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An Open Label, Single Arm, Monocentric Study to Evaluate the Efficacy of a Test Product in Hair Fall Reduction and Scalp Nourishment in Healthy Indian Female Subjects.

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Abstract

The study involves the use of cosmeceuticals for the hair fall reduction and improvement in hair strength and scalp condition in healthy Indian female subjects. The use of these cosmeceuticals as anti-hair fall agents prevents hair damage, nourishes and conditions the hair, reduces breakage, and soothes the scalp. The present trend of using marketed anti hair fall agents has many side effects and there may be a chance of causing further damage to the hair. In order to overcome their side effects and to have maximum therapeutic efficacy present study was aimed to evaluate the treatment for the hair fall with the cosmeceuticals.

Methods: An open-label, monocentric, single arm study was used to evaluate hair fall reduction and scalp nourishment. The natural olive oil along with other excipients like Macademia and Avocado oil and Basil extract was formulated and the study was conducted in 35 numbers of healthy female subjects aged between 25-55 years for a period of approximately 90 days i.e., 3 months for each subject which included a total of three visits.

Parameters: Screening, Dermatological evaluation, instrumental evaluations and subject self assessment were used to evaluate the anti-hair fall and scalp nourishment properties of the test product.

Results and Discussion: Improvement was seen in majority of parameters, starting from 30-90 days. The Product was safe and well tolerated as per the dermatologist and subjects' self-assessment.

Keywords

Cosmeceuticals; Hair oil; Macademia; Monocentric; Hair loss; Hair fall; Scalp nourishment

Introduction

Hair loss is one of the most common problems seen in both men and women. Some experiences less hair fall while it is acute with others. The underlying reason can be genetic or due to the influence of environmental factors. It can be diagnosed by conducting tests on hormone levels in females, serum iron levels, and scalp biopsy, etc., to examine the root cause of the hair fall [1,2]. In general hair fall is seen due to nutrition deficiency, autoimmune disorders or it may be due to environmental causes [3]. The two most common types of hair loss are androgenetic alopecia (male or female pattern baldness) and Alopecia areata (AA), an autoimmune condition that causes patchy hair loss i.e. a single bald patch or extensive hair loss in patches.

Telogen effluvium is one type of temporary hair loss that appears as a thinning of hair on the scalp. TE hair loss can be triggered in many different ways which includes severe stress, sudden change in hormone levels, iron deficiency, environment, physical or emotional trauma, diet and some medications. The best way to treat TE is to figure what is causing the hair loss and also change of lifestyle and diet. Another type of hair loss is due to Alopecia areata, that affects patches on the scalp. AA is an autoimmune disease in which the immune system attacks the hair follicles, mistaking them for pathogens such as viruses. AA can be treated by injecting steroids in the affected areas.

Although hair fall is treated by using various drugs and anti hair fall agents, they have many side effects and one cannot conclude it by saying the problem can be cured without its recurrence, so in order to treat hair fall with minimized side effects, the concept of cosmeceuticals came into existence which is used as a novel approach in the present study.

History

Among other parameters which are taken into consideration for the diagnosis and treatment of hair fall medical and personal history of the concerned person who is facing the problem is taken as the important attribute [4]. The information which is collected from the concerned person should include the signs and symptoms of hair loss, such as loss of hair from certain parts of the scalp, loss of hair after great illness or stress, loss of

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hair after drug treatment, loss of hair due to immune diseases and disorders, history related to hair loss that runs in the family and also the history of Psychological distress. This information must be noted by the patient. Based on this information further treatment methods and methodology for the patient is planned [5,6].

Physical Examination

After taking the detailed information from the patient the doctor examines the patient thoroughly. The first thing to be checked out is the skin type of scalp. The scalp color, distribution and presence of the hair follicles should be noted. The “pull test” and the “comb test” is performed in order to assess the hair shedding level [7-10]. These simple tests can show degree of the hair loss. The pull test is carried out in a way that physician grab 25-35 hairs with their fingers and try to pull apart gently. If in case 10 hairs remain in his/her hand, it indicates a sign of major hair loss. One hair is taken as sample for the microscopic analysis and the analysis was performed by using instruments like Geno dermatoses, which is a light microscopy of the hair. The tensile strength of the hair should also be noted. Leaning over a light colored bed sheet comb from the back of the top of the head forward to the front of the scalp for one minute. Seeing about 10 hair loss indicates abnormality.

