients contained in the test products.
2. Subjects who are required to spend excessive time in the sun (i.e. lifeguards, other outdoor workers).
3. Subjects who are pregnant or nursing or planning to become pregnant during the course of the study.
4. Subjects who are currently participating, or have participated within the last 4 weeks, in a clinical testing study.
5. Subjects viewed by the investigator as not being able to complete the study.
6. Subjects who are unwilling or unable to follow the study instructions.

6.5 CONCOMITANT MEDICATIONS & RESTRICTIONS

There were no concomitant medication restrictions that were followed during the conduct of the study. Subjects used only the study hair care products.

7. CONDUCT OF STUDY: METHODS AND PROCEDURES

7.1 SUBJECT SUITABILITY EVALUATION

7.1.1 INFORMED CONSENT

A signed informed consent form was obtained from each subject prior to performing any study procedures. No study related procedures or activities were performed until each subject was fully informed and the consent form was signed and dated.

7.1.2 MEDICAL HISTORY

An abbreviated medical history including current medications was recorded.

7.1.3 HAIR EXAMINATION

The dermatologist investigator visually performed a hair examination.

7.1.4 STUDY PROCEDURES

The subjects were screened for the inclusion and exclusion criteria prior to study enrollment. Only subjects who met the requirements, signed an informed consent, and gave a medical history were entered into the study. All other subjects were considered screening failures.

7.1.5 STUDY MATERIAL ADMINISTRATION

Hair scalp treatment: Every evening, subjects applied the product directly onto dry scalp and gently massage into the scalp until fully absorbed. The product was not rinsed out.
Shampoo: The subjects applied desired amount to wet hair and gently massaged into lather from scalp to ends of hair. Rinsed thoroughly. Followed with conditioner.
Conditioner: Subjects applied a desired amount of conditioner to washed and damp hair. Left on for at least 1 minute. Rinse well. The study products were not to be applied to the eyes and mouth. A demonstration of proper study product application was performed in the research center following dispensing.

7.2 CLINICAL MEASURES

7.2.1 BASELINE

This was a single site dermatologist investigator evaluated study to evaluate the effect of a 3-step hair care regimen on hair health and appearance. Qualified subjects who met all inclusion criteria and none of the exclusion criteria were enrolled in this 1-week study. Subjects presented to the research facility on a Monday evening, after having used their own self-selected hair care products, to sign consent and receive their hair care products. Subjects were instructed to

shampoo on Wednesday, Friday, and the following Monday morning. Following shampooing, the subjects applied the conditioning treatment followed by rinsing. The scalp treatment was applied each evening prior to bedtime. All applications were recorded in a diary along with subject comments.

At baseline, the subjects underwent an investigator hair and scalp assessment. The investigator evaluated the following hair parameters: poor hair density, poor hair volume (assessed visually as the distance the hair stands away from the scalp), damaged structure (assessed visually as the presence of broken hairs and split ends), scalp irritation, scalp dryness, and overall poor hair health. All investigator scalp treatment assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

The investigator also evaluated the following hair parameters: excessive sebum (assessed as the appearance of greasy hair), poorly moisturized hair (assessed as the appearance of hair frizz due to static electricity), poor hair strength. All investigator shampoo assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

Finally, the investigator assessed hair conditioning via poor tensile strength, UV and heat hair damage, poor resilience, poor hair shine (assessed visually as light reflection from the collective hair surface), poor hair body. All investigator conditioner assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

The subjects evaluated the following hair parameters: poor hair density, poor hair volume, damaged structure, scalp irritation, scalp dryness, and overall poor hair health. All subject scalp treatment assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. In addition, the subjects evaluated the following hair parameters: excessive sebum, poorly moisturized hair, and poor hair strength. All subject shampoo assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

The subjects also assessed hair conditioning via poor tensile strength, UV and heat hair damage, poor resilience, poor hair shine, and poor hair body. All subject conditioner assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

The dermatologist investigator conducted photography of the hair with a Nikon D90 camera with flash in a manner specified by the sponsor. Dr. Draelos took a picture of the back of the head that was nonidentifying. Noninvasive hair assessments were also conducted. Dr. Draelos assessed hair tensile strength by holding 5 hairs between the fingers and exerting pressure to fracture the hair shaft. The number of hairs that broke was recorded. The dermatologist investigator performed all hair tensile strength assessments.

7.2.2 WEEK 1

Subjects returned to the research center on Monday afternoon after shampooing on Monday morning. Subjects shampooed on the prior Wednesday and Friday. All shampooings were recorded in the diary. Following shampooing, the subjects applied the conditioning treatment followed by rinsing.

