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Original Research Article

A single arm, exploratory and pilot study to evaluate the efficacy of a multi-component water-based herbal supplement in hair growth, density, follicle strength and hair fall in healthy male and female subjects

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ABSTRACT

Background: Most available therapeutics to address alopecia are based on singular targets and mechanism of action based on the assumption of sub-classification to reflect morphological or etiological sub-classes such as hereditary vs acquired factors, anti-inflammatory vs. non-inflammatory factors or scarring vs. non-scarring factors.
Aims and Objective: Impact of oral consumption of Diabliss Hair Water, a multi-component herbal water supplement (HWS) on hair fall reduction, hair growth, hair density, hair thickness was investigated in a single arm, exploratory, pilot open label clinical study among healthy male and female subjects of age group between 35-50 years, with hair fall and hair thinning concerns.
Materials and Methods: The study was conducted under dermatological control and included hair fall by comb test, hair pull test, hair thinning measurement using photo numerical scale (modified Norwood and Ludwig scale) and assessment for hair quality along with the phototrichogram assessment using Trichoscan® with Cutiscope.
Results: The Diabliss HWS was efficacious in improving hair growth rate and density as per TrichoScan® assessment, improvement in hair thickness as per Caslite-Nova software. The Diabliss HWS was also efficacious in improving the hair tensile strength (break force by Chatillon Force gauge), reducing hair fall and improving the hair quality. By the end of the study the Diabliss HWS was found to show an improvement in the entire study population in all of the assessments parameters. Dermatologist assessment parameters of hair texture and hair shine also showed improvements in the entire study population.
Conclusion: The Diabliss HWS was found to be efficacious in providing hair fall control and hair growth benefits as per the dermatological and instrumental evaluations using TrichoScan®.
The product was well tolerated with no product related AE or SAE with regular consumption for 06 months.

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1. Introduction

Hair loss is a common problem worldwide, affecting around 50% of all males worldwide and a quarter of females. Hair loss may be interpreted as an abnormality and a failure to conform to societal standards of physical appearance, which has the potential to distinguish individuals in their own and others' estimations. Psychological and social stress on women is "immense" compared to men, which can contribute to hair loss among young women.

Various literatures have documented that hair loss or hair fall is one of the major concerns in men and women of all ages. This problem may start early and may increase significantly with age.[1–5]

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Most available therapeutics to address alopecia are based on singular targets and mechanism of action based on the assumption of sub-classification to reflect morphological or etiological sub-classes such as hereditary vs acquired factors, anti-inflammatory vs. non-inflammatory factors or scarring vs. non-scarring factors. Accordingly, most therapeutic interventions are based on antiandrogen medications also known as androgen antagonists or testosterone blockers (Finasteride, Dutasteride) and vasodilator minoxidil stimulatory effect on hair growth hypothesized to be from the opening of potassium channels by minoxidil sulphate.[6]

Unfortunately, the hair follicle life cycle is a complex process involving four main phases of anagen (growth), catagen (regression), telogen (rest), and exogen (shedding). Each of these phases is impacted by anatomical location, nutritional and hormonal status, age, and environmental factors such as stress.[7] These processes therefore represent a complex, multi-factorial mechanisms where multiple perturbations impact the hair follicle life cycle.

In order to address the complexities associated with hair fall and hair thinning, a novel nutraceutical-based supplement made from 15 different herbs and spices was used.. The feature of the nutraceutical process is a novel water-based extraction of active ingredients to form aqueous moieties that address these complex processes. These extracts are known to provide anti-inflammatory, antioxidant, Dermal Papilla (DP) cells stimulation, follicle strengthening amino acids, and dihydrotestosterone (DHT)-inhibiting properties. In this clinical study the test product was evaluated using Trichoscan® and Dermatological assessments to assess the efficacy of the Diabliss HWS in providing hair fall control along with hair growth benefits as adjuvant therapy.