Although there are many methods and a lot of drugs that are used in the treatment of HF they have many adverse effects so to avoid that the present study was aimed to evaluate the treatment of HF and Reduction and Scalp Nourishment by using a novel approach of cosmeceuticals [11,12]. Cosmeceutical products are marketed as cosmetics, but reputedly contain biologically active ingredients and show their efficacy by minimizing the side effects and produce the maximum therapeutic benefits. The test product was formulated by using the active pharmaceutical ingredient Natural Olive oil along with other excipients like Macademia and Avocado oil and Basil extract.

Materials and Methods

Study Design

This was an open label, single arm, Monocentric study included 35 healthy female subjects aged between 25-55 years and was conducted for a period of approximately 90 days, i.e., 3 months for each subject which included a total of three visits and tested for the signs of scalp hair getting thin or complete hair loss, hair loss after great illness or stress, thinning of hair, Slowly loss of hair from the top and other anti HF products [13,14].

Any history of underlying uncontrolled medical illness including diabetes mellitus, hypertension, HIV, hepatitis, severe anemia, serious disorders of the heart and respiratory apparatus or any other serious medical illness was noted.

The study included 3 following visits:

Visit 1 (Day 0) - comprised of screening, enrollment, dermatological, instrumental, subject self assessment and habit questionnaire for all subjects. Comb test was also a part of a screening test.

Visit 2 (Day 30) - Follow up evaluation

Visit 3 (Day 90) - Follow up evaluation

The subjects were selected based upon the selection criteria, inclusion criteria, exclusion criteria.

Critical selection criteria

- i. Female subjects in general good health (see exclusion criteria)
- ii. Subjects in the age group 25-55 years (both the ages inclusive)
- iii. Subjects having a hair fall concern, seen with more than 30 hairs in the comb test

Inclusion Criteria

- i. Female subjects in general good health
- ii. Subjects in the age group 25-55 years (both the ages inclusive)
- iii. Subjects willing to give a written informed consent and agree to come for a regular follow up visit

- iv. Subjects having hair fall concern seen with more than 30 hairs in the comb test
- v. Subjects willing to abide by and comply with the study protocol
- vi. Subjects who have not participated in a similar investigation in the past three months
- vii. Subjects complaining of hair fall and damage
- viii. Healthy volunteers with no known allergy as established by medical history
- ix. Subjects who do not smoke or drink
- x. Subjects who are not crash dieting
- xi. Subjects willing to refrain from any type of hair treatment like perming, straightening etc. during the study duration
- xii. Negative UPT test for subjects

Exclusion Criteria

- i. Subjects having any active scalp disease which may interfere in the study - dermatologist's judgement
- ii. Subjects who have taken chemotherapy for cancer in the 6 months prior to start of the study or have a plan to do treatments during the study
- iii. Subjects who have a history of alcoholism and/ or psychiatric disorder including trichotillomania
- iv. Subjects who have had a hair transplant
- v. Subjects who take a pharmaceutical product which cause hirsutism (ex. phenytoin) and finasteride for androgenic alopecia
- vi. A known history or present condition of allergic response/ hypersensitivity to any cosmetic ingredients and pharmaceutical products
- vii. Subjects on oral medications which will compromise the study
- viii. Subjects who are pregnant or lactating or nursing as established by medical history
- ix. Under medical treatment for hair problems
- x. Under going any chemical hair salon treatment
- xi. straightening / perming / color
- xii. Pregnant female subjects as determined by UPT test
- xiii. Chronic illness which may influence the cutaneous state. Subjects participating in other similar cosmetic or therapeutic trial within last three months
- xiv. Any history of underlying uncontrolled medical illness including diabetes mellitus, hypertension, HIV, hepatitis, severe anemia, serious disorder of heart and respiratory apparatus or any other serious medical illness

The main objective of the study was to evaluate the efficacy of the test Product after its application process over three months to treat anti HF and the subjects were tested for dermatological assessment, corneometer assessment of scalp, comb test and pull test, subjects self assessment, hair tensile-test. The secondary objective is used for the assessment for application site reaction, activity, tolerance of the test product.

Subject Assessment and Visits

The study was conducted for a period of approximately 90 days for each subject. It included a total of 3 visits i.e., day 0 (screening), day 1 (baseline), day 30, day 60 and day 90 (follow up visits). Dermatologist's assessment of efficacy was done using a dermatological assessment questionnaire. This study was approved by the IEC-Clinicom Ethics Committee. The study was conducted at MS Clinical Research Private Limited, Bangalore.

The subjects who satisfied the study inclusion-exclusion criteria were enrolled after obtaining informed consent. A total of 35 adult female subjects aged between 25-55 years were enrolled in the study. The Studied hair oil was the test product used in this study where the subjects were informed to apply the product thrice in a week.