The investigator evaluated the following hair parameters: poor hair density, poor hair volume (assessed visually as the distance the hair stands away from the scalp), damaged structure (assessed visually as the presence of broken hairs and split ends), scalp irritation, scalp dryness, and overall poor hair health. All investigator scalp treatment assessments were conducted using the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

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After completion of these study activities, the subjects were released from their one week study participation.

8. COMPLIANCE MEASURES

Compliance was determined from the diary sheets where subjects recorded their use of the shampoo, conditioner, and scalp treatment. Diary sheets remained at the study center as part of the source documentation records.

9. FINAL SUBJECT STATUS

A study termination form was completed for each study subject who received study product. This included subjects who completed the study or who withdrew or were withdrawn from study. 50/50 subjects successfully completed the one week study. The demographics of the enrolled subjects are listed in the table presented next.

Demographic Log

Subject #	Subject Initials	Age	Gender	Race
1	C-B	48	F	AA
2	BEG	51	F	C
3	ALB	44	F	C
4	SSC	47	F	C
5	LGF	54	F	C
6	CSB	50	F	C
7	MLC	53	F	C
8	TDC	41	F	C
9	MLC	51	F	C
10	CDS	53	F	C
11	WIP	54	F	H
12	CRF	40	F	C
13	ABC	56	F	C
14	KAB	47	F	C
15	RVB	44	F	C
16	HMA	45	F	C
17	EYA	37	F	C
18	LTD	57	F	C
19	LSB	52	F	C
20	SPC	49	F	C
21	PCA	63	F	C
22	JRC	44	F	C
23	JWC	56	F	C
24	LCF	50	F	C
25	KPG	54	F	C
26	G-B	35	F	H
27	T-M	35	F	H
28	TWD	46	F	C
29	MLA	45	F	C
30	ACD	37	F	H

31	JCB	38	F	H
32	PSD	48	F	C
33	TMC	51	F	C
34	SPG	41	F	C
35	LKC	57	F	C
36	DPC	56	F	C
37	HRB	41	F	C
38	TLG	44	F	C
39	CWB	52	F	C
40	CSA	54	F	C
41	SAB	51	F	C
42	MDD	50	F	C
43	LHB	60	F	C
44	JCD	38	F	C
45	SRJ	41	F	AA
46	T-S	35	F	AS
47	SLD	55	F	AS
48	ERP	41	F	C
49	HME	39	F	C
50	CWL	48	F	C

10. STUDY MEDICATION

10.1 DOSAGE AND FORMULATIONS

The following formulations were tested:

1. Scalp Treatment
2. Shampoo
3. Conditioning Treatment

10.2 APPLICATION INSTRUCTIONS

1. Scalp Treatment Instructions
Apply every night to scalp. Apply the product directly onto dry scalp and gently massage into the scalp until fully absorbed.

2. Shampoo Instructions
Shampoo Wednesday, Friday, and the following Monday morning.

3. Conditioning Treatment Instructions

Condition after shampooing, leave it on for at least one minute or longer and rinse thoroughly in shower.

10.3 PRECAUTIONS

The study products were used in their intended fashion and not orally consumed or placed in the eyes or mouth. If the shampoo, conditioner, or scalp treatment entered the eye, they were flushed with abundant lukewarm water. They were not intended for eye use, but did not cause harm to the eye if immediately flushed out.

10.4 PACKAGING, LABELING, DISTRIBUTION

The study product was dispensed in the packaging provided by the sponsor.

10.5 STORAGE AND ACCOUNTABILITY OF STUDY PRODUCT

The study product was stored at room temperature in a locked, limited access area at the study site. Access to the study product was limited to the investigator and staff members designated to dispense study products. A study product log was used to record the dispensation and return of all study products. The subject number/initials, and the initials and date of the person dispensing and receiving the returned study product was documented on this form. Returned study product was disposed/destroyed at study site after completion of study and approval of final report.

10.6 CODE DISCLOSURE

No code was maintained, as all subjects used the active study products.

11. ADVERSE EVENTS

No serious adverse events, adverse events, or adverse experiences occurred during the conduct of the study.

12. STATISTICAL METHODS

A Mann-Whitney two-tailed t-test was used to analyze the nonparametric investigator and subject efficacy and tolerability data. A t-test was used to analyze the numerical noninvasive hair tensile strength data.

12.1 SAMPLE SIZE RATIONALE

A sample size of 50 subjects was enrolled as requested by the sponsor.

12.2 RANDOMIZATION PROCEDURES

A randomization schedule was not maintained. All subjects received all three study products.

12.3 SIGNIFICANCE LEVEL

Significance was defined at the p=0.05 or less level based on a two-sided test.

