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

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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] FPHL affects approximately 30 million women and MPHL affects 50 million men in the US, with a 40-50% risk of development in people over 50 years of age.[2] While medically benign, hair loss can negatively affect self-esteem, emotional state, and social activity, which may impair health-related quality of life.[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, dermatological 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 but has a low level of evidence for efficacy.[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 efficacy and safety of this needle-free alternative are assessed.

Materials and Methods

To assess the benefits and effectiveness of the device and hair care formulation in FPHL/MPHL, a single-center, open-label study of 11 participants (eight women and three men) was conducted.

Patients enrolled in the study were treated at Duly Health and Care Dermatology in Naperville, IL. Eligible patients 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, immune system disorders, trigeminal neuralgia, and skin disease. Patients with an active infection in the treatment area or known malignancy were also excluded.

Participants were treated for a total of three sessions, 30 days apart. Treatment effect was assessed at 30 and 90 days following the last treatment. For each treatment session **(Table 1)**, all treatment zones were first primed with the Alma TED™ system to condition the stratum corneum for two minutes each (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 is 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	NA	
Step 3	Treat	Alma TED™	50%	2 min**

*Steps 1-3 are repeated in order in each treatment area.
**Or until hair is dry.

At each treatment session, participants answered questions (Y/N) on whether they had observed reduced hair shedding and/or increased hair growth and 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) at baseline, each treatment visit, and 30 and 90 days following the final treatment. Terminal and vellus counts per cm^2 were recorded. Hair growth was also evaluated using the 5-point Subject- and Physician-reported Global Aesthetic Improvement scale and 5-point Subject

Satisfaction **(Table 2)**.

Table 2. Patient Self-Assessment Scores

Scale	Assessment Scores (# of Patients)	
	30-Day Follow-Up	90-Day Follow-Up
Subject Global Aesthetic Improvement Scale (S-GAIS)	Avg score=3.8	Avg score=3.9
1=Worse	0	0
2=No Change	0	1
3=Improved	4	1
4=Much improved	3	5
5=Very much improved	2	2
Subject Satisfaction	Avg score=3.7	Avg score=3.9
1=Very dissatisfied	0	0
2=Dissatisfied	0	1
3=Satisfied	6	1
4=Much Satisfied	0	5
5=Very Much Satisfied	3	2

Results

Data from nine participants (six women and three men) were evaluated. Demographics are shown in (**Table 3)**.

All (100%) participants reported a decrease in shedding (80% after the first treatment and 20% after the second treatment). Increased hair growth was also noted by all (100%) participants, with 40% reporting improvement following the first treatment, and the remaining following treatment two (40%) and three (10%).

Table 3. Demographic Data

Parameter	Value
Cases Evaluated	9
Females	6
Males	3
Median age (range)	55 (29-78)
Ethnicity	
Caucasian	5
Indian Asian	2
African or African American	2
Previous PRP treatment*	4

*PRP consisted of 2-4 treatments with minimal to mild response.

At the 30-day follow-up visit, 100% of patients were improved, much improved, or very much improved (S-GAIS average 3.8), and 100% of participants were satisfied, much satisfied, or very much satisfied. At 90 days, S-GAIS and satisfaction scores both increased to 3.9 **(Table 4)**. In agreement with S-GAIS, the mean P-GAIS score of the nine participants was 3.9 at the 90-day follow-up. Assessment of the Ludwig (female) and Norwood (male) Scales demonstrated a 1.2 and 1.7-grade improvement, respectively.

Hair density measurements per cm^2 as determined by GroTrack analysis demonstrated improvements in hair density at 30 and 90 days (24% and 34% increase, respectively) across all treatment areas and both genders **(Table 5)**. Growth was most pronounced in the temples for both genders, but hair density increased more dramatically in women (52% at day 30 and 65% at day 90; **Table 5**).

Table 4. Average Improvement in Hair Density per cm^2 by Treatment Region

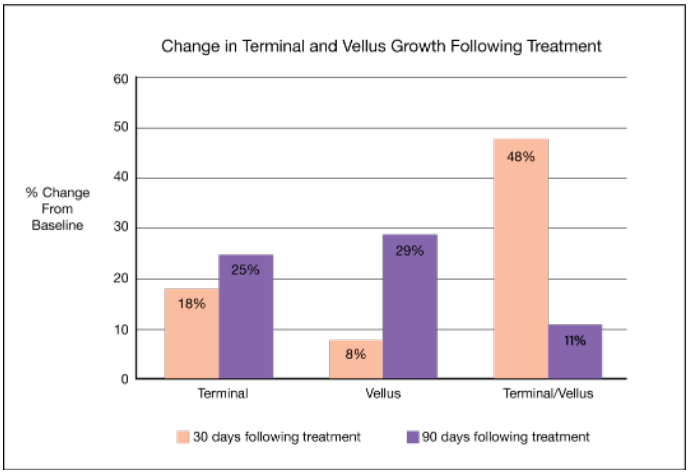
Patient	N	Frontal	Crown	Vertex	Right Temple	Left Temple	Bilateral Temples	Overall Average
30-Day Follow-up Hair Density Summary								
Female	6	8%	18%	-2%	42%	62%	52%	25%
Male	3	52%	15%	6%	15%	26%	20%	21%
Both Genders	9	21%	17%	1%	32%	50%	41%	24%
90-Day Follow-up Hair Density Summary								
Female	6	19%	29%	10%	35%	81%	58%	36%
Male	3	50%	21%	21%	26%	33%	30%	30%
Both Genders	9	31%	26%	14%	32%	65%	49%	34%