Test product: Studies hair Oil

Dermatological assessment:

- A. Hair Fall Evaluation by Comb Test - Comb test was done on visit 1 (Tb, Day 0), visit 2 (Day 30) and visit 3 (Day 90)
- B. Hair Fall Evaluation by Hair Pull Test- Hair pull test was done on visit 1 (Tb, Day 0), visit 2 (Day 30) and visit 3 (Day 90)
- C. Hair texture - Assessment for hair texture (roughness/smoothness), fragility by hair thickness evaluation (comparative scales had been prepared by MSCR using hair swatches to aid in subjective assessment) and improvement of scalp condition which was performed on visit 1 (Tb, Day 0), visit 2 (Day 30) and visit 3 (Day 90).

Assessment for safety

- 11.2.1 Assessment for site application reaction by dermatologist
- Dermatological assessment for local scalp irritation was performed on the following parameters on visit 1, 2 and 3
- 1=Dryness
 - 2=Erythema
 - 3=Scaling
 - 3=Allergic reactions
 - 4=Folliculitis
 - 6= any others

Assessment for site application reaction by subject

The subjects were asked to observe the changes in their scalp conditions of the application site throughout the study term and inform the same to the investigator on their site visits. The subjects were also advised to make a note of any kind of scalp irritation during product usage in the subject diary provided.

This was recorded under subjective assessment for application site reaction in all visits.

- 1= Burning sensation
- 2=Boils on scalp
- 3=Itching
- 4=Oiliness
- 5= any others, specify

11.3 Subject Self Assessment

Subjects were asked to observe their hair fall rate, hair texture and hair volume; they were informed to score the skin attributes as per the scale provided to each attribute in subject self-assessment questionnaire on visit 1, visit 2 and visit 3. The score was recorded in subject self assessment form. At the end of study visit 3 (Day 90), subjects were asked to provide their opinion about test product.

Instrumental Measurements

Corneometer

Corneometer was used to determine the hydration of the scalp. It was used on all visits of the study. The probe of corneometer was placed on the intersection of horizontal and vertical section of the scalp. An average of three measurements was considered for the analysis at each point of the study [15] (Table 1).

Visits on which the measurements are performed	Visit 1 (T _b), 2 & 3
Instrumental Values/readings to be documented	Corneometer unit numerical value
Measurement site	Intersection of horizontal and vertical sectioning
Number of measurements per site	Three measurements were captured

Table 1: Initial determination of the hydration of the scalp using corneometer

Hair tensile test

Total of 15 hair strands were collected from the root where 5 hair strands were used for hair strengthening analysis using hair tensile tester and remaining 10 hair strands were sent to sponsor on first and last visit (Table 2).

Hair fall by comb test: The test was done by observing the amount of hair loss happened after the usual combing process.

Evaluation of hair fall by hair pull test: A bundle of about 50-60 hair was grasped between two fingers. A constant traction force in the direction of hair growth was applied to pull out the hair. Pulled hair was counted and documented. A reduction in hair fall is a sign of hair strengthening from the root at it resists falling due to pull force.

Hair Texture: Hair texture assessments included two different , i.e., hair softness and hair thickness. Each parameter was provided with different separate scales which were used for assessments.

Scalp Condition: Visual assessment was performed using a microscopic camera on the following parameters i.e., dry, oily and normal.

Image Analysis: Image analysis was performed visually by dermatologists, where the images were captured at each visit and these images were compared to baseline images to determine the overall improvement in hair thinning.

Results and Discussions

Efficacy Assessments

Dermatological Assessment

Dermatological assessment was performed on all visits, i.e., baseline, visit 2 (Day 30) and visit 3 (Day 90). The hair fall evaluation was done by comb test and hair pull test. Hair texture assessments included two different parameters, i.e., hair softness and hair thickness. Each parameter was provided with different separate scale which was used for assessments.

Evaluation of hair fall by comb Test

Comb test was performed to evaluate the efficacy of test product post application in reducing the hair fall due to combing force. The count of fallen hair with a bulb and without bulb was then recorded separately. Hair fibre with bulb represents hair fall from root and hair fibre without bulb represents hair fall due to breakage from the shaft.

Subjects were asked to partition their hair into two equal halves. Subjects were provided with a standard tooth comb, to comb each half of the hair in continuous stroking. The fallen hair was collected on a white sheet and was recorded.

