

## Original Article

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# Use of Low-Level Laser Therapy as Monotherapy or Concomitant Therapy for Male and Female Androgenetic Alopecia

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## ABSTRACT

**Background:** Androgenetic alopecia (AGA) is the most common form of hair loss in men and in women. Currently, minoxidil and finasteride are the treatments with the highest levels of medical evidence, but patients who exhibit intolerance or poor response to these treatments are in need of additional treatment modalities. **Objective:** The aim was to evaluate the efficacy and safety of low-level laser therapy (LLLT) for AGA, either as monotherapy or as concomitant therapy with minoxidil or finasteride, in an office-based setting. **Materials and Methods:** Retrospective observational study of male and female patients with AGA, treated with the 655 nm-HairMax Laser Comb<sup>®</sup>, in an office-based setting. Efficacy was assessed with global photographic imaging. **Results:** Of 32 patients (21 female, 11 male), 8 showed significant, 20 moderate, and 4 no improvement. Improvement was seen both with monotherapy and with concomitant therapy. Improvement was observed as early as 3 months and was sustained up to a maximum observation time of 24 months. No adverse reactions were reported. **Conclusions:** LLLT represents a potentially effective treatment for both male and female AGA, either as monotherapy or concomitant therapy. Combination treatments with minoxidil, finasteride, and LLLT may act synergistic to enhance hair growth.

**Key words:** Androgenetic alopecia, concomitant therapy, HairMax Laser Comb<sup>®</sup>, low level laser therapy, monotherapy

## INTRODUCTION

The ability of lasers to induce hair growth was incidentally noted as early as 1967 when Mester *et al.* used low-level laser therapy (LLLT) to treat cancer in mice with shaved backs.<sup>[1]</sup> Since then, hypertrichosis has been recognized to be a possible side-effect of laser treatment. First described in 2002 with intense pulsed light therapy,<sup>[2]</sup> this phenomenon has now been widely acknowledged to occur with an incidence rate ranging from 0.6% to 10% with low fluences and all laser types.<sup>[3]</sup> It is thought to be the result of suboptimal fluences that are too low to induce thermolysis, but high enough to stimulate follicular growth.

Eventually, LLLT has been developed for the treatment of androgenetic alopecia (AGA). As opposed to other currently marketed systems, the laser comb utilizes hair parting teeth for optimal delivery of laser energy to the exposed scalp. In 2007, the HairMax Laser Comb<sup>®</sup> (Lexington International, LLC) received 510 (k) clearance from the Food and Drug Administration (FDA) for the treatment

of AGA for men, and 2011 for women. This clearance means that the device is considered a moderate-risk medical device by the FDA and is thereby solely screened for safety. The HairMax Laser Comb<sup>®</sup> has been tested in a company-sponsored study of 110 male patients with the claim of a significant increase in mean terminal hair density when compared to a sham device.<sup>[4]</sup> Avram and Rogers conducted the first independent blinded study of LLLT and hair growth with seven patients and found that on average, there was a decrease in the number of vellus hairs, an increase in the number of terminal hairs, and an increase in shaft diameter.<sup>[5]</sup> A consensus written by hair loss experts states that based on anecdotal experience, LLLT, particularly 650-900 nm wavelengths at 5 mW, may be an effective treatment option for patients with AGA.<sup>[6]</sup> In recent times, Kim *et al.* reported an increase of hair density with the use of LLLT, when compared to the sham device in a 24-week, randomized, double-blind, sham-device-controlled trial.<sup>[7]</sup>

To evaluate efficacy of the 655 nm-HairMax Laser Comb<sup>®</sup> either as monotherapy or as concomitant therapy for

treatment of male and female AGA, we performed a retrospective observational study of global photographic assessments of patients in an office-based setting.

### MATERIALS AND METHODS

The study design was retrospective and observational. Patients who had purchased a HairMax Laser Comb® between July 2011 and July 2013 for treatment of AGA at the Center for Dermatology and Hair Diseases Prof. Trüeb were retrieved for assessment of global photographic images performed at follow-up visits. Patients on concomitant treatment had been treating with topical minoxidil or oral finasteride for at least 9 months, before starting therapy with the HairMax Laser Comb®. Patients used the HairMax Laser Comb® at home according to instructions 3 times weekly between 8 and 15 min depending on the model purchased (Advanced 7, Lux 9, or Professional 12). Global photographs were performed at 3, 6, 12, and 24 months of treatment follow-up in a standardized manner with a stereotactic camera device of Canfield Scientific Inc., in which the patient's chin and forehead are fixed and on which digital camera and flash device are mounted, ensuring that view and lighting are the same at consecutive visits, thus enabling precise follow-up of the same scalp area of interest with frontal and vertex views. Global photographs were evaluated by two of the authors (AM and RMT), and scored as significant, moderate, or no improvement. In the case of diverging opinions, the inferior score was given.

