



EVALUATION OF CLINICAL EFFICACY OF AN AYURVEDIC HAIR VITALIZER (REGEN)

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ABSTRACT

Hair vitalizers or other topical hair and scalp preparations are widely used for prevention and treatment of hair fall. There are several preparations available for fair fall, weak limp and damaged hair and receding hairline. The selection of any Hair vitalizer depends on its ability of stimulating and nourishing the hair follicles for hair growth, minimal risk of irritation and allergenicity. REGEN HAIR VITALIZER is nature's way to achieve healthy strong and luxuriant hair growth. To investigate the efficacy of Regen Hair Vitalizer in the treatment of hair fall, premature hair greying and promoting hair growth. A non-randomized, open-label, non-comparative, prospective clinical study to investigate the efficacy of REGEN HAIR VITALIZER in the treatment of hair fall, premature greying and promoting hair growth. Subjects were evaluated at screening/enrolment, and at the end of treatment. Patients was treated with local application of Regen Hair Vitalizer on the scalp every day for a period of 90 days. Regen Hair Vitalizer has been found to be a safe and effective water based hair vitalizing lotion and excellent for arresting hair fall and promoting hair growth by stimulating hair follicles. It also prevents further premature hair greying.

Key Words: Regen hair vitalizer, hair fall, hair greying, Amla, Bhringaraj, Tulsi.

INTRODUCTION

The selection of any Hair vitalizer depends on its ability of stimulating and nourishing the hair follicles for hair growth, minimal risk of irritation and allergenicity [1]. Bhringaraj or *Eclipta alba* is considered to be the best ayurvedic remedy for hair loss, premature greying and is also make hair dark, dense and lustrous [2]. The herb has also been used in Traditional Ayurveda as a rejuvenative tonic for the liver, for various skin conditions and as a tonic for the mind. Amla is one a natural and fast hair growing herb. It's a known fact that massaging the scalp increases blood circulation but massaging the hair scalp with amla has many added benefits. Not only does it help in blood circulation [3], amla is known to remove the unwanted flakes off the scalp [4]. It also helps in opening

of the pores thereby giving room to the scalp to produce nutrition. This encourages hair regrowth. One of the prime reasons for hair breakage is the deficiency of vitamin C and one of the easiest ways to replenish vitamin C back into the system is by amla for it is highly rich in Vitamin C [5]. Along with vitamin C, amla is also very rich in antioxidants. Antioxidants carry out anti-ageing mechanisms which can prevent hair from premature greying. Applying amla in any form on the tips of hair condition hair to a great extent there by preventing split ends. Basil leaves are equally beneficial for a host of hair problems which can occur due to itchiness and sweatiness of scalp [6]. It will keep your scalp cool, reduce itchiness and promote hair growth by improving circulation in your scalp. Basil prevents greying of hair as well as hair fall as they are effective in strengthening the hair shaft. Basil leaves help in rejuvenating and producing healthy hair by stimulating the hair follicles. Basil leaves have antioxidant properties [7]. They contain the flavonoids, orientin and vicenin that protect the chromosomes and cell structures

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from oxidation, thus preventing cell ageing and death and providing protection against radiation damage [8]. Some of the other Pandanaceae species have been discovered for treating certain illness, whether from the leaves, fruits or roots part. An example is the constituent of *P. odoratus* root, which is 4-hydroxybenzoic acid, showed a hypoglycaemic effect [9]. Some researchers also discovered that a component from Pandanaceae leaves such as Pandanin exhibited hemagglutinating activity and showed antiviral activities against human viruses, herpes simplex virus type-1 (HSV-1) and influenza virus (H1N1) [10]. Basically, there is a very few research that has been performed on Pandanus plants. There are still a lot more things to be discovered about Pandanus. For example, there is a study that has found alkaloids in Pandanaceae root. It is established that freshly picked Pandanus and blended in a certain ratio with roots of shedari, stops hair fall and generates growth of new hair [11]. REGEN HAIR VITALIZER is an effective, well established and widely used 100% Natural hair vitalizer. It has been developed after years of research, testing and study. It's a unique blend of rare and essential herbs from the Himalayan Mountain. REGEN HAIR VITALIZER is nature's way to achieve healthy strong and luxuriant hair growth. A clinical study is planned with REGEN HAIR VITALIZER to investigate the efficacy of Regen hair Vitalizer in the treatment of hair fall and promoting hair growth.