Hair fall with bulb (Table 3)(Figure 1):

After 30 days of test product application, there was a slight decrease in hair fall rate but it was not found to be significant. The hair fall reduced by 15.71%. After 90 days of test product application, significant reduction in the hair fall was observed in comparison to

Visits on which the measurements are performed	Visit 1 (T _b), 2 & 3
Instrumental Values/readings to be documented	Numerical Value
Measurements	Total 5 different hair strands
Number of measurements per site	Five measurements were captured

Table 2: Hair strengthening analysis using hair tensile tester

Hair count			
With bulb			
	Day 0	Day 30	Day 90
Mean ± SD	35 ± 19.65	29.5 ± 17.81	17.76 ± 10.17
% reduction	-	15.71%	49.26%
P-value		0.2309	<0.0001

Table 3: Determination of hair count with bulb

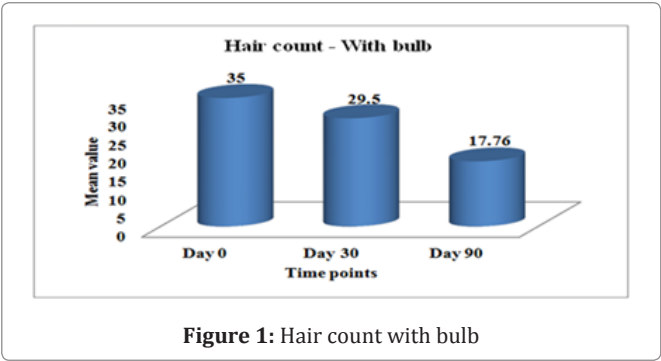


Figure 1: Hair count with bulb

baseline. The hair fall reduced by 49.26% at last visit in comparison to baseline. This infers that the test product was efficacious in reducing the hair fall.

The hair fall with bulb was approximately 1.97 times lesser at the end of study over baseline.

Hair fall without bulb (Table 4) (Figure 2)

After combing the hair, the fallen hair without bulb was counted and documented.

After 30 days of test product usage, reduction was noted in hair fall without bulb but it was not found to be significant. After 90 days of test product application, significant reduction in the hair fall was observed in comparison to baseline. About 40.54% of hair fall reduction was noted at last visit in comparison to baseline. This infers that the test product was efficacious in reducing the hair breakage.

The hair fall without bulb was approximately 1.68 times lesser at the end of study over baseline

Result Observed: After 90 days of test product usage, significant reduction in the hair fall was observed in comparison to baseline. Hair fall with bulb reduced by 15.71% and 49.26% at day 30 and day 90, respectively in comparison to baseline. This implies that the test product was efficacious in reducing the hair fall with bulb.

After 30 days of test product usage, reduction was noted in hair fall without bulb but it was not found to be significant. Further with continuous usage of test product (90 days), there was significant reduction noted in the hair fall when compared to baseline. About 40.54% of hair fall reduction was noted at last visit in comparison to baseline. This infers that the test product was efficacious in reducing the hair breakage.

The test product was efficacious in reducing the hair fall and hair breakage after application of test product when subjected to combing force.

	Day 0	Day 30	Day 90
Mean ± SD	27.65±22.39	21.79±13.12	16.44±10.52
% reduction	-	21.19%	40.54%
P-value		0.1941	0.01119

Table 4: Determination of hair count without bulb

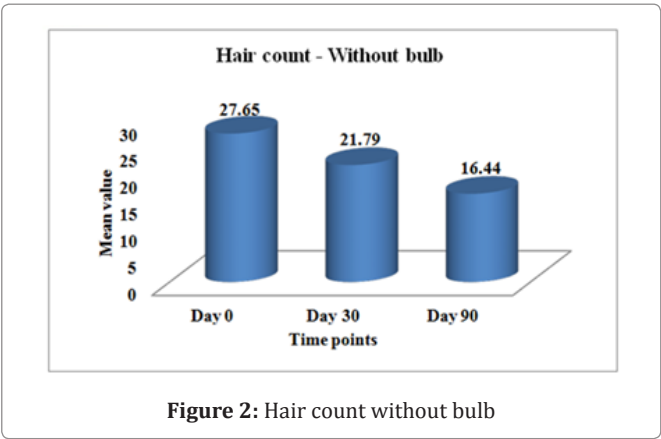


Figure 2: Hair count without bulb

Number of hair pulled: Number of hair pulled out was counted and documented (Table 5).

Sum of all 4 sections was calculated for each visit and then analysis was performed.