### RESULTS

In total, 32 patients with AGA were involved in the study, of which 21 were females, aged 22-73 (mean: 43.6 ± 15.19 standard deviation [SD]), and 11 were males, aged 20-70 (mean: 39 ± 15.01 SD) total mean: 42 ± 15.1 SD. The duration of hair loss in years for men and women was mean 7.1 ± 5.2 SD. The duration of LLLT in months for men and women was mean 8.7 ± 5.2 [Table 1]. The patient characteristics, with respect to gender, age, classification of AGA according to Ludwig and Hamilton-Norwood scales, duration of hair loss, and concomitant treatments are recorded in Table 2.

The results for the scoring of the global photographic assessment in relation to treatment duration with the HairMax Laser Comb® are demonstrated in Table 3. In summary, eight patients (three female, five male) showed significant improvement, 20 patients (14 female,

six male) moderate improvement, and four patients (four female, zero male) no improvement [Figure 1]. Of 32 patients, the HairMax Laser Comb® was used as monotherapy in six patients (two female, four male), and as a concomitant therapy in 26 patients (19 female, seven male). In the monotherapy group, two patients (one female, one male) showed significant improvement [Figure 2], four patients (one female, three male) moderate improvement, and zero patients no improvement [Table 3]. In the concomitant therapy group, six patients (two female, four male) showed significant improvement [Figures 3 and 4], 16 patients (13 female, three male) moderate improvement, and four patients (four female, zero male) no improvement. There was no statistical significant difference between LLLT monotherapy and concomitant therapy with either minoxidil and/or finasteride ( $P = 0.829$ ), and regarding male or female AGA ( $P = 0.091$ ) [Table 4].

Treatment was well tolerated and no serious adverse events were reported.

### DISCUSSION

Androgenetic alopecia is the most common form of hair loss in men and in women. Currently, topical 2% and 5% minoxidil solution and 1 mg oral finasteride are

**Table 1: Improvement of alopecia in relation to the variables: Age, duration of hair loss, and duration of LLLT**

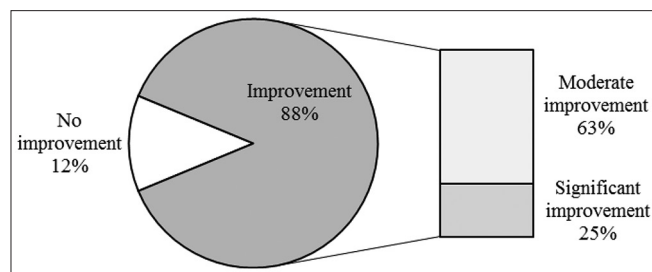
Variables	Statistics	Total	Improvement			P value of Kruskal-Wallis test
			Number	Moderate	Significant	
Age (years)	<i>n</i>	32	4	20	8	0.381
	Mean	42.0	33.0	44.8	39.6	
	Standard deviation	15.1	6.8	16.4	13.5	
	Minimum	20.0	25.0	22.0	20.0	
	Maximum	73.0	40.0	73.0	62.0	
Duration of hair loss* (years)	<i>n</i>	24	4	13	7	0.892
	Mean	7.1	7.3	7.0	7.4	
	Standard deviation	5.2	3.9	5.8	5.6	
	Minimum	0.5	3.0	0.5	1.5	
	Maximum	20.0	11.0	20.0	16.0	
Duration of LLLT (months)	<i>n</i>	32	4	20	8	0.549
	Mean	8.7	12.0	8.0	8.8	
	Standard deviation	5.2	8.1	3.7	6.9	
	Minimum	2.0	6.0	2.0	3.0	
	Maximum	24.0	24.0	18.0	24.0	

