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**Original Research Article**

# A clinical investigation on the safety and effectiveness of an ayurvedic hair oil in controlling hair fall (khalitya) in healthy adult human subjects: a study on hair fall management

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## ABSTRACT

**Background:** Hair loss, commonly associated with genetics, hormones, or health conditions, is prevalent. Dandruff, resulting in flaky scalp skin, is also widespread. Ayurvedic herbal remedies show potential for addressing these hair issues. This clinical trial assesses the efficacy and safety of an ayurvedic hair oil in healthy adults with hair loss (alopecia). The aim is to evaluate its purported benefits in reducing hair fall, stimulating hair growth and alleviating scalp dandruff.
**Methods:** This 8-week study involved 30 subjects with hair fall. After obtaining subject consent, a test hair oil was applied topically. Assessments included evaluating hair-fall, scalp dandruff, hair-growth rate, density, and thickness. Ayurvedic assessment determined hair type. Phototrichogram, pluck-test measured growth, with endpoints including pull-test, combing-test, dermatological evaluation, and subjective questionnaires. Statistical analysis used R software (Version: 4.1.2).
**Results:** The study revealed significant therapeutic efficacy. The mean hair-growth rate increased significantly by 227µm/day (79.92±69.31%) over 8 weeks ($p<0.01$). Hair-fall decreased by 63.49±21.44%, from 97 to 31 hairs. Hair-thickness and density improved by 34.26±16.36% ($p<0.01$) and 39.82±34.3% ($p<0.01$) respectively. Scalp dandruff showed a reduction of 76.33±15.95% ($p<0.01$). The A:T ratio shifted positively from 3:1 to 5:1, indicating an increase in hairs in the anagen phase. No adverse effects were observed.
**Conclusions:** Consistent use of 'moha: 5-in-1' hair oil over 8 weeks was well-tolerated and found effective. It significantly decreased hair fall, promoted hair growth, and improved scalp health by reducing dandruff. This confirms its safety and efficacy among study participants, establishing it as suitable choice for holistic daily hair care.

**Keywords:** Alopecia, Dandruff, A:T ratio, Hair growth rate, Hair fall, Hair oil

## INTRODUCTION

Ayurveda is traditional Indian medical science which describes in detail systemic as well as local diseases and also suggests ways to prevent and treat it. Hair fall is one such disease which is affecting approximately 1.7% of the world population and challenging task for physicians. Hair fall has been described in Ayurveda by the name of khalitya roga under the heading of shiroroga (diseases of head & scalp). Dandruff is a common condition that

affects the skin on the scalp, causing it to flake. Hair fall and dandruff are progressing disorders for people living in sedentary ways of life and stress induced hectic schedules, along with indiscriminate dietary habits. The result is many disturbances and deficiencies in the body which directly reflect in the health of the scalp and hair. We can reduce and manage these rising problems through modifying life style, purification therapy and medication practicing in Ayurveda.[1] The test treatment used in this study is one such ayurvedic preparation for treating problems like hair-fall, dandruff, itching, flaking, and improving the hair growth-rate, thickness and density. The rationale of the study was to assess the safety and effectiveness of a hair-care product in healthy human adults dealing with hair-loss and dandruff. The hair oil consists of multiple herbal and essential oils which are well known traditionally to improve hair growth by strengthening and nourishing the hair roots and improving hair and scalp health. It consists of Coconut Oil that helps in healthy growth of hair a shiny quality, Almond Oil that has high vitamin E content which is particularly helpful for conditioning the hair, Jojoba Oil that acts as moisturizer by producing a thin film on the hair shaft and scalp to maintain optimal hydration, Rosemary Oil which works by keeping the scalp clean, thereby avoiding infections, Argan Oil whose phenol content supports and strengthens hair follicles, Wheatgerm Oil which is a natural hair nourisher, Hibiscus Oil - known to prevent split ends and dandruff, Tea tree Oil that has antifungal, antimicrobial and antiseptic properties, and Sesame Oil that rich in minerals like phosphorous, magnesium, calcium and protects hair from heat damage.[2-10] Each of these herbs and essential oils is useful to treat hair and scalp related diseases.

### *Aim and objectives*

This clinical study was conducted to investigate the outcome of regular application of the test product, with the aim to reduce hair-fall and scalp dandruff, and improve hair growth. This was an open-label, single-arm, single centre, proof-of-concept safety, and efficacy clinical study.