Significant decrease in the number of hair pulled out was noted at day 30 and day 90 in comparison to baseline. Hair fall reduced by 58.43% at the end of the study when compared to baseline. It was noted that the hair fall was approximately 2.41 times lesser at the end of study over baseline

	Day 0	Day 30	Day 90
Mean ± SD	3.32 ± 1.53	2.29 ± 1.55	1.38 ± 0.92
% reduction		31.02 %	58.43 %
p value	-	<0.0001	<0.0001

Table 5: Number of hair pulled count

Hair pull test score Number of hairs pulled out was counted and a score was allotted based on the scale given below

Scale: 1=None (0 hair strands), 2=Negligible (1-2 hair strands), 3=Mild (3-4 hair strands), 4=Moderate (5-6 hair strands), 5=Severe (More than 6 hair strands)

An average of 4 sections at each visit was calculated and analysis was performed on the average value (Table 6) (Figure 3).

Reduction in the score is a sign of improvement, Significant reduction in the score was observed at day 30 and it continued till day 90 in comparison to baseline. Hair fall reduced by 22.09% at the end of the study when compared to baseline.

It was noted that the hair fall was approximately 1.28 times lesser at the end of study over baseline

Result Observed: In hair pull test where a force was applied to pull the hair out, significant reduction in the hair fall was noted at day 30 and day 90 in comparison to baseline.

Hair Texture

Hair Thickness: Hair thickness was performed to determine the fragility of hair. The scale mentioned below was used by dermatologists

Scale: 1=Very fine hair, 2=Fine hair, 3=Medium thick hair, 4=Thick hair, 5=Very thick hair (Table 7) (Figure 4).

There was no significant change in the thickness of hair.

	Day 0	Day 30	Day 90
Mean±SD	1.72±0.26	1.52±0.30	1.34±0.21
% reduction	-	11.62%	22.09%
P value		<0.0001	<0.0001

Table 6: Hair pull test score

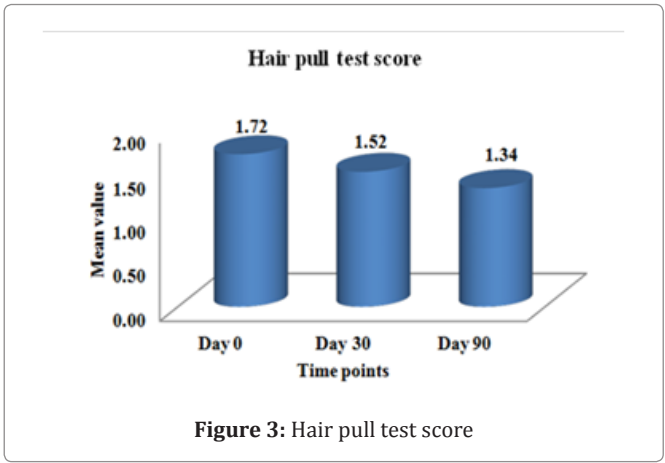
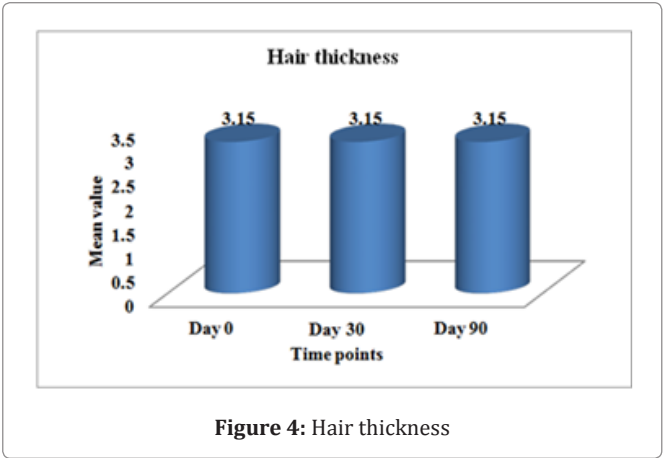


Figure 3: Hair pull test score

	Day 0	Day 30	Day 90
Mean ± SD	3.15 ± 0.61	3.15 ± 0.61	3.15 ± 0.61
p value	-	0.9999	0.9999

Table 7: Hair thickness test to determine the fragility of hair



Hair Softness

The scale mentioned below was used by dermatologists to assess the hair texture in terms of smoothness/roughness

Scale: 1=Very rough hair, 2= Rough hair, 3=Average hair texture (neither rough nor smooth), 4= Smooth hair, 5= Very smooth hair (Table 8) (Figure 5) (Figure 6).

After 30 days of test product application (Visit 2), significant improvement in hair texture i.e., softness, was observed in comparison to baseline and it continued till the end of the study.

