

# Role of Hair Zone Solution in the management of diffuse hair loss: An open clinical study

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## ABSTRACT

*Hair loss has multiple causes and more loss can impact the psychological phenomenon of the person. The purpose of this study is to evaluate the safety and efficacy of Hair Zone Solution in diffuse hair loss. The cases were included in the study according to the subject selection criteria. All the patients were advised to gently massage the solution into the scalp part by part, covering the whole area of the scalp and to rinse it in the morning. The response to therapy was evaluated at intervals of two weeks upto the 6<sup>th</sup> week. The changes in various parameters from baseline values and the values at each visit for 6 weeks were evaluated by "Paired 't' test". The criteria for evaluation was the signs and symptoms like reduction in hairfall, reduction in associated symptoms like itching, dryness of scalp, pull test, 1 minute comb test and overall impression. This clinical study clearly demonstrates the beneficial effects of Hair Zone Solution in diffuse hair loss as evidenced by decrease in hair fall by hair pull test, 1 minute combing test, in addition to improving moisturising and relief from itching. Further safety of the product was also substantiated by clinical parameters. Therefore it can be concluded that Hair Zone Solution is safe and effective in diffuse hair loss.*

**Key words:** Hair Zone Solution, Diffuse hair loss

## INTRODUCTION

Hair is one of the vital parts of the body derived from ectoderm of skin, is protective appendages on the body and considered accessory structure of the integument along with sebaceous glands, sweat glands and nails<sup>1</sup>. The main component of hair fiber is keratin. Keratins are proteins: long chains (polymers) of amino acids. Hair has great social significance for human beings.

Each hair grows in three cyclic phases viz., anagen [growth], catagen [involution] and telogen [rest]. The anagen phase can be as short as 2-6 years. In the catagen phase, the growth activity increases and hair moves to the next phase, catagen

phase is between 2-3 weeks. The telogen phase is a state at which the hairs move into resting state. This phase lasts for 2-3 months. In general, 50-100 hairs at random are shed everyday<sup>2</sup>.

Various factors contribute to hair fall/loss. Genetic predisposition and hormonal factors predominantly contribute to the above. Diseases state such as typhoid, malaria, jaundice etc, also cause hair fall. The use of chemotherapeutic agents also causes hair fall<sup>3</sup>.

Hair loss has multiple causes and more loss can impact the psychological phenomenon of the person. There are several other kinds of hair loss like:

- Traction alopecia is most commonly found in people with ponytails or cornrows who pull on their hair with excessive force.
- Trichotillomania is the loss of hair caused by compulsive pulling and bending of the hairs. It tends to occur more in children than in adults. In this condition the hairs

are not absent from the scalp but are broken. Where they break near the scalp they cause typical, short, "exclamation mark" hairs.

- Traumas such as chemotherapy, childbirth, major surgery, poisoning, and severe stress may cause a hair loss condition known as telogen effluvium.
- Worrisome hair loss often follows childbirth without causing actual baldness. In this situation, the hair is actually thicker during pregnancy due to increased circulating oestrogens. After the baby is born, the oestrogen levels fall back to normal pre-pregnancy levels and the additional hair foliage drops out. A similar situation occurs in women taking the fertility-stimulating drug clomiphene.
- Iron deficiency is a common cause of thinning of the hair, though frank baldness is not usually seen.
- Radiation to the scalp, as happens when radiotherapy is applied to the head for the

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treatment of certain cancers there, can cause baldness of the irradiated areas.

- Some mycotic infections can cause massive hair loss.
- Alopecia areata is an autoimmune disorder also known as “spot baldness” that can result in hair loss ranging from just one location (*Alopecia areata monocularis*) to every hair on the entire body (*Alopecia areata universalis*).
- Localized or diffuse hair loss may also occur in cicatricial alopecia (lupus erythematosus, lichen plano pilaris, folliculitis decalvans, central centrifugal cicatricial alopecia, postmenopausal frontal fibrosing alopecia, etc.). Tumours and skin outgrowths also induce localized baldness (sebaceous nevus, basal cell carcinoma, squamous cell carcinoma).
- Hypothyroidism can cause hair loss, typically frontal, and is particularly associated with thinning of the outer third of the eyebrows (syphilis also can cause loss of the outer third of the eyebrows)
- Hyperthyroidism can also cause hair loss, which is parietal rather than frontal.
- Temporary loss of hair can occur in areas where sebaceous cysts are present for considerable duration; normally one to several weeks in length.
- Diffuse Hair Loss: Brings about 20% reduction in hair loss in 2 weeks, and continuous use over 6 months reduces hair fall by 70%.
- Alopecia areata: Helps to re-grow 40% of hair on the bald area within 3 months.

Management of hair fall is extremely complex. Hormone therapy, use of  $\alpha$ -reductase inhibitors, vasodilators like minoxidil are widely used to reduce the hair fall / loss<sup>3</sup>. Synthetic drug, minoxidil is a potent vasodilator appears safe for long-term treatment.