## METHODS

### *Ethical conduct of the study*

The Good Clinical Practices (GCP) for clinical research in India, the 2019 regulations for new drugs and clinical trials, the ICH GCP E6 (R2) guidance on good clinical practice, the October 2013 Declaration of Helsinki, and the 2017 National ethical guidelines for biomedical and health research involving human participants were all followed in the conduct of the study. Independent ethics committee had approved the study protocol; version #01 (Final), informed consent form version #01 (Final), case report form version #01 (Final) and other necessary documents before commencement of the study procedures. This clinical study was registered with the Clinical Trial Registry of India (CTRI) with registration number CTRI/2022/02/040209. A written informed consent was obtained from subjects before enrolment.

### *Study design and plan*

This study was an open-label, single-arm, single-centre, safety and efficacy clinical study of an ayurvedic hair oil in management of hair fall (Khalitya) in healthy adult human male and female subjects after 8 consecutive weeks of usage. The potential subjects were screened as per the inclusion and exclusion criteria only after obtaining written informed consent from the subjects. The study had duration of 60 days, and included a sequence of six visits scheduled at Day -04, Day 01, Day 27, Day 30, Day 57, and Day 60 with a 2-day window period. Subjects underwent screening based on predetermined inclusion and exclusion criteria. The test treatment was applied thrice in a week to hair and scalp, followed by a massage on the scalp with fingertips for 10 minutes in circular motion and left for an hour before washing. The First Subject's First Visit (FSFV) was on 12 February 2022, and the Last Subject's Last Visit (LSLV) was on 10 May 2022. The study was conducted at NovoBliss Research Private Limited, Office; A-206, 2nd Floor, Shaligram Lakeview, Nr. Vaishnodevi Circle, Khoraj, Gandhinagar, Gujarat, India.

A detailed ayurvedic examination for general wellness, and determination of *Vikruta* and *Prakruta* forms of hair was conducted by an AYUSH registered ayurvedic doctor. Assessments made to determine efficacy of the hair oil included an instrumental evaluation of hair growth via a phototrichogram generated using CASLite Nova (Catseye Systems & Solutions Pvt Ltd, India) from a designated shaved area on the scalp. A tattoo made by permanent ink was used to mark a location for standardisation. Hair-fall assessment was done by employing a 60-seconds hair combing test. Further assessments included a hair pluck test for determination of the hair growth phases in terms of Anagen to Telogen (A:T) ratio. Dermatological evaluation of the general appearance of hair (i.e., hair volume, hair density, hair plasticity, hair smoothness, hair oiliness, and hair shininess) was done with the assessment of Adherent Scalp Flaking Score (ASFS). Safety of hair and scalp regarding any treatment-emergent adverse events such as erythema, oedema, pain, pruritus, and urticaria was assessed by the dermatologist. These assessments were conducted by the Dermatologist and the Dermatologist's trained evaluator. Subjects' perception in terms of hair quality was assessed using the Subjective Perception Questionnaire. Dermatologist-trained evaluator was a study personnel with relevant experience in conducting research and had qualification as a paramedic, who was trained by dermatologist for the evaluation of subjects using different assessment methods which are used in this clinical study. In order to prevent operator and evaluator variability, a single operator took all of the readings for all visits in this study.[11]

***Study participants***

33 healthy subjects with hair fall complaints, aged 18 to 44 years, were enrolled with the aim of obtaining 30 evaluable healthy adult subjects at the conclusion of the study, of which all 30 (6 males and 24 females) successfully completed the study. The mean age of all subjects was 30.50 years *(*σ=8.23 years*)*. One enrolled subject withdrew his participation soon after the enrolment, so one additional subject was enrolled in the study. (Table 1).

**Table 1: Test treatment details.**

| Parameters | Details |
|---|---|
| **Product name** | moha: 5 in 1 hair oil; key ingredients: coconut oil, almond oil, jojoba oil, rosemary oil, argan oil, wheatgerm oil, hibiscus oil, tea tree oil, sesame oil. Adjunct Product: 'moha: herbal shampoo' |
| **Storage condition** | Stored in cool and dry place below 25°C. |
| **Dosage form** | Hair Oil |
| **Dosage** | Apply the oil three times a week for 60 days, massage the scalp gradually, and cleanse with 'moha: Herbal Shampoo'. |
| **Route of administration** | Topical |
| **Manufactured by** | Charak Pharma Private Limited |
| **Marketed by** | Vedistry Private Limited |

***Inclusion criteria***

The study enrolled healthy subjects aged 18 to 44 years of both the genders with all the natural hair colours except grey, and self-proclaimed non-pathological thinning of hair. Only the subjects with mild to moderate dandruff on scalp as determined by ASFS score, with the females having 40-50 counts of hair fall, and the males having 25-30 counts of hair fall as determined from the 60-second hair combing method – at the screening visit before treatment were enrolled. Only the individuals who willingly provided written informed consent and committed to completing all the study-related activities, including regular follow-up appointments, were included. The subjects were also required to have had an unwashed and untreated scalp in the past 5 days.