	Day 0	Day 30	Day 90
Mean ± SD	3.24 ± 0.5	3.56 ± 0.56	3.79 ± 0.41
p value		0.0004	<0.0001

Table 8: Assessment of the hair texture

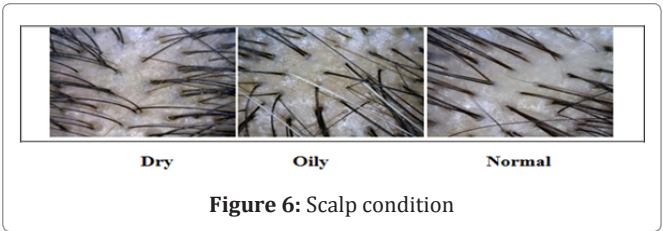
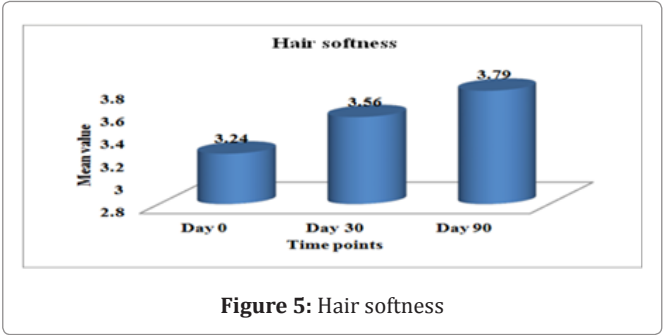


Figure 6: Scalp condition

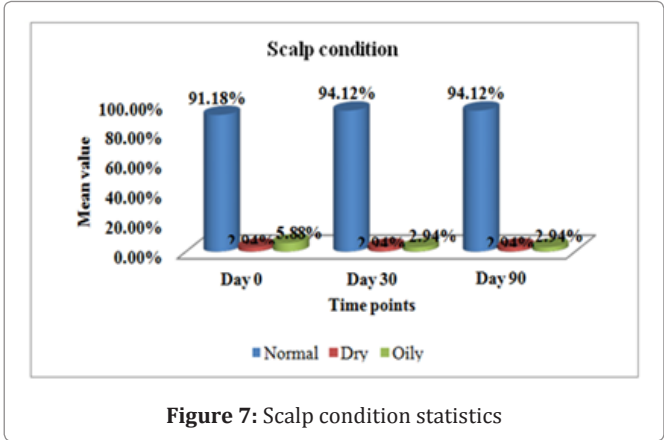
Scalp Condition (Table 9) (Figure 7)

At baseline, 91.18% of the study population already had normal scalp which increased after 30 days of product usage to 94.12% of the study population had normal scalp.

Result Observed: There was no significant change noted in the

	Day 0	Day 30	Day 90
Normal	91.18%	94.12%	94.12%
Dry	2.94%	2.94%	2.94%
Oily	5.88%	2.94%	2.94%

Table 9: Scalp condition analysis



thickness of hair at any time point of the study. However, there was a significant improvement noted in hair texture i.e., softness, at day 30 in comparison to baseline and it continued till the end of the study. At baseline, 91.18% of the study population had normal scalp whereas after 90 days of product usage, 94.12% of the study population had normal scalp.

Image Analysis (Table 10)

Significant improvement was noted at the end of the study as per the image analysis. The improvement was noted in 16 subjects, out of 34 subjects at the end of the study

Result Observed: Significant improvement was noted at the end of the study as per the image analysis performed by dermatologists based on the provided scale. Out of 34 subjects, the visual improvement was noted in 16 subjects with continuous usage of test product at the end of the study (Figure 8).

Instrumental Measurement

Hair tensile tester and corneometer was performed on all the visits of the study to determine the efficacy of test product in hair strengthening and providing the hydration to the scalp.

Hair Tensile Strength: Tensile test was performed to determine the strength of hair when subjected to force until hair breakage and it was done on all visits (Table 11) (Figure 9).

With continuous application of test product, significant increase in hair tensile strength was observed at day 30 and day 90 in comparison to baseline. Tensile strength increased by 33.80% at day 90 in comparison to baseline. This infers that the test product improved the hair tensile strength.

Image Analysis			
	Day 0	Day 30	Day 90
Mean ± SD	2.71 ± 1.24	2.66 ± 1.25	2.36 ± 1.33
% improvement	-	1.85%	12.92%
p value	-	0.1836	0.0004

% improvement	No. of subjects showing improvement	
	Day 30	Day 90
1-25%	1	7
26%-50%	1	6
51%-75%	0	1
76%-100%	0	2

Table 10: Improved statistics as per the image analysis



Figure 8: Image analysis

	Day 0	Day 30	Day 90
Mean $\pm$ SD	0.71 $\pm$ 0.21	0.89 $\pm$ 0.23	0.95 $\pm$ 0.14
% improvement	-	25.35%	33.80%
P-value		0.0004	<0.0001