MATERIALS AND METHOD

Study Objectives

To investigate the efficacy of Regen hair vitalizer in the treatment of hair fall, premature hair greying and promoting hair growth.

Selection of Study Population

Inclusion Criteria: To be eligible for study entry patients had to satisfy all of the following criteria: [12]

1. Male or female outpatients aged 10 to 80 years
 2. Patients with hair loss.
 3. Patients with weak limp and damaged hair and receding hairline.
 4. Patients ready to give written informed consent.
- Exclusion Criteria:** Patients were excluded from the study if one or more of the following criteria were applicable:
1. Patients with cuts, wounds or any type of chronic skin disease (Eczema, Psoriasis, Seborrheic dermatitis) of scalp.
 2. Patient with known allergy to Bhringaraj (*Eclipta alba*), Amla (*Emblia officinalis*), Tulsi (*Ocimum sanctum*) and Kewra (*Pandanus odoratissimus*).
 3. Patient receiving corticosteroids or any other immunosuppressive treatment.
 4. Pregnant and lactating females.

Investigational Products: Regen Hair Vitalizer

Investigational Products Administered

The investigational product is REGEN HAIR Vitalizers be applied on the scalp daily for a period of at

least 90 days. To be rubbed gently with finger tips for 2-3 minutes. The scalp should be cleaned and patted dry before application of the REGEN HAIR VITALIZER. Person applying this should wash his hand before and after the use. As it is a single arm study, all the patients were assigned the same treatment without any randomization.

Selection of Doses in the Study

Dose selection was not the case in this study.

Selection and Timing of Dose for Each Patient

REGEN HAIR VITALIZER to be applied on the scalp daily for a period of at least 90 days. No specific timings were followed and required.

Blinding: The treatment was administered without any randomization. So, blinding was not performed and maintaining was not required [13].

Prior and Concomitant Therapy: Medications other than the study drugs which would be considered necessary for the patient's welfare and which would not interfere with the study medication or efficacy evaluation may be allowed at the discretion of the investigator, and an appropriate record would be maintained in the CRF [14].

Efficacy, and Safety Variables

Efficacy assessment

Hair fall was evaluated at the end of therapy with topical lotion with the help of Comb & Paper Test. Also the signs and symptoms of Hair growth were recorded through VAS score.

Assigning Patients to Treatment Groups

Drug name/Product	Test
Product	Regen Hair Vitalizer
Dosage form	Lotion
Route of administration	Topical
Frequency	Once daily
Batch number(s)	Batch No: V04
Manufacturer	Raylon Industries

Primary Efficacy End Points

Incidence of hair falls at the end of treatment.

Secondary Efficacy End Points

Improvement in signs and symptoms of Hair Growth and premature greying [15].

Drug Concentration Measurements

Not applicable

Data Quality Assurance

The Sponsor implemented and maintained quality assurance and quality control systems with written Standard Operating Procedures (SOPs) in accordance with the Guidelines of Good Clinical Practice of CDSCO.

Prior to the start of the study, the principal investigator will be contacted and informed of any impending visits and the frequency of such visits. The investigator will allow and assist the Sponsor's study monitor to review study progress, allow source data verification (checking of CRFs against original source documents) for accuracy of data recording, review of study drug logs and facilities, collect completed documents. Any deficiency found will be reported, and signed by the principal investigator and Sponsor Monitor. Also action taken for the last visits decision will be signed. Site monitoring visit log will be updated after every monitoring visit. Changes in planned analysis: No changes in the conduct of the study or planned analysis were instituted after the start of the study [16].