Willing female participants of childbearing potential maintained an established method of birth control, which could include options such as an Intrauterine Device (IUD), hormonal implant device/injection, regular use of birth control pills or patches, diaphragms, condoms with spermicide, sponges with spermicidal jelly, cream, or foam, partner vasectomy, or practicing abstinence. Furthermore, female participants who were not of childbearing potential due to surgical sterility, having been post-menopausal for at least 1 year, or having undergone a tubal ligation were also considered for inclusion. These individuals did not use any medicated or prescription shampoos, hair care products containing Minoxidil, or any other hair growth or hair care products apart from the test product for the entire duration of the study. Subjects who consistently adhered to these criteria and agreed to use the test product throughout the entire study period were included in the research.

***Exclusion criteria***

Strict exclusion criteria were used in this clinical study ensuring the selection of very specific patients. Excluded were the individuals with a documented history of a dermatological condition of the scalp other than hair loss or dandruff, a history of alcohol or drug addiction, or a chronic illness which may potentially influence the cutaneous state, prior use of topical hair loss treatments within 4 weeks or any such systemic treatment within 3 months, or history of any previous hair growth procedures (e.g., hair transplant or laser therapy).

Subjects with a history of severe hair fall caused by any clinically significant problem(s) like anaemia, thyroid problems, etc. Subjects using other marketed hair fall control and/or hair growth products during the study, or who have been on chronic oral steroids within previous 3 months, or with a history of severe hair fall condition caused by any clinically significant problem(s) like anaemia, thyroid problems, etc., were ineligible for participation in the study.

Additionally, individuals with history of, or present irritated or visibly inflamed scalp or a severe scalp disease, or with a history of allergic response to any cosmetic product were excluded. Other exclusion criteria included participants who had participated in similar therapeutic or cosmetic trials in the previous four weeks, those the investigator/expert physician deemed unfit for enrolment, and anyone who refused to give informed permission.

***Test product***

The test product, 'moha: 5-in-1 Hair Oil', is a blend of ayurvedic oils, developed by Charak Pharma and Marketed by Vedistry Private Limited (India), enriched with Coconut Oil, Almond Oil, Jojoba Oil, Rosemary Oil, Argan Oil, Wheatgerm Oil, Hibiscus Oil, Tea tree Oil, and Sesame Oil that take complete care of hair and scalp with multiple benefits (Table 1).

***Dermatological evaluation***

The changes in general appearance of hair and scalp were evaluated by a dermatologist trained evaluator under supervision of dermatologist on Day 01, Day 30, and Day 60, as compared to baseline visit i.e. Day 01 before

product application. A standard clinical questionnaire was used to examine changes in the overall appearance of hair, and the replies were categorized based on their answers. The questionnaire included evaluation for hair volume, meaning the amount of scalp hairs, by categorizing it into full, medium or small. Similarly, hair reflection was categorised into shiny or blunt, hair density into dense or thinned/shade, hair plasticity into waved or flat, hair shininess into poor, average or good and hair smoothness into poor, average or good. The general appearance of the scalp was then assessed with respect to the presence of symptoms such as itching, dryness, redness, roughness, and scaliness.

### *Ayurvedic evaluation*

Prakruta and Vikruta are core concepts of Ayurveda that are used to determine the body's nature possessed by birth, and the current state of the body's health respectively. These are influenced by another underlying concept of three doshas - Vata, Pitta, and Kapha that make up the constitution of the body. Each individual possesses a combination of these doshas.[12] Prakruta represents the physiological stage of hair, while Vikruta represents pathological. The Vata dosha hair of Prakruta type are thin, less in quantity, ruksha (dry), brittle, dull brown hair, with high porosity, while those of Vikruta type are knotted, very dry and dull, frizzy, with an itchy scalp. The Pitta dosha hair of Prakruta type are thin, soft, straight, snigdha (oily), brownish hair, with medium porosity, similarly, the Kapha dosha hair of Prakruta type are thick, dense, more oily, soft and smooth, black, with dense curls and low porosity. The Vikruta type of hair are generally dull, oily, with foul smell, and an itchy scalp. Three diagnostic techniques (trividha pariksha) are used in an Ayurvedic clinical examination: palpation, questioning, and inspection. It was done for general wellness, and the determination of Vikruta and Prakruta form of hair by an AYUSH registered ayurvedic doctor.[13]

