

A 6-month Dual-center Study Evaluating Alma TED™ and a Peptide-based Topical Hair Care Formula for Female and Male Pattern Hair Loss

Alan J. Bauman, MD, ABHRS, IAHRS, FISHRS¹, Shraddha Desai, MD, FAAD²

¹Bauman Medical, Boca Raton, USA, ²Duly Health and Care, Naperville, USA

Background

Female or male pattern hair loss (FPHL/MPHL) is a common hair disorder characterized by progressive hair thinning and loss, particularly in the frontal, crown, and vertex regions of the scalp.¹ It affects upwards of 30 million women and 50 million men in the US. While prevalence is increasing in younger patients, there remains a 40-50% risk of developing pattern hair loss in people over 50 years of age.² While medically benign, hair loss can negatively affect health-related quality of life by impairing self-esteem, emotional state, and social activity.³

The progressive hair loss characteristic of FPHL/MPHL is thought to be primarily mediated by the miniaturization of hair follicles, resulting in the conversion of large (terminal) hairs into small (vellus) hairs and the shortening of successive anagen (growth phase) cycles.^{1,5} The reduced anagen phase leads to increasingly thinner, shorter hairs ultimately unable to penetrate the epidermis.^{4,6}

Treatment options for FPHL/MPHL include medical, surgical, and light-based interventions.¹ Current FDA-approved therapies include topical minoxidil and oral finasteride (only for MPHL); however, these options come with undesirable side effects including excessive facial hair growth, dermatologic conditions, and sexual dysfunction.¹ Platelet-rich plasma (PRP) is an emerging treatment with few side effects, but the harvesting and processing of PRP is time-consuming, treatment effect is variable, and many consider injections painful.^{1,7} Low-level light therapy (LLLT) offers another alternative to standard treatments; however, results can be limited as monotherapy with clinical benefit only appreciated over an extended period, making LLLT better suited to a long-term multimodality approach.^{1,8} Thus, an unmet clinical need remains for consistent treatment options with few side effects that prevent hair loss and restore growth.

Here, we present a treatment for FPHL/MPHL using the Alma TED™ system + Hair Care Formula (Alma Lasers, Inc, Chicago, IL)- a combination of proprietary technology with a novel peptide-based topical hair formulation. Alma TED is a Class I medical device using a propriety tip (Patent No: US 10,238,849 B2) engineered with Impact Delivery™. Coupling the device with the TED + Hair Care Formula (cosmetics) addresses hair loss concerns by facilitating hair and scalp health and fortifying follicular integrity. Here, the safety of this needle-free alternative is assessed.

Materials and Methods

To assess the benefits and effectiveness of the device and hair care formulation in FPHL/MPHL, a dual-center, open-label evaluation of 33 participants (30 women and 3 men) was conducted.

Patients enrolled in the evaluation were treated at either Bauman Medical in Boca Raton, FL, or Duly Health and Care Dermatology in Naperville, IL. Eligible participants were 18 years or older with a history of FPHL/MPHL according to the Ludwig and Norwood scales.⁹ Key exclusion criteria included current use of PRP, history of hair transplantation, skin disease, active infection, or immune system disorders affecting the scalp. Pregnant patients or those with known malignancy or trigeminal neuralgia were also excluded.

Participants received three monthly treatments. Treatment effect was assessed at 1 and 6-months following the final treatment. For each treatment session (**Table 1**), a single treatment zone was first primed with the Alma TED system to condition the stratum corneum for two minutes (30% Impact). The peptide-based hair formulation was then applied throughout a single treatment zone. Next, the Alma TED system was used again for two minutes or until the hair was damp dry (50% Impact). These three steps were repeated for each treatment zone. Female treatment zones included the frontal scalp, crown, and temples, while male treatment zones included the crown, vertex, and frontotemporal scalp.