2. Aims and Objectives

To assess the impact of oral consumption of Diabliss Hair Water, a multi-component herbal water supplement (HWS) on hair fall reduction, hair growth, hair density, hair thickness

3. Materials and Methods

The study was designed as a pilot, exploratory, investigator driven single group clinical trial. Prior clearance from an independent ethics committee followed by written informed consent was taken from each study participants before any study related activities. A total of 40 male and female subjects (in 1:3 ratio) between the ages of 35-50 years, who satisfied the inclusion and exclusion criteria were enrolled in the study with 36 subjects completing the study. Based on the primary end-points and overall treatment duration a sample size of more than 33 subjects was sufficient to achieve statistical significance with 80% power and 5% level of significance. The sample size was calculated considering the Trichoscan® hair density data generated in previously conducted hair growth studies. The trial was registered on the clinical trial registry of India (CTRI) website at http://ctri.nic.in/ (CTRI number: CTRI/2020/03/023682).

The study was conducted for a period of 6 months for each subject and included a total of 9 visits. On the first visit, the subjects were screened on the study inclusion-exclusion criteria and blood samples were collected to check CBC and thyroid condition. Each assessment cycle encompassed two visits, 2 days apart as per the TrichoScan® SOP. On the first day of an assessment cycle, a small area of about 1.5cm in diameter was shaved and tattooed in the center. The assessments were performed in the same area at +2 days with TrichoScan®. The final eligibility was confirmed with density evaluation two days after shaving, i.e., on day 3. The selected subjects were provided with the Diabliss HWS along with a neutral shampoo for use. Along with daily consumption of the HWS, subjects were also advised to continue their normal nutrition and lifestyle.

Follow up evaluations were performed on day 60 & 62 (Week 8), day 120 &122 (Week 16), day 178 & 180 (Week 24). On the first visit of every assessment cycle, dermatological assessment, digital imaging was performed along with subject self-assessment questionnaire.

Subjects were asked to report any discomfort or adverse event, after starting the treatment on every follow-up visit. Subjects were assessed for overall change in health and fitness levels. Subjects were assessed for other health parameters including appetite, bowel movements, digestion, fatigue, stress level etc.

3.1. Assessment Details

Clinical evaluations were conducted with various established instruments along with clinical dermatological assessments for hair improvement:

1. Comb test
2. Hair pull test by a dermatologist
3. Hair thinning measurement on a photo numerical scale by a dermatologist
4. TrichoScan® assessments including Hair Growth Rate, Hair density, A:T ratio etc under phototrichogram assessment using Cutiscope on TrichoScan® software
5. Hair tensile strength using Chatillon Motorized Force Tester
6. Hair thickness by Denolite camera using Caslite Software

3.2. Test product

The HWS was prepared by Diabliss Consumer Products from a combination of water-based extracts of the following ingredients with known hair care benefits:

Sweet Potato (Ipomoea batatas),[8–10] Snake Gourd (Trichosanthes Anguina L),[4,11–13] False Daisy (Eclipta prostrata),[14–16] Curry Leaves (Murraya koenigii),[17–19] Indian Gooseberry (Phyllanthus emblica),[20–22] Almond (Prunus dulcis),[23,24] Walnut (Juglans regia),[24] Groundnut (Arachis hypogaea),[25] Flaxseed (Linum usitatissimum),[26–28] Chia Seed (Salvia hispanica),[29,30] Lemon (Citrus x limon),[31–33] Chickpea (Cicer arietinum),[34] Cinnamon (Cinnamomum Zeylanicum Blume),[35,36] Guava (Psidium guajava),[37–39] Cumin (Cumin cyminum),[40,41] Spinach (Spinacia oleracea).[42]

3.3. Daily intake

15ml of Diabliss HWS was mixed in 500 ml of drinking water. 150 ml each was consumed at breakfast, lunch and dinner and balance 50 ml at bed time. Further, all other hair care regimens remained unchanged as per individual's regular habit.

3.4. Statistical methodology

Statistical software R version 3.1.2 was used to analyse the data. Shapiro-Wilk Test was performed to check the normality of data. Paired t-test/Wilcoxon signed rank test for paired samples was performed for mean value comparison. P value <0.05 was considered to be significant

4. Results

Table 1 summarizes average values of various parameters investigated during the clinical trial. The data clearly demonstrates significant improvement in hair density, hair growth rate, hair thickness, hair tensile strength, hair loss reduction as measured by number of hairs from Comb test with bulb and comb test without bulb, hair pull, hair shine, hair texture and hair thinning characteristics.