LLLT – Low-level laser therapy

**Table 2: Patient characteristics**

Gender	Age	Classification	Duration of hair loss	Concomitant treatments
Male	25	Hamilton-Norwood III	NOS*	Nil**
Male	54	Hamilton-Norwood IV	20 years	Nil**
Male	34	Hamilton-Norwood IV	10 years	Nil**
Male	70	Hamilton-Norwood III	NOS*	Nil**
Male	28	Hamilton-Norwood IV	9 years	5% minoxidil solution
Male	32	Hamilton-Norwood IIIv	2 years	5% minoxidil solution
Male	56	Ludwig pattern	7 years	5% minoxidil solution
Male	20	Hamilton-Norwood IIIv	18 months	1 mg oral finasteride 1 mg+5% minoxidil solution
Male	34	Hamilton-Norwood IIIv	NOS*	1 mg oral finasteride 1 mg+5% minoxidil solution
Male	38	Hamilton-Norwood V	16 years	1 mg oral finasteride 1 mg+5% minoxidil solution
Male	38	Hamilton-Norwood IV	12 years	1 mg oral finasteride 1 mg+5% minoxidil solution
Female	73	Ludwig II	6 months	Nil**
Female	62	Ludwig I-II	2 years	Nil**
Female	71	Ludwig II	12 years	0.025% estradiol solution
Female	38	Ludwig II	NOS*	5% minoxidil solution
Female	31	Ludwig II	3 years	5% minoxidil solution
Female	39	Ludwig II	NOS*	5% minoxidil solution
Female	44	Ludwig I	15 years	5% minoxidil solution
Female	30	Ludwig I	10 years	5% minoxidil solution
Female	52	Ludwig II	3 years	5% minoxidil solution
Female	40	Ludwig I	3 years	5% minoxidil solution
Female	40	Ludwig I	30 months	5% minoxidil solution
Female	37	Ludwig I	3 years	5% minoxidil solution
Female	37	Ludwig I	5 years	5% minoxidil solution
Female	25	Ludwig I	11 years	5% minoxidil solution
Female	50	Ludwig I	4 years	5% minoxidil solution
Female	33	Ludwig II	8 years	5% minoxidil solution
Female	22	Ludwig I	NOS*	5% minoxidil solution
Female	24	Ludwig I	4 years	5% minoxidil solution
Female	69	Ludwig I	8 years	5% minoxidil solution
Female	45	Ludwig I	NOS*	5% minoxidil solution
Female	53	Ludwig I	NOS*	5% minoxidil solution

\*NOS – Not otherwise specified; \*\*NIL – Nothing



**Figure 1:** Graphic summary of results

the treatments with the highest levels of medical evidence,<sup>[8]</sup> but patients who exhibit intolerance or poor response to these treatments are in need of additional treatment modalities. Although low-level energy lasers have been therapeutically used in medicine for photobiostimulation

in a variety of indications more than 30 years,<sup>[9]</sup> it has only recently found the attention of the scientific community for the treatment of AGA.<sup>[6,10,11]</sup>

We have chosen the 655 nm-HairMax Laser Comb<sup>®</sup> for several reasons: First, it represents the device with the most clinical study reports regarding its efficacy,<sup>[4,5,12]</sup> secondly, the cost of the device is affordable, and thirdly, the device is simple enough for patients to use at home. Finally, the fact that the device is safe, for which it received 510 (k) clearance from the FDA for the treatment of AGA, was also an important consideration.

Our study demonstrates clinical efficacy of the device for treatment of male and female AGA, both as monotherapy

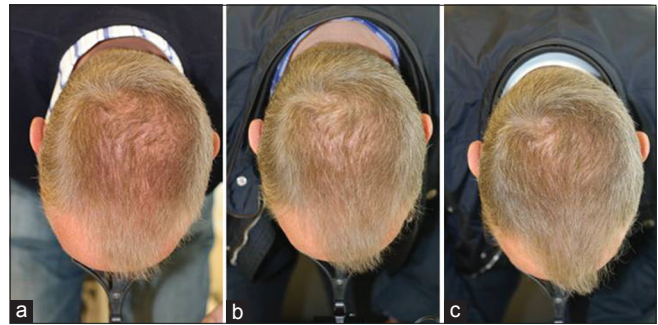
**Table 3: Scoring of global photographic assessment in relation to treatment duration**