12.4 DROP-OUT (TOLERABILITY) ASSESSMENT

No subjects discontinued during the conduct of the study, thus there was no drop-out assessment.

12.5 SAFETY ASSESSMENT

The safety endpoint was the overall incidence of adverse events reported during the study related to the active product. The primary safety analysis was the calculation of the incidence of any adverse event that occurred from Day 0 through the end of the study at week 1. No safety issues arose during the conduct of the study.

13. RESULTS

The results are presented in the attached Excel data tables.
Table 1: Hair Tensile Strength Assessment
Table 2: Investigator Conditioner Assessment
Table 3: Investigator Scalp Treatment Assessment
Table 4: Investigator Shampoo Assessment
Table 5: Subject Conditioner Assessment
Table 6: Subject Scalp Treatment Assessment
Table 7: Subject Shampoo Assessment

Since all subjects used the same active product regimen consisting of a shampoo, conditioner, and scalp treatment; the data was analyzed as change from baseline in a longitudinal fashion. A lower number was indicative of a superior rating in all parameters (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe). For the hair tensile strength assessment, a lower number was also better as fewer hairs broke with tension.

14. DISCUSSION

The results are discussed separately for each data set.

Table 1: Hair Tensile Strength Assessment
The hair tensile strength assessment was conducted by the investigator to assess the reduction in hair breakage following use of the study hair regimen. At

baseline, an average of 1.58 hairs out of 5 hairs broke with consistent tension. This decreased to 0.66 hairs breaking with the same tension after one week of study regimen use representing a highly statistically significant 58% improvement ($p<0.001$). This improvement in hair tensile strength as demonstrated by a reduction in hair breakage could be due to improved hair shaft strength and reduced hair shaft friction after using the study hair products.

Hair Tensile		
Wilcoxon Rank-Sign two tailed paired	**Baseline**	**Week 1**
Mean A	1.58	0.66
Baseline A		1.58
% Change		-58%
A v. Baseline p =		**<.001**

Table 2: Investigator Conditioner Assessment
The investigator assessed hair attributes associated with conditioner use to include: poor tensile strength, UV and heat hair damage, poor resilience, poor hair shine, and poor hair body (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe). After one week of conditioner use, there was a highly statistically significant ($p<0.001$) percentage improvement of 36% in tensile stremgth, 18% in UV/heat damage, 30% in resilience, 44% in hair shine, and 42% in hair body. These are excellent results in hair appearance attributes after using the conditioner for one week.

Inv Condition										
	Baseline					Week 1				
Wilcoxon Rank-Sign two tailed paired	**Strength**	**Damage**	**Resilience**	**Shine**	**Body**	**Strength**	**Damage**	**Resilience**	**Shine**	**Body**
Mean A	2.34	2.88	2.30	2.92	2.46	1.50	2.36	1.60	1.64	1.42
Baseline A						2.34	2.88	2.30	2.92	2.46
% Change						-36%	-18%	-30%	-44%	-42%
A v. Baseline p =						**<.001**	**<.001**	**<.001**	**<.001**	**<.001**

Table 3: Investigator Scalp Treatment Assessment
The investigator evaluated the following hair parameters as related to the scalp treatment: poor hair density, poor hair volume (assessed visually as the distance the hair stands away from the scalp), damaged structure (assessed visually as the presence of broken hairs and split ends), scalp irritation, scalp dryness, and overall poor hair health (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe) The investigator assessed excellent percentage improvement for scalp treatment with a 33% improvement in hair density, a 38% improvement in hair volume, 44% reduction in scalp irritation, 48% reduction in scalp dryness, and 39% improvement in hair health. All of these findings are highly statistically significant ($p<0.001$). Several subjects (11 subjects) commented on the poor smell and greasiness of the scalp treatment. The individuals who commented on the greasiness had oily hair/scalp. Conversely, subjects with dry hair/scalp felt the product was excellent.

Inv Scalp												
	Baseline						Week 1					
Wilcoxon Rank-Sign two tailed paired	**Density**	**Volume**	**Structure**	**Irritation**	**Dryness**	**Health**	**Density**	**Volume**	**Structure**	**Irritation**	**Dryness**	**Health**
Mean A	2.08	2.12	2.70	1.64	1.78	2.56	1.40	1.32	1.72	0.92	0.92	1.56
Baseline A							2.08	2.12	2.70	1.64	1.78	2.56
% Change							-33%	-38%	-36%	-44%	-48%	-39%
A v. Baseline p =							**<.001**	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**

Table 4: Investigator Shampoo Assessment
The investigator also evaluated the following hair parameters for shampoo performance: excessive sebum (assessed as the appearance of greasy hair), poorly moisturized hair (assessed as the appearance of hair frizz due to static electricity), poor hair strength (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe). The

shampoo performed excellently with highly statistically significant ($p<0.001$) improvement in all parameters. Subjects commented to investigator that the shampoo was remarkable in its ability to reduce hair frizz.