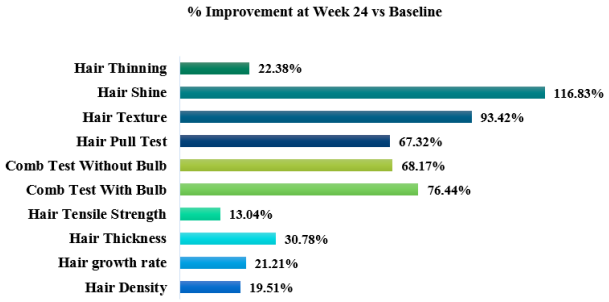

Fig. 1: Average percent changes of parameters

As per Dermatological assessment (Figure 1), a statistically significant improvement in hair texture and hair shine in comparison to baseline was observed as early as 8 weeks and was noted to be progressive till the end of the study. A significant improvement in hair thinning (using a 10-point photo numerical linear in-house scale) in comparison to baseline was also observed as early as 8 weeks and progressive till the end of the study.

Significant improvement in hair growth rate, hair density in comparison to baseline was observed as early as 8 weeks and was noted to be progressive till the end of the study.

Significant improvement in hair thickness was noted in comparison to the baseline as early as 8 weeks and was noted to be progressive till the end of the study.

Significant improvement in hair strength by tensile test in comparison to the baseline, was observed as early as 8 weeks and was noted to be progressive till the end of the study.

Significant Hair fall reduction by hair pull and hair comb test in comparison to the baseline was observed as early as 8 weeks and was noted to be progressive till the end of the study.

Review of the individual values for the clinical trial participants for these parameters are summarised in Figures 2, 3, 4 and 5. Hair Density, Hair Growth Rate, Hair Tensile Strength and Hair Fall with Bulb are plotted in Figures 2, 3, 4 and 5 respectively and confirm that all subjects showed a positive response to the Diabliss HWS intervention.

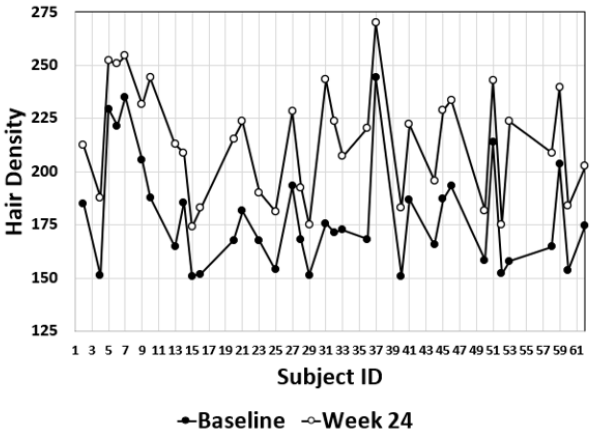

Fig. 2: Hair Density showing improvement in 100% of subjects.

4.1. Male & Female Subjects Hair Coverage

Male and female subject's hair coverage was photographed during each visit. Fig 6 and 7 shows representative female and male subjects hair coverage at the start and end of the trail showing visible improvement in the hair coverage.

4.2. Feedback Questionnaire Summary

As summarized in Table 2, 100% of the study population agreed that with continuous intake of the Diabliss HWS, there was an improvement in Hair length, Hair Density, Hair Volume, Hair thickness and a reduction in Hair Fall. The test