Treatments for the various forms as available alopecia have limited success. Some hair loss sufferers make use of so-called “clinically

proven treatments” in an attempt to prevent further loss and re-grow hair. As a general rule, it is easier to maintain remaining hair than it is to re-grow; however, the success rate is very less with unwanted adverse effects. There are new technologies in cosmetic transplant surgery and hair replacement systems are available and that can be completely undetectable. So, Hair Zone Solution, a polyherbal formulation is evaluated for its safety and efficacy in diffuse hair loss. It consists of extracts of *Butea monosperma* and *Butea parviflora*.

#### AIM OF THE STUDY:

The purpose of this study is to evaluate the safety and efficacy of Hair Zone Solution in diffuse hair loss.

#### MATERIALS AND METHODS

This study was an open clinical trial conducted at outpatient Department of Dermatology, STD, AIDS & Leprosy, NHL Medical College & Seth Vadilal Sarabhai General Hospital, Ellisbridge, Ahmedabad, India. The study protocol, case report forms, regulatory documents, product information, and informed consent forms were submitted to the “Institutional Ethics Committee”, and were approved by the same. A total of 100 patients of both sexes, in the age group of 18-40 years, who were suffering from diffuse hair loss, and who were willing to give informed written consent were enrolled in the study. Patients on immunosuppressive drugs, patients applying other topical therapy for diffuse hair loss, in the last 2 weeks prior to the initiation of the study, patients with evidence of skin infection and pregnant and lactating women were excluded from the study. Also, those patients who were not willing to give informed written consent were excluded from the study.

#### Study Procedure

Each patient’s demographic medical history (*esp.* local fungal infection, dandruff, pediculosis, trichotillomania, stress, diet, past illness, and drugs), and treatment details were recorded. All the enrolled patients underwent a thorough

clinical examination, and scalp skin examination (which included the assessment of number of hairs lost in one minute combing test, presence of alopecic patches. All the patients were advised to gently massage the solution into the scalp part by part, covering the whole area of the scalp and to rinse it in the morning. The response to therapy was evaluated at intervals of two weeks upto the 6<sup>th</sup> week. The criteria for evaluation was the signs and symptoms like reduction in hairfall, reduction in associated symptoms like itching, dryness of scalp or moisturiser effect, hair pull test, 1 minute comb test and overall impression. Response was evaluated on an analogue scale of 0-3 (0- Nil, 1- Moderate, 2- Good, 3- Excellent). The overall response was inturn correlated with response to the treatment as follows: Grade 0 – no improvement, 1 – Poor response is <25% reduction, 2 – Moderate response is -25-49% reduction, 3 – Good response is 50-74% reduction, 4 – Excellent response is >75% reduction.

All the adverse events, either reported or observed by the patients, were recorded with information about severity, date of onset, duration, and action taken regarding the study drug. Relation of adverse events to study medication was predefined as “Unrelated” (a reaction that does not follow a reasonable temporal sequence from the administration of the drug), “Possible” (follows a known response pattern to the suspected drug, but could have been produced by the patient’s clinical state or other modes of therapy administered to the patient), and “Probable” (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient’s clinical state).

Patients were allowed to voluntarily withdraw from the study, if they had experienced serious discomfort during the study or sustained serious clinical events requiring specific treatment. For patients withdrawing from the study, efforts were made to ascertain the reason for dropout. Non-compliance

(defined as failure to take less than 80% of the medication) was not regarded as treatment failure, and reasons for non-compliance were noted.

**Primary and Secondary Endpoints**

The predefined primary efficacy endpoint was a decrease in the symptom score for diffuse hair loss. The predefined secondary safety endpoints were acute and chronic safety, as assessed by the incidence of adverse events and patient compliance to therapy

**Statistical Analysis**

Statistical analysis was done according to intention-to-treat principles. The changes in various parameters from baseline values and follow up visits at once in 2 weeks for 6 weeks were evaluated by “Paired ‘t’ Test”. Statistical analysis was performed using GraphPad Prism Version 4.03 for windows, GraphPad Software, San Diego, California, United States.

**RESULTS:**

The demographic details of subjects included in the study are listed in Table 1. The mean hair fall at entry was  $123.4 \pm 7.4$  which significantly ( $p < 0.05$ ) improved from 2<sup>nd</sup> week onwards, which further improved with continued treatment with Hair Zone Solution treatment until the end of treatment at 6<sup>th</sup> week. Itching was present in 40 cases at entry, which reduced significantly by 2<sup>nd</sup> week onwards presenting in only 23 cases and continued to show improvement with only 2 cases presenting with itching ( $p < 0.05$ ) at 6<sup>th</sup> week. Mean hair fall in 1 minute comb test which was  $72.8 \pm 8.6$  at entry, decreased markedly to  $54.6 \pm 2.8$  at 2 weeks and further decreased to  $9.2 \pm 1.5$  at 6 weeks, with a significance of  $p < 0.05$ . The hair fall in hair pull test also showed significant improvement from second week onwards and further improved with treatment till the end of 6 weeks with continued treatment. Moisturising effect was appreciated by 25 cases at 2 weeks, 58 cases at 4 weeks, 75 cases at 6 weeks of treatment with a significance of  $p < 0.05$  (Table 2).