Table 11: Determination of the strength of hair using hair tensile strength

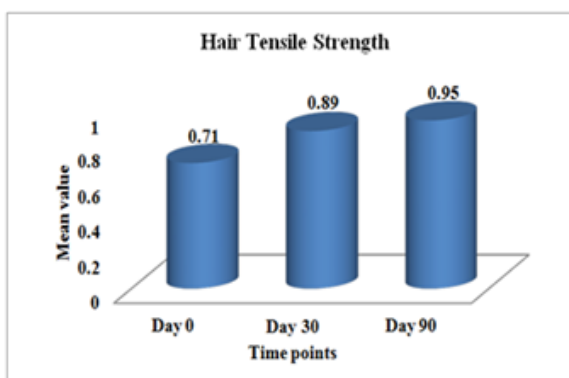


Figure 9: Hair tensile strength

The hair tensile strength was approximately 1.34 times higher at the end of study over baseline.

Results observed: With continuous application of test product, significant increase in hair tensile strength was observed at day 30 and day 90 in comparison to baseline. Tensile strength increased by 33.80% at day 90 in comparison to baseline. This infers that the test product was efficacious in the improvement of hair tensile strength. A slight increase in the value was noted at the end of the study in comparison to baseline but the change was not significant. Throughout the study there was no difference in scalp hydration level.

With continuous application of the test product, about 60% of the study population had hair fall less than 30 strands, about 80% of study population had normal and soft hair and 8.82% of the study population graded that their hair volume was good at the end of the study.

Corneometer (Table 12) (Figure 10)

Corneometer was used to determine the hydration of the scalp. It was used on all visits of the study. The probe of corneometer was placed on the intersection of horizontal and vertical section of the scalp. An average of three measurements was considered for the analysis at each point of the study.

	Day 0	Day 30	Day 90
Mean $\pm$ SD	1.12 $\pm$ 2.4	0.52 $\pm$ 1.45	2.17 $\pm$ 3.37
P-value	-	0.2525	0.1361

Table 12: Final determination of the hydration of the scalp using corneometer

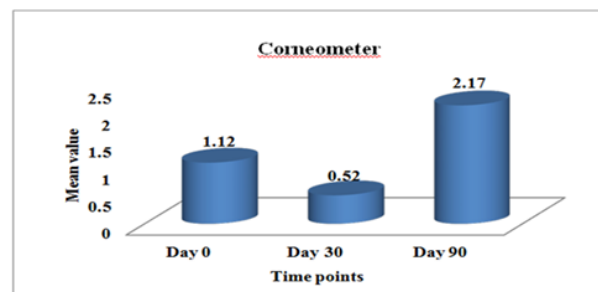


Figure 10: Corneometer test to determine the hydration of the scalp using corneometer

Post 90 days of product application, slight increase was noted in the hydration level in comparison to baseline but it was not found to be significant. Throughout the study there was no difference in scalp hydration level.

Subject Self Assessment

The Subjective self assessment was performed to determine the product's efficacy after the application. Subject self assessment was performed on all visits.

Current Hair Fall Rate (Table 13)

At baseline, 41.18% of the study population had hair fall more than 50 hair strands and 58.82% of the study population had hair fall more than 30-50 hair strands. However, after 90 days (Visit 3) of product usage, none of the subjects had hair fall more than 50 hair strands and 67.65% of the study population had hair fall less than 30 hair strands. The test product received positive response.

Current Hair Texture (Table 14)

At baseline, 23.53% of the study population perceived to have rough hair. However, after 90 days (Visit 3) of product usage, 5.88% of the population perceived to have rough hair. About 17.65% of study population changed their perception from rough to normal and soft hair after application of test product at the end of the study.

How do you grade your current hair fall rate?			
Grades	Day 0	Day 30	Day 90
More Than 50 hair strands	41.18 %	29.41 %	0.00 %
30-50 hair strands	58.82 %	47.06 %	32.35 %
Less than 30 hair strands	0.00 %	23.53 %	67.65 %
p-value	0.3035	0.0164	0.0396

Table 13: The hair shedding grades before using the test product

After usage of test product Hair texture results in terms of grades			
Grades	Day 0	Day 30	Day 90
Rough Hair	23.53%	20.59%	5.88%
Normal Hair	44.12%	41.18%	47.06%
Soft Hair	32.35%	38.24%	47.06%
p-value	0.002	0.0006	<0.0001

Table 14: Hair texture grading after the usage of test product

Current Hair Volume (Table 15)

At baseline, 32.35% of the study population perceived to have less hair volume and 67.65% of the study population perceived to have average hair volume. After 90 days (Visit 3) of test product usage, 2.94% of the study of population perceived to have less hair volume, 88.24% of the study population perceived to have average hair volume and 8.82% of the study population perceived to have good hair volume.