RESULTS

Disposition of Patients

A total of 30 patients were screened at 1 centre in

Kolkata, India. A total of 30 patients were assigned and all of them received study medication and completed the study. The patients were recruited from Namita Medical Hall, Amarapuri, Sodepur, Kolkata - 700 111, West Bengal, India for this study.

Demographic and Other Baseline Characteristics

Demographic data are summarised for all the patients in following table.

Vital Signs

Vital signs of subject during different visit are summarised in the following table

Medical History and Examinations

The following tables details about the medical history of subject.

Table 1. Demographic and Other Baseline Characteristics

Subject Identification Number	Subject Initials	ICF Signed by Subject	Gender	Age years	Weight Kg	Height cm
1	A-B	20-July—14	Female	31	55.00	160
2	A-S	20-July—14	Female	35	60.00	164
3	A-J	20-July—14	Male	49	72.00	170
4	B-B	20-July—14	Male	64	74.00	172
5	B-C	20-July—14	Male	75	70.00	168
6	C-B	20-July—14	Male	31	64.00	170
7	C-S	20-July—14	Male	68	75.00	174
8	D-S	21-July—14	Female	19	40.00	150
9	D-B	21-July—14	Female	13	35.00	138
10	D-P	21-July—14	Female	35	50.00	160
11	R-B	21-July—14	Male	14	15.00	60
12	J-B	21-July—14	Female	24	45.00	150
13	M-B	21-July—14	Female	51	70.00	172
14	N-B	22-July—14	Female	38	65.00	165
15	K-M	23-July—14	Female	33	55.00	156
16	G-P	23-July—14	Male	42	78.00	180
17	H-S	23-July—14	Male	72	81.00	172
18	RKM	24-July—14	Male	34	41.50	161
19	J-C	24-July—14	Male	18	32.60	158
20	T-B	25-July—14	Male	39	70.00	170
21	S-N	25-July—14	Female	23	42.50	164
22	RNB	25-July—14	Male	74	69.00	162
23	L-M	25-July—14	Female	25	49.00	162
24	S-R	26-July—14	Female	34	49.00	162
25	A-R	26-July—14	Male	53	72.00	170
26	A-D	26-July—14	Female	41	60.00	167.2
27	A-S	26-July—14	Male	44	69.50	170
28	A-D	26-July—14	Female	19	47.50	157.3
29	S-C	26-July—14	Female	51	69.50	167.2
30	R-J	26-July—14	Female	20	49.50	159.5
Mean				37.83	58.51	162.1
SD				198.595	15.789	20.756