Table 1: Clinical Data Summary – Average Values

Parameter		Baseline	Week 8	Week 16	Week 24
Hair Density (number of hair/cm^2)	Mean	178.98	188.7	201.34	213.9
	SD	25.55	26.63	26.18	26.26
	CFB	-	9.72**	22.36**	34.92**
Hair growth rate (μm/ day)	Mean	273.7	287.36	311.53	331.76
	SD	36.44	37.19	30.43	30.49
	CFB	-	13.66**	37.82**	58.06**
Hair Thickness (μm)	Mean	40.54	46.31	49.59	53.02
	SD	4.61	4.54	3.96	4.19
	CFB	-	5.77**	9.05**	12.48**
Hair Tensile Strength (N)	Mean	0.69	0.72	0.76	0.78
	SD	0.04	0.03	0.03	0.03
	CFB	-	0.03	0.07	0.1
Comb Test With Bulb (count)	Mean	31.54	20.35	10.86	7.43
	SD	13.47	10.58	5.13	3.85
	CFB	-	11.19**	20.68**	24.11**
Comb Test Without Bulb (count)	Mean	16.46	12.73	7.62	5.24
	SD	8.27	6.65	4.45	3.08
	CFB	-	3.73**	8.84**	11.22**
Hair Pull Test (score, where lower value is a sign of improvement)	Mean	2.57	2.24	1.66	0.84
	SD	0.43	0.37	0.39	0.43
	CFB		0.32**	0.91**	1.73**
Hair Texture (score, where higher value is a sign of improvement)	Mean	2.43	3.00	4.19	4.70
	SD	0.50	0.00	0.40	0.46
	CFB	-	0.57	1.76	2.27
Hair Shine (score, where higher value is a sign of improvement)	Mean	2.08	3.00	4.14	4.51
	SD	0.28	0.00	0.35	0.51
	CFB	-	0.92	2.05	2.43
Hair Thinning, (On MSCR photonumerical scale, modified linear scale based on Norwood/Ludwig scale)	Mean	3.62	3.42	3.07	2.81
	SD	1.01	1.02	1.04	0.97
	CFB	-	0.2	0.55	0.81

CFB= Change from Baseline, **= significant value

Table 2: Feedback Questionnaire Summary

N=37	Options	Week 8	Week 16	Week 24
Do you feel that your hair length has improved since you have started using the product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Do you feel that your hair density has improved since you have started using the test product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Do you feel that you have more voluminous hair since you have started using the product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Do you feel that there is an improvement in the hair thickness since you have started using the product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Do you feel that your hair fall has reduced since you have started using the test product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Do you feel that your hair is healthier since the time you have used the product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Do you feel that your hair is softer since the time you have used the product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Do you feel that your hair shine has improved since the time you have used the product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Do you feel that you have bouncy hair since the time you have used the product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%
Are you satisfied with the product?	Agree	100% **	100% **	100% **
	Disagree	0%	0%	0%

**significant

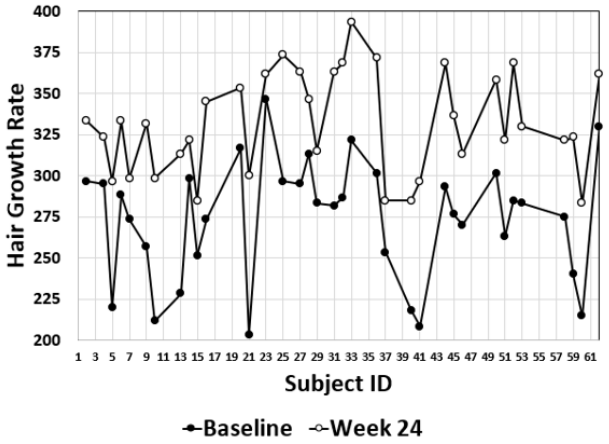

Fig. 3: Hair growth rate showing improvement in 100% of subjects

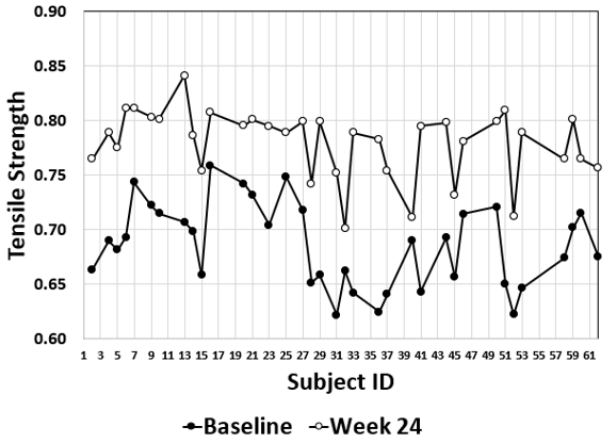

Fig. 4: Hair tensile strength showing improvement in 100% of subjects.