After usage of test product Hair volume results in terms of grades			
Grades	Day 0	Day 30	Day 90
Less Volume	32.35%	17.65%	2.94%
Average	67.65%	79.41%	88.24%
Good volume	0.00%	2.94%	8.82%
p-value	0.0396	0.0002	<0.0001

Table 15: Hair volume grade after the usage of test product**Merits 's about product (Table 16)**

17.65% of the study population liked colour, texture, fragrance and felt that it was easy to use and also, 32.35% of the study population liked the fragrance of the test product.

Product effectiveness in reducing hair fall (Table 17)

67.65% of the study population felt that test product was efficacious in reducing the hair fall.

Positives of the test product	
Likes	Day 90
Color, Texture, Fragrance, Easy to use	17.65%
Color, Texture, Easy to use	5.88%
Color, Fragrance	2.94%
Color, Fragrance, Easy to use	2.94%
Color, Easy to use	2.94%
Texture, Fragrance	14.71%
Texture, Fragrance, Easy to use	5.88%
Texture, Easy to use	2.94%
Fragrance, Easy to use	8.82%
Fragrance	32.35%
Easy to use	2.94%

Table 16: Merits of the test product in terms of color, texture, fragrance

	Dryness			Erythema			Scaling			Allergic reaction			Folliculitis			Any other		
	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90
None	33	33	34	35	34	34	26	28	32	35	34	34	35	34	34	35	34	34
Mild	2	1	0	0	0	0	9	6	2	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Extensive	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 19: Safety assessment of the product

Severity	Burning sensation			Boils on scalp			Itching			Oiliness			Any others, specify		
	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90	Day 0	Day 30	Day 90
None	34	34	34	35	34	34	15	25	31	28	31	34	35	34	34
Mild	1	0	0	0	0	0	11	8	3	6	3	0	0	0	0
Moderate	0	0	0	0	0	0	7	1	0	1	0	0	0	0	0
Severe	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
Extensive	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 20: Safety assessment of the product**Demerits about the product (Table 18)**

About 76.47% of the study population did not mention any parameter which they did not like about test product.

Safety Assessment (Table 19)

Dryness: At baseline, two subjects had mild dryness which continued in one subject and resolved in another subject on next

Day 90	
Poor	0%
Average	17.65%
Good	67.65%
Very Good	14.71%
Excellent	0%

Table 17: Effectiveness of the test product after its usage

Dislikes	Day 90
NA	76.47%
Colour	8.82%
Texture	5.88%
Fragrance	5.88%
Others	2.94%

Table 18: Demerits about the test product

visit i.e., day 30. At the end of the study, none of the subjects had any dryness.

Scaling: At baseline, nine subjects were noted with mild scaling which resolved in three subjects and further continued in six subjects when evaluated on next visit i.e., day 30. On day 90, mild scaling resolved in four subjects but continued in two subjects.

None of the subjects had **erythema, folliculitis and allergic reactions** (Table 20).

Burning Sensation: At baseline, one subject perceived mild burning sensation and it resolved on next visit.

Itching: Twenty subjects perceived itching where 11 subjects perceived mild itching, 7 subjects perceived moderate and 2 subjects perceived severe itching at baseline i.e., before application. At day 30, 8 subjects perceived mild itching, 1 subject perceived moderate itching and none of the subjects perceived severe itching. At last visit (day 90), 3 subjects perceived mild itching and none of the subjects perceived moderate itching.

Oiliness: At baseline, 6 subjects experienced mild oiliness and one subject experienced moderate oiliness. At the end of the study, none of the subjects experience oiliness.

None of the subjects experienced boils on scalp during the study period.

Conclusion

From the above results, it can be concluded that the test product was efficacious in reducing the hair fall and hair breakage when subjected to comb and hair pull test with the results of 49.26% at 90th day, Hair texture and scalp condition was improved upto 91.18% and 94.12% respectively, Image analysis showed that out of 34 subjects, the visual improvement was noted in 16 subjects with continuous usage of test product at the end of the study, Hair strength and scalp hydration Tensile strength increased by 33.80% at day 90 in comparison to baseline. With continuous application of test product, about 60% of the study population had hair fall less than 30 strands, about 80% of study population had normal and soft hair and 8.82% of the study population graded that their hair volume was good at the end of the study. It was found that the test product was able to nourish the scalp and resulted in healthier hair, with improved hair tensile strength and hair quality. The test product was overall safe and well tolerated.

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