Table 2. Vital signs of subject during different visit

Visit 1 Date		Visit -1 Vital Signs				Visit 2 Date		Visit-2 Vital Signs			
Sl	Date of visit	PR	BP	RR	Temp	Date of visit	PR	BP	RR	Temp	
1	20-July—14	80	124/80	14	98	20-July—14	80	120/84	16	99	
2	20-July—14	76	122/82	14	99	20-July—14	74	124/80	14	99	
3	20-July—14	76	136/86	14	99	20-July—14	72	130/84	14	99	
4	20-July—14	84	150/100	16	99	20-July—14	76	146/100	14	99	
5	20-July—14	80	154/100	14	99	20-July—14	78	154/100	14	99	
6	20-July—14	74	120/80	16	99	20-July—14	74	120/80	16	99	
7	20-July—14	80	140/90	16	99	20-July—14	80	140/90	14	99	
8	21-July—14	74	120/80	14	99	21-July—14	80	120/80	16	99	
9	21-July—14	74	120/80	14	99	21-July—14	80	120/80	14	99	
10	21-July—14	74	120/80	14	99	21-July—14	80	120/80	16	99	
11	21-July—14	90	124/80	18	99	21-July—14	90	120/80	14	99	
12	21-July—14	74	120/80	14	99	21-July—14	80	120/80	20	99	
13	21-July—14	76	120/80	16	99	21-July—14	80	120/80	14	99	
14	22-July—14	74	120/80	14	99	22-July—14	80	120/80	16	99	
15	23-July—14	76	120/80	14	99	23-July—14	80	120/80	14	99	
16	23-July—14	74	120/80	14	99	23-July—14	80	120/80	14	99	
17	23-July—14	80	120/80	14	99	23-July—14	80	120/80	14	99	
18	24-July—14	81	110/85	15	98.6	24-July—14	78	110/80	14	98.6	
19	24-July—14	79	100/80	17	98.3	24-July—14	72	100/80	14	98.7	
20	25-July—14	76	120/80	15	98.9	25-July—14	78	120/80	17	98.1	
21	25-July—14	79	105/75	18	98.5	25-July—14	82	100/79	17	98.5	
22	25-July—14	80	120/85	18	98.7	25-July—14	82	120/79	18	98.2	
23	25-July—14	80	110/80	17	98.9	25-July—14	78	110/78	17	98.7	
24	26-July—14	79	110/75	17	98.3	26-July—14	79	100/79	19	98.5	
25	26-July—14	79	120/80	15	98.2	26-July—14	73	115/80	19	98.9	
26	26-July—14	77	110/78	17	98.3	26-July—14	80	115/70	14	98.2	
27	26-July—14	82	120/86	14	98.3	26-July—14	83	115/85	20	98.7	
28	26-July—14	81	100/75	14	98.2	26-July—14	82	100/78	17	98.9	
29	26-July—14	77	120/80	17	98.8	26-July—14	78	120/80	19	98.3	
30	26-July—14	81	110/75	20	98.3	26-July—14	79	105/75	18	98.3	
	Mean	78.33		15.80	98.74		78.93		16.0	98.79	
	SD	3.77		1.86	0.34		3.59		2.07	0.30	

PR= pulse rate, BP= blood pressure, RR=respiratory rate

Table 3. Medical History and Examinations

Subject no.	Subject initial	Physical examination	Medical histories	Allergies	Recent Hospitalization	Medical histories	Surgical histories
1	A-B	None	None	None	None	None	None
2	A-S	None	None	None	None	None	None
3	A-J	None	None	None	None	None	None
4	B-B	None	None	None	None	None	None
5	B-C	None	None	Yes 2008 (Asthma)	None	None	None
6	C-B	None	None	None	None	None	None
7	C-S	None	None	None	None	None	None
8	D-S	None	None	None	None	None	None
9	D-B	None	None	None	None	None	None
10	D-P	None	None	None	None	None	None
11	R-B	None	None	None	None	None	None
12	J-B	None	None	None	None	None	None
13	M-B	None	None	None	None	None	None

14	N-B	None	None	None	None	None	None
15	K-M	None	None	None	None	None	None
16	G-P	None	None	None	None	None	None
17	H-S	None	None	None	None	None	None
18	RKM	None	None	None	None	None	None
19	J-C	None	None	None	None	None	None
20	T-B	None	None	None	None	None	None
21	S-N	None	None	None	None	None	None
22	RNB	None	None	None	None	None	None
23	L-M	None	None	None	None	None	None
24	S-R	None	None	None	None	None	None
25	A-R	None	None	None	None	None	None
26	A-D	None	None	None	None	None	None
27	A-S	None	None	None	None	None	None
28	A-D	None	None	None	None	None	None
29	S-C	None	None	None	None	None	None
30	R-J	None	None	None	None	None	None

Baseline Characteristics (Visit 1)**Table 4. Baseline Characteristics (Visit 1)**