Table 1. Technical Details of a Single Treatment Session*

Procedure Step	Description	Product	Impact Settings	Time
Step 1	Prime	Alma TED	30%	2 min
Step 2	Application of hair formulation	Peptide-based Hair Care Formula	N/A	N/A
Step 3	Massage	Alma TED	50%	2 min**

*Steps 1-3 are repeated in order in each treatment area.

**Or until hair is damp dry.

At each treatment session, participants were asked if they experienced any pain using the 11-point Subject Pain Assessment Scale (0=no pain-10=extreme pain). Changes in global presentation and hair density were measured using the GroTrack hair growth tracking system (GRO Technologies, Santa Monica, CA) and validated by manual count at baseline, each treatment visit, and 1 and 6-months following the final treatment. Terminal and vellus counts per cm² were recorded.

This clinical evaluation was conducted following the principles outlined in the current revised version of the Declaration of Helsinki, Good Clinical Practice (GCP), and in compliance with all applicable laws and regulatory requirements relevant to the use of medical devices in the US.

Results

Data from 31 participants (29 women and 2 men) were evaluated; 2 participants (1 woman and 1 man) were lost to follow-up. Demographics are shown in (Table 2).

Table 2. Demographic Data

Parameter	Value
Cases Evaluated	31
Females	29
Males	2
Median age (range)	50 (21-78)
Ethnicity	
Caucasian	16
African or African descent	4
Hispanic or Latino	7
Asian	4
Previous PRP treatment*	8

*PRP consisted of 2-4 treatments with minimal to mild response with a 6-month wash-out period prior to treatment with Alma TED.

Hair density measurements per cm², as determined by GroTrack analysis, demonstrated improvements in hair density at 1 and 6-month follow-up assessments (23% and 31% increase, respectively) compared to baseline across all treatment areas (Table 3). Hair density improvements were most pronounced in the temples, appreciating 37% improvement at 1-month and 44% improvement at 6-months (Table 3).

Table 3. Average Improvement in Hair Density per cm² by Treatment Region

Follow-up Timeline	N	Frontal	Crown	Vertex	Right Temple	Left Temple	Bilateral Temples	Overall Average
1-Month	27	15%	12%	15%	42%	32%	37%	23%
6-Month	31	20%	20%	26%	42%	46%	44%	31%

Terminal and vellus hair counts per cm² were reported by GroTrack and confirmed by manual count (Table 4). Relative to baseline, terminal hair count increased for for all participants across all treatment areas by 13% at 1-month and continued to increase to 23% at 6-months following treatment (Table 4). Concomitantly, vellus hair initially decreased by 6% at 1-month and by 2% at 6-months compared to baseline (Table 4). The terminal-to-vellus ratio (T/V) for all treatment zones combined increased by 23% at 1-month and by 9% at 6-months following treatment (Table 4).

Table 4. Terminal and Vellus Count per cm²

Follow-up Timeline	N	Frontal	Crown	Vertex	Right Temple	Left Temple	Average	% Change from Baseline
Terminal								
Baseline	33	82.16	84.70	79.34	68.90	70.30	77.08	N/A
1-Month	27	87.95	93.32	90.83	83.21	81.22	87.31	13%
6 Month	31	96.18	100.85	99.46	85.14	90.79	94.48	23%
Vellus								
Baseline	33	5.19	6.00	5.13	5.47	4.94	5.34	N/A
1-Month	27	4.25	5.56	4.70	4.89	5.85	5.05	-6%
6 Month	31	5.09	4.81	5.42	5.23	5.67	5.24	-2%
Terminal/Vellus (T/V)								
Baseline	33	18.64	17.62	22.44	13.95	16.53	17.83	N/A
1-Month	27	27.59	19.82	24.68	21.63	15.96	21.94	23%
6 Month	31	20.21	22.61	19.58	17.80	17.29	19.50	9%

Importantly, none of the participants reported pain (mean score=0) at any of the treatment sessions, and there were no adverse events recorded throughout the evaluation period. Four case examples are presented in Figures 1-4 showing the transformation in hair density for female participants with FPHL; case 2 (Figure 2) highlights a mixed presentation of FPHL with traction alopecia related to hair styling.