**Table 1: Demographic data of patients on entry**

Number of patients	100
Male: Female	Male: 35; Female: 65
Diet	Vegetarian: 60 Mixed: 40
Mean age	Male : $35.5 \pm 6.9$ years Female : $31.5 \pm 2.9$ years
Weight in Kg (mean $\pm$ SD)	$68.80 \pm 12.50$
History of smoking	17
History of alcohol consumption	12

**Table 2: Clinical evaluation of the effect of Hair Zone Solution**

Parameters	At entry	Week 2	Week 4	Week 6
Mean hair fall	$123.4 \pm 7.4$	$72.5 \pm 12.5^*$	$39.2 \pm 11.8^*$	$14.8 \pm 4.6^*$
Itching	40	23*	8*	2*
Mean hair fall in 1 minute comb test	$72.8 \pm 8.6$	$54.6 \pm 2.8^*$	$24 \pm 6.1^*$	$9.2 \pm 1.5^*$
Hair fall in hair pull test	$65.5 \pm 8.1$	$31.6 \pm 12.2^*$	$14.6 \pm 6.6^*$	$6.6 \pm 3.4^*$
Moisturizing effect	-	25*	58*	75*

\* $p < 0.05$  as compared to ‘At entry’ values

**Table 3: Overall response to the treatment (%).**

Response score	At entry	Week 2	Week 4	Week 6
No response	-	23	06	02
Poor	-	39	45	10
Moderate	-	38	32	25
Good	-	-	17	47
Excellent	-	-	-	16

**Table 4: Dermal Safety Evaluation Of Hair Zone Solution (n=100)**

Signs & Symptoms	On application				
	Initial	After 1 <sup>st</sup> application	Week 2	Week 4	Week 6
Erythema	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$
Edema	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$
Pain	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$
Pruritus and Urticaria	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$
Burning sensation	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$	$0.00 \pm 0.00$

Values are expressed in mean  $\pm$  SD.

Assessment of overall response is listed in Table 3. At the end of the study, 16 cases reported excellent response, 47 cases reported good response, 25 cases reported moderate response, 10 cases reported poor response and 2 cases reported no response to Hair Zone Solution. The safety evaluation of the investigational product was also evaluated and found that there were no adverse effects on application of the product (Table 4).

## DISCUSSION

Management of hair fall is extremely complex. Hormone therapy, use of  $\alpha$ -reductase inhibitors, vasodilators like minoxidil are widely used to reduce the hair fall/loss. Synthetic drug, minoxidil is a potent vasodilator appears safe for long-term treatment. Treatments for the various forms as available alopecia have limited success with unwanted adverse effects. There are new technologies in cosmetic transplant surgery and hair replacement systems are available and that can be completely undetectable.

The present study shows that Hair Zone Solution is beneficial in the management of diffuse hair loss. Hair Zone Solution consists of potent herbs *Butea monosperma* and *Butea parviflora*.

*Butea monosperma* inhibits the hair follicular degeneration and extend the anagen phase of hair growth cycle; enhances proliferation and maturation of precursor epithelial cells of the final hair strand. It prevents the massive apoptosis in the proximal hair bulb. It stimulates the multiplication of hair fiber cells with the stimulation of anagenic phase, and reduce the catagenic and telogenic phase.<sup>4</sup> *Butea monosperma* displays anti-fungal activity against *Cladosporium cladosporioides*.<sup>5</sup> It also has a significant bactericidal effect.<sup>6</sup> *Butea monosperma* has potential antiviral activities.<sup>7</sup> *Butea monosperma* has astringent action.<sup>8,9</sup> This action tends to shrink or constrict body tissues, usually locally after topical medicinal application.

Externally applied astringents that cause mild coagulation of skin proteins, dry, harden, and protect the skin. Mildly astringent solutions are used in the relief of such minor skin irritations as those resulting from superficial cuts, allergies, insect bites, or fungal infections. *Butea monosperma* has potent free radical scavenging activity, and proves to be effective in promoting the therapeutic activity of Hair Zone Solution.<sup>10</sup> *Butea parviflora* inhibits the hair follicular degeneration and extend the anagen phase of hair growth cycle; enhances proliferation and maturation of precursor epithelial cells of the final hair strand. It prevents the massive apoptosis in the proximal hair bulb. It stimulates the multiplication of hair fiber cells with the stimulation of anagenic phase, and reduce the catagenic and telogenic phase.<sup>2</sup> *Butea parviflora* has antimicrobial action.<sup>11</sup>

The efficacy of Hair Zone Solution can be attributed to the synergistic effects of both the herbs *Butea monosperma* and *Butea parviflora*.

## CONCLUSION:

This clinical study clearly demonstrates the beneficial effects of Hair Zone Solution in diffuse hair loss as evidenced by decrease in hair fall by hair pull test, 1 minute combing test, in addition to improving moisturising and relief from itching. Further safety of the product was also substantiated by clinical parameters. Therefore it can be concluded that Hair Zone Solution is safe and effective in diffuse hair loss.

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