SL.	Subject Initial	Hair fall / Premature Greying	Number of Strands	Hair Colour
1	A-B	Hair Fall	18	Black
2	A-S	Hair Fall	17	Black
3	A-J	Hair Fall	11	Black
4	B-B	Hair Fall	13	Black
5	B-C	Hair Fall	24	Black
6	C-B	Hair Fall & Hair greying	29	Grey
7	C-S	Hair Fall & Hair greying	26	Grey
8	D-S	Hair Fall & Hair greying	16	Grey
9	D-B	Hair Fall & Hair greying	21	Grey
10	D-P	Hair Fall & Hair greying	17	Grey
11	R-B	Hair Fall	14	Black
12	J-B	Hair Fall & Hair greying	22	Grey
13	M-B	Hair Fall & Hair greying	27	Grey
14	N-B	Hair Fall	09	Black
15	K-M	Hair Fall	13	Black
16	G-P	Hair greying	00	Grey
17	H-S	Hair greying	00	Grey
18	RKM	Hair Fall	04	Black
19	J-C	Hair greying	07	Grey
20	T-B	Hair Fall	32	Black
21	S-N	Hair Fall & Hair greying	13	Grey
22	RNB	Hair Fall	27	Black
23	L-M	Hair Fall & Hair greying	11	Grey
24	S-R	Hair Fall	17	Black
25	A-R	Hair Fall & Hair greying	24	Grey
26	A-D	Hair Fall	21	Black
27	A-S	Hair Fall & Hair greying	23	Grey
28	A-D	Hair Fall	11	Black
29	S-C	Hair Fall & Hair greying	16	Grey
30	R-J	Hair Fall	19	Black
Hair Fall Mean = 502/30=16.7333				

Table 5. End Characteristics (Visit 2)

Sl.	Subject Initial	Hair fall /Premature Greying	Number of Strands	Hair Colour
1	A-B	Hair Fall	04	Black
2	A-S	Hair Fall	09	Black
3	A-J	Hair Fall	07	Black
4	B-B	Hair Fall	05	Black
5	B-C	Hair Fall	03	Black
6	C-B	Hair Fall & Hair greying	00	Black
7	C-S	Hair Fall & Hair greying	02	Black
8	D-S	Hair Fall & Hair greying	01	Black
9	D-B	Hair Fall & Hair greying	02	Black
10	D-P	Hair Fall & Hair greying	07	Grey
11	R-B	Hair Fall	04	Black
12	J-B	Hair Fall & Hair greying	02	Grey
13	M-B	Hair Fall & Hair greying	07	Grey
14	N-B	Hair Fall	01	Black
15	K-M	Hair Fall	04	Black
16	G-P	Hair greying	00	Black
17	H-S	Hair greying	00	Black
18	RKM	Hair Fall	00	Black
19	J-C	Hair greying	01	Black
20	A-S	Hair Fall	11	Black
21	S-N	Hair Fall & Hair greying	03	Grey
22	RNB	Hair Fall	07	Black
23	L-M	Hair Fall & Hair greying	01	Grey
24	S-R	Hair Fall	06	Black
25	A-R	Hair Fall & Hair greying	09	Black
26	A-D	Hair Fall	07	Black
27	A-S	Hair Fall & Hair greying	05	Black
28	A-D	Hair Fall	00	Black
29	S-C	Hair Fall & Hair greying	00	Grey
30	R-J	Hair Fall	07	Black
Hair Fall Mean = 115/30 = 3.8333				

Table 6. Hair Growth Analysis by Visual assessment of Hair density (VAS)

Subject no	Hair growth(Visit 1)	Hair growth(Visit 2)
1	0	4
2	0	4
3	0	5
4	0	4
5	0	4
6	0	5
7	0	5
8	0	5
9	0	4
10	0	5
11	0	4
12	0	5
13	0	5
14	0	5
15	0	5
16	0	5
17	0	3