### *60-seconds hair count (hair combing method)*

The sixty-second (60s) hair count was aimed to find out a range of shedding hair during a 60 seconds hair combing period. The test was done by flipping the subjects' hair upside-down and combing for 60 seconds over a sheet of contrasting colour to the hair – starting from the back to the front of the scalp via the top. The hairs were counted and stored in separate bags with labelling. This was done by a designated trained study staff.[14]

### *Phototrichogram*

The quantification of hair growth is best done with the method of Phototrichogram, which is a non-invasive and reproductible method. The study staff shaved a small area ($1cm^2$) on the subjects' scalp - 30 cm from the tip of the nose to vertex (possibly centre of vertex area). A permanent ink marker was used to standardize the location of the assessment and the same site was captured in the camera. A digital picture of the head crown was obtained to verify the tattoo area. CASLite-Nova was used to take the images at the same location and at each of the designated visits.[15]

### *Trichogram (hair pluck test and microscopic evaluation)*

The Trichogram, also known as the hair pluck test, is a quantitative, qualitative, and semi-invasive technique that expresses the quantity and percentage of hairs in each phase of the hair cycle. The roots of hair are examined using standardized light microscopy, which allows for root-typing and the counting of anagen, catagen, telogen, and dystrophic hair. Hairs were taken from the vertex region (marked 30 cm from the tip of nose of the subject) from the predefined site on the day of enrolment. The photos and pictures were kept for reference, and the ratio of anagen to telogen (A:T) was computed. Throughout the study, the site was standardized for each participant in order to provide consistent reading and ensuing outcomes.[16]

### *Hair pull test*

The hair pull test is based on the concept of 'gentle' pulling of the hair to bring about the shedding of telogen hairs. Approximately 20-60 hairs were grasped between the thumb, index, and middle fingers from the base of the hairs near the scalp and tugged away firmly, but not forcefully. If more than 10% of hair were pulled away from the scalp, it constituted a positive pull test, implying active hair shedding.

### *Statistics*

Demographic characteristics and results of the study were summarized with descriptive statistics including mean and Standard deviation (SD) for continuous variables, and frequency and percentages for categorical variables. The statistical analysis was done using R software (Version: 4.1.2) with a 5% level of significance. Withdrawn subjects were not included in the statistical analysis.

## RESULTS

In this study, there were 24 (80.0%) females and 6 (20.0%) males; age of the subjects ranged from 18 to 44 years with the average being 30 years. The mean age was 30.50±8.23 years (Table 2).

### *Primary endpoints efficacy results*

Hair-fall evaluation done using the 60-seconds combing test, showed statistically highly significant reduction from baseline visit to visit 04 and visit 06. Total hair fall reduction stood at 48.07%±25.52% ($p<0.01$) at visit 04 and 63.49%±21.44% ($p<0.01$) at visit 06. Hence, a good improvement was observed in hair fall reduction at visit

6. The mean hair fall at baseline was 97.13 hairs, that reduced to 47.53 hairs at visit 04 and further to 31.2 hairs at visit 06. The hair fall reduction at post-baseline visits is shown in Table 3.

**Table 2: Summary of demographic characteristics (n=30).**

| Parameter | Statistic | N |
|---|---|---|
| **Gender** | Female | 24 (80%) |
| | Male | 6 (20%) |
| **Race** | Asian | 30 (100%) |
| **Age (years)** | Mean (SD) | 30.50 (8.23) |
| | Median | 27.50 |
| | Minimum, Maximum | 18.00, 44.00 |
| **Height (cm)** | Mean (SD) | 161.17 (8.64) |
| | Median | 161.00 |
| | Minimum, Maximum | 149.00, 190.00 |
| **Weight (kg)** | Mean (SD) | 57.69 (15.37) |
| | Median | 54.25 |
| | Minimum, Maximum | 31.10, 108.30 |

**Table 3: Descriptive Statistics of Hair Fall Reduction (n=30).**

| Statistics | Day 30 | Day 60 |
|---|---|---|
| **%CFB Mean (SD)** | -48.07 (25.52) | -63.49 (21.44) |
| **Median** | -51.23 | -71.16 |
| **Minimum, Maximum** | -88.51, 9.09 | -90.86, 18.75 |
| **P value** | <0.01 | <0.01 |

% CFB = (Postbaseline-Baseline)/Baseline) *100, visit 01 is considered as baseline.