Figure 1. Case 1: 30-year-old female with Diffuse Female Pattern Hair Loss. At 6 months, overall hair density improved 26% with vertex hair density improving 45%.



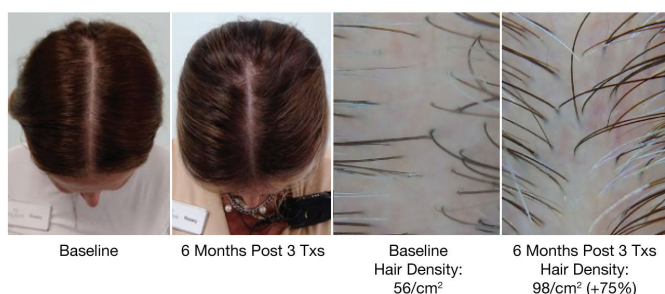
Figure 2. Case 2: 41-year-old female with Diffuse Female Pattern and Traction Hair Loss. At 6 months, overall hair density improved 45% with left temple hair density improving 108%.



Figure 3. Case 3: 52-year-old female with Diffuse Female Pattern Hair Loss. At 6 months, overall hair density improved by 54% with left temple hair density improving by 152%.



Figure 4. Case 4: 63-year-old female with Diffuse Female Pattern Hair Loss. At 6 months, overall hair density improved by 30% with left temple hair density improving by 75%.



Discussions

The Alma TED system + Hair Care Formula is safe at increasing terminal hair growth and hair density in all evaluated treatment zones for FPHL/MPHL. This treatment demonstrated improvement via all evaluated metrics, including objective measurements of hair density and terminal/vellus hair counts. Taken together, the improvements in hair density and the changes in terminal and vellus counts signify early and durable terminalization coupled with new hair growth.

These positive improvements were noted across all treatment areas for all participants. Analysis of hair composition through the 6-month follow-up period revealed that the increase in terminal hair density throughout the evaluation period is consistent with FPHL/MPHL reversal. The 23% improvement in T/V ratio at 1 month results from early terminalization supported by both the increased terminal and decreased vellus counts. The 9% T/V ratio at 6-month follow-up may seem less impressive but remains highly clinically significant, considering the terminal and vellus counts show continued terminalization coupled with new hair growth consistent with follicular de-miniaturization.¹⁰

As an efficacious treatment with no observed side effects, this therapy represents a favorable treatment option that helps meet the need for safe alternatives to standard hair loss treatments.¹¹ Side effects of minoxidil and finasteride may be a deterrent for some patients. For example,

women may avoid minoxidil for fear of excessive facial hair growth.¹ Minoxidil also loses effectiveness over time, and the hair gained during treatment falls out upon discontinuation.¹² Additionally, the potentially irreversible male sexual dysfunction occurring with finasteride may prevent its widespread usage among men, and its efficacy has not been established in women.^{1,13} In contrast, the Alma TED system + Hair Care Formula appears to be an effective treatment option for hair restoration with no observed adverse effects.

When compared with PRP and LLLT, the Alma TED system + Hair Care Formula is distinguished by its convenience and patient comfort. The absence of pain in this treatment may be a differentiating advantage over PRP. Furthermore, the harvesting and processing of PRP is time-consuming and disruptive to clinical workflow, whereas LLLT is inconvenient to the patient as it may require daily sessions for an extended period to achieve results.^{1,7,14} In contrast, the Alma TED system + Hair Care Formula is an easy and convenient procedure capable of achieving durable results over three short sessions.

Conclusion

In this dual-center evaluation, treatment of FPHL/MPHL using the Alma TED system + Hair Care Formula improved hair density and global appearance. Clinically meaningful results are achieved as early as 1 month following treatment initiation and continue to improve 6 months following treatment completion. Because hair loss severity varies and is influenced by both intrinsic and extrinsic factors, maintenance therapy should likely be utilized every 3-6 months to preserve the results achieved.

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