18	0	3
19	0	5
20	0	4
21	0	5
22	0	5
23	0	4
24	0	5
25	0	5
26	0	6
27	0	2
28	0	4
29	0	5
30	0	4
Mean	0.00	4.33
SD	0.000	0.819

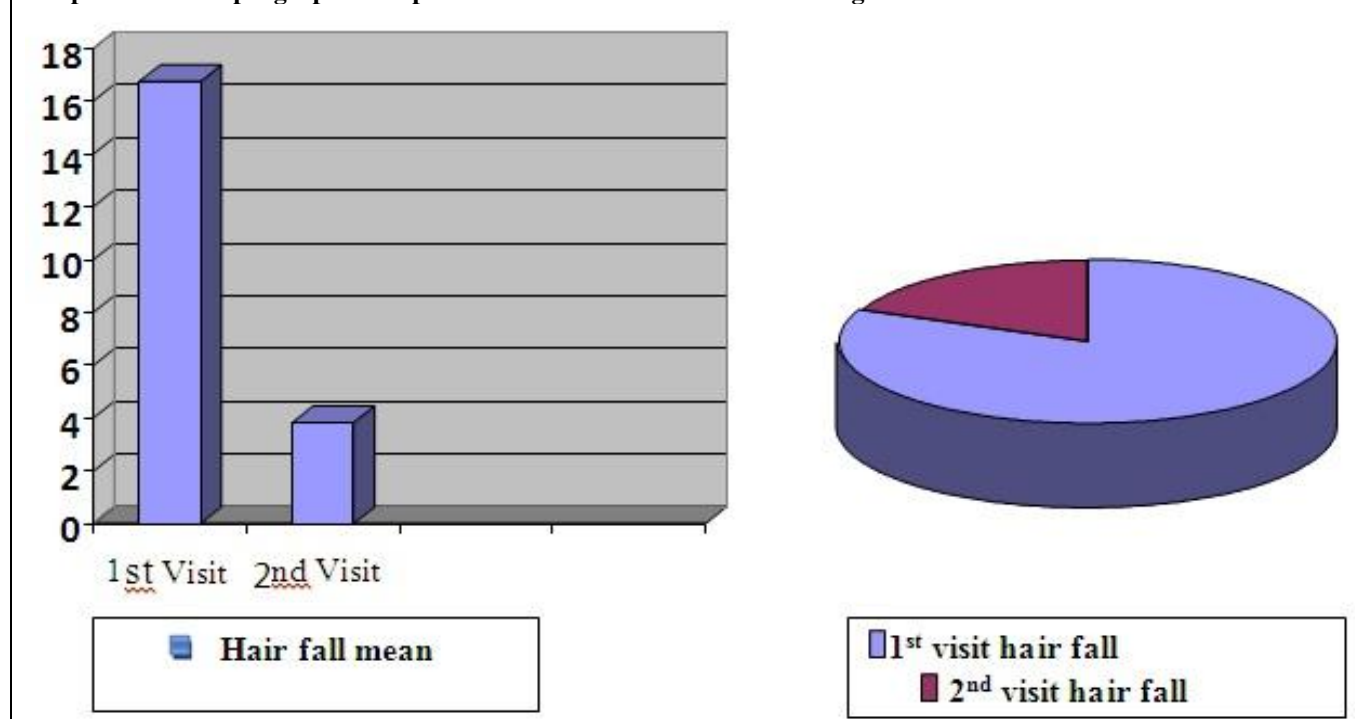
Table 7. Hair growth at different visit

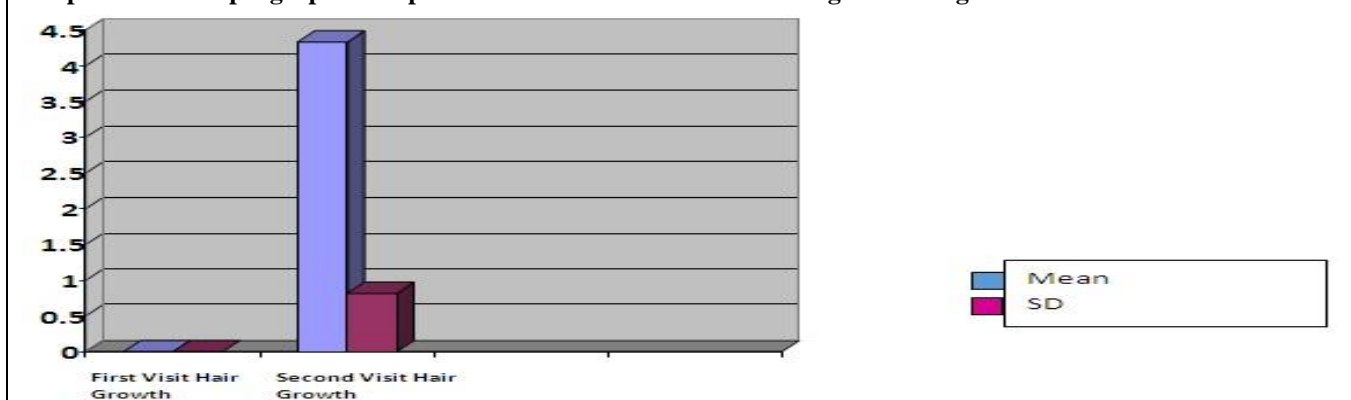
	First visit hair growth	Second visit hair growth
Mean	0	4.33
SD	0	0.819

VAS score	Visit 1	Visit 2
Score	0.00	4.33
p-value	< 0.0001	<0.0001
95% confidence interval of difference	4.17-4.33	4.17-4.33
Inference		Highly significant development

The mean VAS score has been increased from 0.0 from Visit 1 to 4.47 in Visit 2. This increment in VAS score is statistically significant for reduction from Visit 1 to Visit 3 (<0.0001).

Graph 1. Bar and pie graphical representation of Mean of hair fall during different visit



Graph 2. Bar and pie graphical representation of mean and SD of hair grow during different visit**Photograph of case no 03(A-J) during different visit****Photograph of case no 27(A-S) during different visit**

DISCUSSION

Bhringaraj or *Eclipta alba* is considered to be the best Ayurvedic remedy to prevent hair loss, premature greying and is also make hair dark, dense and lustrous. The herb also has use in Traditional Ayurveda as a rejuvenative tonic for liver, for various skin conditions and as a tonic for the mind. Amla is one a natural and fast hair growing herb. It's a known fact that massaging the scalp increases blood circulation but massaging the hair scalp with amla has the many added benefits. Not only it help in blood circulation but also amla is known to remove the unwanted flakes off the scalp. It also helps in opening of the pores thereby giving room to the scalp to produce nutrition. This encourages hair regrowth. One of the prime reasons for hair breakage is the deficiency of vitamin C and one of the easiest ways to replenish vitamin C back into the system is by amla for it is highly rich in Vitamin C. Along with vitamin C, amla is also very rich in antioxidants.

From the above tables it is found that the mean VAS score has been increased from 0.0 from Visit 1 to 4.47 in Visit 2. This increment in VAS score is statistically significant for reduction from Visit 1 to Visit 3 (<0.0001). The analysis data is presented below. After application of

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REGEN HAIR VITALIZER for 60 days it can be concluded that the development of VAS score is statistically significant for increment from Visit 1 to Visit 2 and this reduction in size of lesion is statistically significant for reduction from Visit 1 to Visit 2 and from Visit 1 to Visit 3. Also notable conclusion is no medically important change in vital signs has been observed and also no adverse event either treatment related or unrelated has been reported during the course of the study.

CONCLUSION

REGEN HAIR VITALIZER has been found to be a safe and effective water based hair vitalizing lotion and excellent for arresting hair fall and promoting hair growth by stimulating hair follicles. It also prevents further premature hair greying.

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