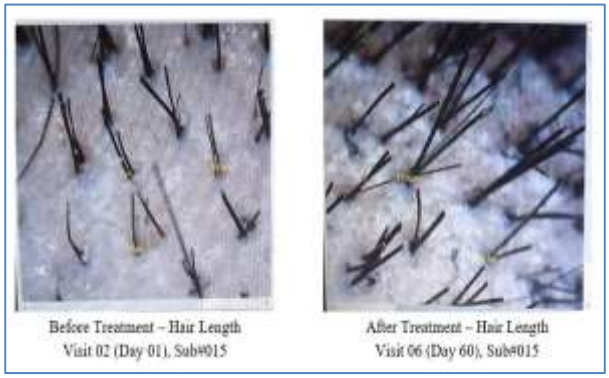


**Figure 1: Hair-growth assessment using CASLite Nova, before and after treatment.**

Significant difference was observed in hair growth rate, hair thickness & hair density from baseline visit to visit 04 and visit 06. Hair growth rate increased by 40.91%±36.51% ($p<0.01$) at visit 04 and 79.92%±69.31% ($p<0.01$) at visit 06. The mean hair growth rate at baseline was 319.13µm/day, that increased to 433.73µm/day at visit 04 and to 546.13µm/day at visit 06 (Table 4, Figure 1). Similarly, hair thickness showed an increase from baseline mean of 16.30µm to a mean of 21.70µm (34.26%±16.36% increase) with a $p<0.01$, at visit 06 (Figure 3). The hair density too, showed an increase from baseline mean of 177.63cm$^2$ to a mean of 242.27cm$^2$ demonstrating an increase of 39.82%±34.30% *($p<0.01$)* at visit 06 (Table 4). Statistically highly significant difference was observed in ASFS score showing notable reduction in scalp dandruff from baseline visit ($\bar{x}$=23.47) to visit 04 ($\bar{x}$=6.2) and visit 06 ($\bar{x}$=5.4), showing a total reduction of 76.33% ±15.95% from baseline, with $p<0.01$ (Table 5). Based on ayurvedic and statistical analysis of Vikruta and Prakruta form of hair, it has been observed that vitiation of kapha is said to be the most important factor in the causation of itching. In fact, the pathological increase of kapha is often correlated with kandu & 20% of subjects with severe itching (+++) experienced significant reduction down to 1%. Other 18% had mild itching (+). Vata aggravation leads to knotting, dullness, dryness and frizzy hair which reduced significantly in subjects by the use of this product at visit 06 (Table 6-7).


**Figure 2: Trichogram assessment before and after treatment.**

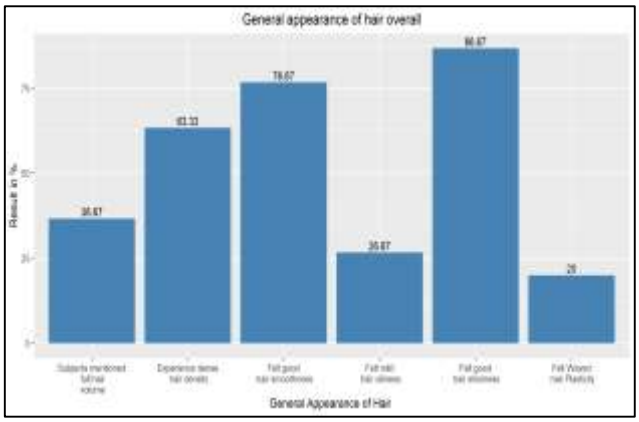


**Figure 3: Perception assessment of general appearance of hair.**

***Secondary endpoints efficacy results***

The hair-pluck test performed at the baseline visit showed that the mean Anagen/Telogen ratio of hair growth cycle of subjects was 3:1, with 72.67% hair in anagen phase, and 27.33% in telogen phase.