Inv Shampoo						
	Baseline			Week 1		
Wilcoxon Rank-Sign two tailed paired	**Sebum**	**Frizz**	**Health**	**Sebum**	**Frizz**	**Health**
Mean A	1.62	2.78	2.76	1.16	1.76	1.84
Baseline A				1.62	2.78	2.76
% Change				-28%	-37%	-33%
A v. Baseline p =				**<.001**	**<.001**	**<.001**

Table 5: Subject Conditioner Assessment

The subjects also assessed the benefits of the hair conditioner via poor tensile strength, UV and heat hair damage, poor resilience, poor hair shine, and poor hair body (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe). The subjects rated the improvement in all parameters as highly statistically significant with the following percentage improvements: 30% improvement in hair strength, 40% improvement in hair damage, 35% improvement in hair resilience, 36% increase in hair shine, and 41% increase in hair body. These findings mirror and confirm the investigator findings indicating an excellent performance for the conditioner.

Sub Condition										
	Baseline					Week 1				
Wilcoxon Rank-Sign two tailed paired	**Strength**	**Damage**	**Resilience**	**Shine**	**Body**	**Strength**	**Damage**	**Resilience**	**Shine**	**Body**
Mean A	2.84	2.98	2.92	2.84	2.96	1.98	1.80	1.90	1.82	1.74
Baseline A						2.84	2.98	2.92	2.84	2.96
% Change						-30%	-40%	-35%	-36%	-41%
A v. Baseline p =						**<.001**	**<.001**	**<.001**	**<.001**	**<.001**

Table 6: Subject Scalp Treatment Assessment

The subjects evaluated the scalp treatment in terms of poor hair density, poor hair volume, damaged structure, scalp irritation, scalp dryness, and overall poor hair health (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe). Other than the previously mentioned comments from 11 subjects regarding poor smell and product greasiness, the product was rated very highly by the subjects. There was a 28% improvement in hair density, 32% increase in hair volume, 30% reduction in damaged hair structure, 49% reduction in scalp irritation, 51% reduction in scalp dryness, and a 35% increase in hair health. These findings are also consistent with the dermatologist investigator findings for the scalp treatment.

Sub Scalp												
	Baseline						Week 1					
Wilcoxon Rank-Sign two tailed paired	**Density**	**Volume**	**Structure**	**Irritation**	**Dryness**	**Health**	**Density**	**Volume**	**Structure**	**Irritation**	**Dryness**	**Health**
Mean A	2.76	2.94	2.94	2.24	2.42	2.72	2.00	2.00	2.06	1.14	1.18	1.76
Baseline A							2.76	2.94	2.94	2.24	2.42	2.72
% Change							-28%	-32%	-30%	-49%	-51%	-35%
A v. Baseline p =							**<.001**	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**

Table 7: Subject Shampoo Assessment

Subjects evaluated the following hair parameters based on the shampoo performance: excessive sebum, poorly moisturized hair, and poor hair strength (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe). The subjects gave the shampoo excellent ratings with highly statistically significant improvement indicated by a 39% reduction in sebum, 39% reduction in hair frizz, and a 35% improvement in hair health.

Sub Shampoo						
	Baseline			Week 1		
Wilcoxon Rank-Sign two tailed paired	**Sebum**	**Frizz**	**Health**	**Sebum**	**Frizz**	**Health**
Mean A	2.22	3.14	2.80	1.36	1.90	1.82
Baseline A				2.22	3.14	2.80
% Change				-39%	-39%	-35%
A v. Baseline p =				**<.001**	**<.001**	**<.001**

15. SUMMARY

15.1 PRIMARY EFFICACY ENDPOINT

The primary efficacy endpoint was the statistically significant improvement in hair volume, density, strength, shine, body, ease of detangling/combing, resilience and overall hair appearance health after 7 uses of study scalp treatment and 3 uses of study shampoo and conditioning treatment as assessed by the investigator. The primary efficacy endpoint was met.

15.2 SECONDARY EFFICACY ENDPOINT

The secondary efficacy endpoint was the statistically significant improvement in hair volume, density, strength, shine, body, ease of detangling/combing, resilience and overall hair appearance health after 7 uses of study scalp treatment and 3 uses of study shampoo and conditioning treatment as assessed by the subject. The secondary efficacy endpoint was met.

15.3 SAFETY

The safety endpoint was the incidence of all adverse events reported during the study. The safety endpoint was met as no adverse events occurred during the conduct of the study.