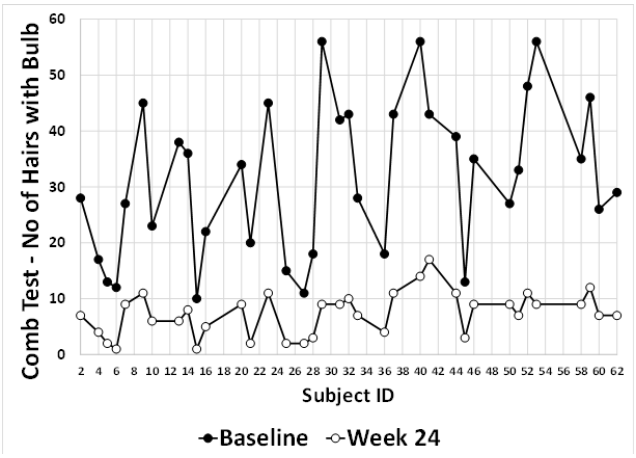

Fig. 5: Hair fall with bulb showing improvement in 100% of subjects.

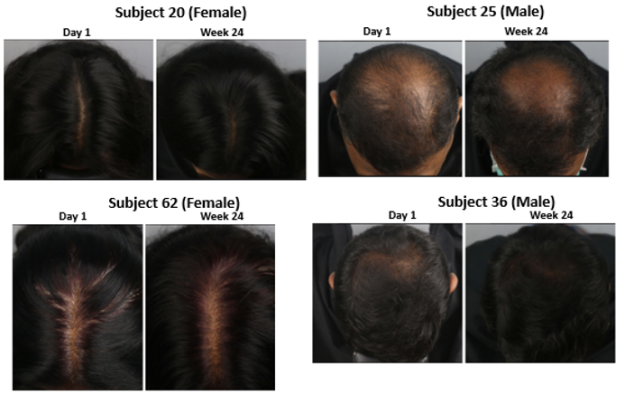

Fig. 6: Representative photographs of Female and Male subjects showing improved coverage.

Fig. 7: Representative hair density changes during the course of the clinical trial

product had no side effects on the general well-being of the study population.

There was no product related AE/SAE or local intolerance of clinical significance.

5. Conclusions

There are various literature documenting the efficacy of various ingredients in the present formulation from Ayurveda to current medicine, as an individual ingredient as well as when used in combination. Nutraceutical products and supplements containing herbal ingredients are present in various forms. Herbal ingredients are also present in topical forms, however this product is prepared with a novel technique to provide the supplements in higher concentrations with an ease of its consumption. The study was planned to explore the benefits of the Diabliss HWS as a nutraceutical herbal adjuvant supplement for hair fall, hair growth and overall hair quality.

The product was found to be efficacious in providing hair fall control and hair growth benefits. The test product has improved organoleptics, making it easy to consume with no intolerance and AE reported in the study.

Regular consumption of HW water was found to be efficacious in various parameters as summarised below:

1. Increase in hair growth rate and density as per TrichoScan® assessment.
2. Increase in hair thickness as per Caslite software.
3. Increased hair tensile strength.
4. Reduction in hair fall.
5. Improvement in hair texture and hair shine.

Improvement was noted in the entire population in all the measured assessments, i.e., hair growth, hair density, hair thickness, hair tensile strength and hair fall reductions. Dermatologist assessment parameters of hair texture and hair shine also showed improvement in 100% of the subjects when compared to the baseline. There was no product related AE/SAE or local intolerance of clinical significance. This initial pilot exploratory study demonstrate that the Diabliss HWS shows a significant impact on hair fall reduction, hair quality and growth attributes. Further, placebo and regimen controlled clinical studies are recommended to evaluate long term safety and efficacy of the HWS.

6. Source of Funding

No external funding was received to carry out this work.

7. Conflict of Interest

None.

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