**Table 4: Phototrichogram data descriptive statistics (n=30).**

| Parameter | Statistics | Day 30 | Day 60 |
|---|---|---|---|
| **Per day hair growth rate (µm)** | %CFB Mean (SD) | 40.91 (36.51) | 79.92 (69.31) |
| | Median | 27.41 | 69.33 |
| | Minimum, Maximum | 1.29, 123.62 | -100.00, 246.04 |
| | P value | <0.01 | <0.01 |
| **Hair thickness (µm)** | %CFB Mean (SD) | 24.30 (15.63) | 34.26 (16.36) |
| | Median | 21.83 | 34.31 |
| | Minimum, Maximum | 0.00, 64.29 | 7.69, 75.00 |
| | P value | <0.01 | <0.01 |
| **Hair density ($cm^2$)** | %CFB Mean (SD) | 25.31 (15.30) | 39.82 (34.30) |
| | Median | 22.71 | 40.64 |
| | Minimum, Maximum | 3.81, 68.21 | -100.00, 93.44 |
| | P value | <0.01 | <0.01 |

**Table 5: Descriptive statistics of adherent scalp flaking score (ASFS) (n=30).**

| Parameter | Statistics | Day 30 | Day 60 |
|---|---|---|---|
| **ASFS score** | %CFB Mean (SD) | -73.54 (14.28) | -76.33 (15.95) |
| | Median | -75.00 | -77.35 |
| | Minimum, Maximum | -100.00, -42.86 | -100.00, -33.33 |
| | P value | <0.01 | <0.01 |

**Table 6: Number and proportion of prakruta hair type.**

| Form of hair | Score | Day 1, N (%) | Day 60, N (%) |
|---|---|---|---|
| **Vata** | Thin | 10 (4.76) | 9 (4.29) |
| | Less quantity | 6 (2.86) | 7 (3.33) |
| | Ruksha (Dry) | 20 (9.52) | 21 (10) |
| | Low Porosity | 17 (8.1) | 17 (8.1) |
| | Brittle | 21 (10) | 22 (10.48) |
| | Long Curly | 9 (4.29) | 9 (4.29) |
| | Dull Brown Black Hair | 13 (6.19) | 13 (6.19) |
| **Pitta** | Thin | 15 (7.14) | 16 (7.62) |
| | Less quantity | 16 (7.62) | 15 (7.14) |
| | Snigdha (+) Oily | 7 (3.33) | 7 (3.33) |
| | Medium Porosity | 13 (6.19) | 13 (6.19) |
| | Soft | 7 (3.33) | 7 (3.33) |
| | Straight Hair | 19 (9.05) | 19 (9.05) |
| | Brownish, greying of hair | 15 (7.14) | 15 (7.14) |
| **Kapha** | Thick | 5 (2.38) | 5 (2.38) |
| | Dense Hair | 8 (3.81) | 8 (3.81) |
| | Snigdha (++) Oily | 3 (1.43) | 2 (0.95) |
| | Soft Smooth | 1 (0.48) | 1 (0.48) |
| | Dense Curly | 2 (0.95) | 2 (0.95) |
| | Black oily Hair | 2 (0.95) | 2 (0.95) |
| **Vata, Pitta** | Brittle, Soft | 1 (0.48) | 0 (0.00) |

The test performed at visit 06 observed an increase in the mean number of hairs in the anagen phase, with the ratio coming out at 5:1 (84.21% anagen: 15.79% telogen) (Figure 2).

**Table 7: Number and proportion of vikruta hair type.**

| Form of hair | Score | Day 1, N (%) | Day 60, N (%) |
|---|---|---|---|
| **Vata** | Knotted | 16 (7.62) | 2 (0.95) |
| | Dry ++ | 26 (12.38) | 3 (1.43) |
| | Dull +++ | 22 (10.48) | 1 (0.48) |
| | Brown hair colour | 12 (5.71) | 12 (5.71) |
| | Frizzy hair | 27 (12.86) | 5 (2.38) |
| | Itchy scalp + | 4 (1.9) | 18 (8.57) |
| **Pitta** | Dry ++ | 4 (1.9) | 7 (3.33) |
| | Dull +++ | 5 (2.38) | 4 (1.9) |
| | Straight | 7 (3.33) | 20 (9.52) |
| | Grey | 15 (7.14) | 13 (6.19) |
| | Oily with foul smell | 12 (5.71) | 1 (0.48) |
| | Itchy scalp ++ | 6 (2.86) | 11 (5.24) |
| | Brownish, greying of hair | 0 (0.00) | 2 (0.95) |
| **Kapha** | Curls | 0 (0.00) | 7 (3.33) |
| | Dry | 0 (0.00) | 20 (9.52) |
| | Dull + | 3 (1.43) | 25 (11.9) |
| | Brown | 1 (0.48) | 3 (1.43) |
| | Oily without foul smell | 6 (2.86) | 14 (6.67) |
| | Itchy scalp +++ | 20 (9.52) | 1 (0.48) |
| **Vata, Kapha** | Knotted, Curls | 1 (0.48) | 1 (0.48) |
| **Vata, Pitta** | Knotted, straight | 6 (2.86) | 0 (0.00) |
| | Brown hair colour, Grey | 2 (0.95) | 0 (0.00) |
| **Missing** | | 15 (7.14) | 40 (19.05) |