Gender	Age	Duration of LLLT	No improvement	Moderate improvement	Significant improvement
Male	25	4 months		X	
Male	54	12 months		X [Figure 2]	
Male	34	7 months			X
Male	70	7 months		X	
Male	28	4 months		X	
Male	32	6 months		X	
Male	56	3 months			X [Figure 3]
Male	20	10 months			X
Male	34	12 months		X	
Male	38	24 months			X [Figure 4]
Male	38	5 months			X
Female	73	2 months		X	
Female	62	06 months			X
Female	71	12 months		X	
Female	38	12 months			X
Female	31	3 months			X
Female	39	7 months		X	
Female	44	6 months		X	
Female	30	6 months	X		
Female	52	6 months		X	
Female	40	9 months	X		
Female	40	8 months		X	
Female	37	9 months		X	
Female	37	24 months	X		
Female	25	9 months	X		
Female	50	9 months		X	
Female	33	5 months		X	
Female	22	6 months		X	
Female	24	6 months		X	
Female	69	9 months		X	
Female	45	18 months		X	
Female	53	12 months		X	

LLLT – Low-level laser therapy

**Table 4: Comparative assessment of efficacy between monotherapy and concomitant for male and female androgenetic alopecia**

	Total (n (%))	Improvement (n (%))			P value of Fisher test
		Number	Moderate	Significant	
Gender					
Male	11 (34.4)	0	6 (30.0)	5 (62.5)	0.091
Female	21 (65.6)	4 (100.0)	14 (70.0)	3 (37.5)	
Therapy					
Monotherapy	6 (18.8)	0	4 (20.0)	2 (25.0)	0.829
Concomitant therapy	26 (81.3)	4 (100.0)	16 (80.0)	6 (75.0)	



**Figure 2:** Monotherapy in a 54-year-old male (a) Before treatment, and improvement after (b) 6 months, and (c) 12 months of low-level laser therapy



**Figure 3:** Concomitant treatment with topical 5% minoxidil in a 55-year-old male adding on low-level laser therapy (LLLT) to 4 year pretreatment with 5% topical minoxidil solution (a) Before, and (b) After 3 months of added LLLT



**Figure 4:** Concomitant treatment with topical 5% minoxidil and 1 mg oral finasteride in a 34-year-old male (a) Before, (b) After 9 months treatment with 1 mg oral finasteride and topical 5% minoxidil solution bid, and (c) After 3 months after adding on low-level laser therapy

and as concomitant therapy, in terms of clinically relevant improvement of appearance of hair. Of 32 patients, eight patients (25%) showed significant improvement, and 20 patients (62.5%) showed moderate improvement in global photographic assessments. The effect was observed

as early as 3 months of treatment, and was sustained up to a maximum observation time of 24 months. The technology appears to work better for some than for others, and predictive factors which will most benefit from LLLT are to be determined. It seems though, that patients with intermediate alopecia (Hamilton-Norwood III and IV, and Ludwig I and II, respiratory) respond best, since effective photobiostimulation depends on a minimum of hair for effective photobiostimulation, and on a maximum of hair for the laser beam to reach the scalp without absorption or interference from existing hairs.

The hypothesized mechanisms of action of LLLT are increased adenosine tri-phosphate (ATP) production, modulation of reactive oxygen species (ROS), and induction of transcription factors. The proposed cellular chromosphere responsible for the effect of visible light is cytochrome c oxidase (COX) with absorption peaks in the near infrared, and mitochondria the likely site for the initial effects. It is believed that LLLT displaces nitric oxid from COX allowing an influx of oxygen to bond to COX and progress forward in the respiratory process to ATP production and ROS signaling. These effects in turn lead to increased cellular proliferation, modulation in levels of cytokines, growth factors and inflammatory mediators, and increased tissue oxygenation. While the effects of these biochemical and cellular changes have broadly been studied in both animal models and clinical studies with patients, and have shown benefits in diverse conditions, such as increased healing in chronic wounds, improvements in sports injuries and carpal tunnel syndrome, pain reduction in arthritis and neuropathies, and amelioration of damage after heart attacks, stroke, nerve injury and retinal toxicity,<sup>[7,9]</sup> the effects on hair growth stimulation have only recently gained the attention of the scientific community.

## CONCLUSIONS

From our own observations, we share with other authors the opinion that LLLT represents a safe and potentially effective treatment option for patients with AGA who do not respond or are not tolerant to standard treatment of AGA.<sup>[6,7]</sup> Moreover, combining LLLT with topical minoxidil solution and oral finasteride may act synergistic to enhance hair growth. Due to the known beneficial effect on wound healing, it is conceivable that LLLT as an adjunctive therapy

in hair transplant surgery may also reduce postoperative shedding, reduce healing time, and increase graft patency. The scientific basis for such an approach is given, but there is a need for controlled studies with a higher number of patients to establish an increase in efficacy of combination regimens.<sup>[13]</sup>

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