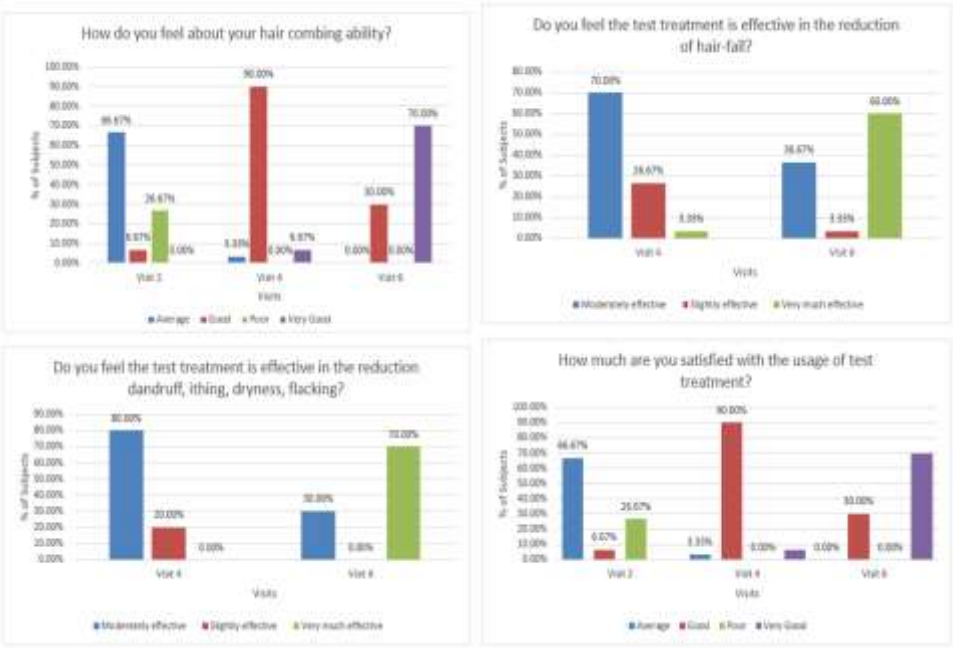


**Figure 4: Perception assessment of test treatment effectiveness.**

Dermatological evaluation of the general appearance of hair showed statistically significant improvement in the hair smoothness, hair oiliness, and hair shininess from baseline visit to visit 06. The assessment by pull test showed statistically non-significant improvement in the hair strength of the subjects. (Table 8).

No statistically significant change in hair volume, hair density, and hair plasticity was observed. However, % improvement in these parameters was seen. The subjective evaluation regarding the general appearance of hair showed self-evaluated increased density, good hair smoothness, and good hair shininess (Figure 3).

After use of treatment, there was statistically highly significant difference in the self-observed hair frizziness, hair shininess and hair softness of the subjects. All the subjects experienced non-frizziness of hair and got no irritation reactions on day 60 of using the treatment. Perceived hair softness and hair shininess showed increased at visit 04 and visit 06 (Table 9). A total of 70% subjects felt very good combing ability after using treatment. 60% subjects observed that the treatment is effective to reduce hair fall and 70% subjects observed relief from the dandruff, dryness, itching and flacking. Overall, 83% subjects reported their satisfaction with the treatment to large extent (Figure 4). Other data extrapolated from the study showed the breakdown of both Prakruta and Vikruta forms of hair. There were no adverse events reported neither subject's self-reporting nor by the Investigator.

**Table 8: Change from baseline in general appearance and strength of hair.**

| Parameter | Statistics | Visit-04 | Visit-06 |
|---|---|---|---|
| **Change in the general appearance of hair** | | | |
| Hair smoothness | N | 30 | 30 |
| | %CFB Mean (SD) | 0.47 (0.57) | 1.13 (0.73) |
| | Median | 0.00 | 1.00 |
| | P value | <0.01 | <0.01 |
| Hair oiliness | N | 30 | 30 |
| | %CFB Mean (SD) | -0.10 (0.40) | -0.47 (0.63) |
| | Median | 0.00 | 0.00 |
| | P value | 0.2330 | <0.01 |
| Hair shininess | N | 30 | 30 |
| | %CFB Mean (SD) | 0.60 (0.56) | 1.27 (0.64) |
| | Median | 1.00 | 1.00 |
| | P value | <0.01 | <0.01 |
| **Change in the hair strength** | | | |
| Hair strength | N | 30 | 30 |
| | %CFB Mean (SD) | 0.03 (0.18) | 0.03 (0.18) |
| | Median | 0.00 | 0.00 |
| | P value | 1.0000 | 1.0000 |

**Table 9: Change in the subjective perception assessment.**

| Parameter | Statistics | Visit-04 | Visit-06 |
|---|---|---|---|
| **How would you describe your hair fizziness?** | %CFB Mean (SD) | -1.07 (0.58) | -1.23 (0.63) |
| | Median | -1.00 | -1.00 |
| | P value | <0.01 | <0.01 |
| **Did you experience any irritation reactions such as redness, dryness, itchiness, burning sensation, etc of the scalp?** | %CFB Mean (SD) | 0.13 (0.51) | 0.00 (0.00) |
| | Median | 0.00 | 0.00 |
| | P value | 0.3458 | - |
| **Do you feel that your hair becomes shiny?** | %CFB Mean (SD) | 1.20 (0.61) | 2.03 (0.81) |
| | Median | 1.00 | 2.00 |
| | P value | <0.01 | <0.01 |
| **Do you feel that your hair became soft and silky?** | %CFB Mean (SD) | 1.53 (0.94) | 2.43 (1.04) |
| | Median | 2.00 | 2.00 |
| | P value | <0.01 | <0.01 |

## DISCUSSION

The study provided insights on the efficacy and safety of the test ayurvedic hair oil in the reduction of hair fall and improvement of the general appearance of hair and scalp in healthy human subjects suffering from hair loss. There are very few studies that have been conducted on the effectiveness of such ayurvedic preparations. There are other hair treatments available like topical Minoxidil solution.[17] But studies have shown it to cause skin irritation at the application site, scalp itchiness, slight burning sensation, and even skin rashes for people with sensitive skin.[18] Similarly, the use of other available dandruff treatments like topical Ketoconazole solution has reported side effects like itchy scalp, that may worsen the scalp's sensitivity and may lead to hair loss.[19,20] Thus, alternative treatments with little/no side effects are required. Ayurveda shows promise in treating hair problems without causing side-effects. Studies on hair growth-promoting activities of phytochemicals have proved effective in managing hair loss.[21] The use of such naturally derived ingredients eliminates the side-effects, while providing the required therapeutic benefit. Likewise, it was observed that our test treatment–an ayurvedic hair oil, proved to work well in the management of hair fall. It also significantly reduced the scalp dandruff as determined by the ASFS scoring. The treatment also proved effective in improving the hair smoothness and shine. Further, on top of treating hair loss, also demonstrated improvement in the hair growth rate, hair thickness and hair density significantly. The A:T ratio is a crucial parameter that is used to determine the proportion of active hair follicles and is an essential diagnostic tool for hair loss.[22] A higher anagen:telogen ratio indicates a higher number of active hair follicles, which is desirable for hair growth treatment.[23] The test product in the study demonstrated significant improvement in the anagen:telogen ratio of hairs. The novelty of the test product is that the ayurvedic preparation is infused with a blend of natural oils. The test product contains Coconut Oil, Almond Oil, Jojoba Oil, Rosemary Oil, Argan Oil, Wheatgerm Oil, Hibiscus Oil, Tea tree Oil, and Sesame Oil, each of which has been proven to treat hair problems.[24] The mixture of all these ingredients works as an effective hair loss treatment in population with hair loss complain. The absence of product related adverse events makes it a safe and well tolerable product for its utilization in targeted population.

### *Limitations*

There are certain limitations to our study. The study has been conducted on small number of subjects. Study involving larger number of subjects is required further establish the efficacy and safety for larger groups. Moreover, the study lacks comparative nature with placebo or similar substances.

## CONCLUSION

Regular use of the test treatment is well-tolerated and effective in reducing hair fall, normalizing hair growth rate, and improving scalp health after 8 weeks. No adverse effects on skin or scalp were observed. The study suggests that continuous use of the 'moha: 5-in-1' hair oil throughout the hair life cycle aids in reducing hair fall, alleviating dandruff, and enhancing the hair growth phase. Overall, the treatment is considered natural, well-accepted, safe, and effective for all study participants, establishing it as suitable choice for holistic daily hair care.

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