Terminal and vellus hair counts per cm^2 were reported by GroTrack and confirmed by manual count **(Table 5)**. Relative to baseline, terminal hair count increased for both genders across all treatment areas at 30 days following treatment and continued to increase at 90 days **(Table 5)**. The average increase of terminal hair in all areas combined represents an 18% increase relative to baseline at 30 days and a 25% increase at 90 days post-treatment **(Figure 1)**. When averaged across all treatment zones, an increase in terminal hair count was observed at 30 days and continued at 90 days **(Table 5)**. The change in vellus hair is reflected by an 8% increase in vellus count at 30 days following treatment, which increased to 29% at 90 days **(Figure 1)**. Unlike terminal hair count, an increase in vellus hair count was not observed at 30 days or 90 days post-treatment in the crown. The terminal-to-vellus ratio (T/V) for all treatment zones combined increased at 30 days following treatment, representing a 48% increase relative to baseline. The degree of the change was reduced to an 11% increase at 90 days following treatment **(Figure 1)**.

Table 5. Terminal and Vellus Count per cm^2

Days Following Treatment	Frontal	Crown	Vertex	Right Temple	Left Temple	Overall Average
Terminal						
Baseline	61.33	63.11	69.67	48.33	47.22	57.93
30 Days	72.29	73.11	70.22	62.13	64.56	68.46
90 Days	72.38	78.78	76.78	62.25	72.00	72.44
Vellus						
Baseline	4.78	6.56	5.33	4.78	4.11	5.11
30 Days	4.57	6.33	4.89	4.63	7.11	5.51
90 Days	6.71	6.11	6.22	7.00	7.00	6.61
Terminal/Vellus (T/V)						
Baseline	12.84	9.63	13.06	10.12	11.49	11.43
30 Days	23.11	13.23	22.82	15.85	9.73	16.95
90 Days	12.24	14.06	16.10	9.37	11.46	12.65

Figure 1. Change in Terminal and Vellus Growth for All Treatment Areas Combined



Importantly, none of the participants reported pain (mean score=0) at any of the sessions and there were no adverse events recorded throughout the evaluation period. Two case examples are presented in Figures 2 and 3. Case 1 **(Figure 2)** shows the transformation in hair density for a female patient and Case 2 **(Figure 3)** shows a male patient.

Figure 2. Case 1: Diffuse Female Pattern Hair Loss. At 90 days, overall hair density improved 27% with frontal hair density improving 21%.

Baseline | 90 days Post Tx 3 | Baseline Hair Density: 55/cm² | 90 days Post Tx 3 Hair Density:68/cm² (+24%)

Figure 3. Case 2: Diffuse Male Pattern Hair Loss. At 90 days, overall hair density improved 22% with crown hair density improving 24%.

Baseline | 90 Days Post Tx 3 | Baseline Hair Density: 55/cm² | 90 Days Post Tx 3 Hair Density: 68/cm² (+24%)

Discussions

The Alma TED™ system + Hair Care Formula is safe and efficacious 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 measures of hair density, terminal/vellus hair counts, and change on the Ludwig/Norwood scales as well as subjective measures of global improvement (P-GAIS and S-GAIS), hair growth/shedding surveys, and subject satisfaction. Positive results were apparent early on and durable through 90 days.

A durable improvement in hair density across all treatment areas and both genders was noted, and analysis of hair composition revealed that terminal hair density increased over the course of the study, consistent with FPHL/MPHL reversal. Somewhat surprisingly, the T/V ratio decreased from 30 to 90 days following treatment. However, the decrease in the ratio is a result of an increase in vellus hair rather than a reduction in terminal hair. For example, a decrease in the telogen (resting phase) to anagen (growth phase) ratio of the vellus hair from 30 to 90 days may be indicative of improvement considering its increase is a histopathological feature of FPHL/MPHL.[10]

As an efficacious treatment with no observed side effects, this therapy represents a favorable treatment option that helps meet the need for safe and effective 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 single-center evaluation, treatment of FPHL/MPHL using the Alma TED™ system + Hair Care Formula was improved hair density and global appearance. Importantly, participants recognized decreases in shedding and increases in growth early following treatment initiation and are overall highly satisfied with the results. Results are apparent as early as one month after treatment initiation and durable for at least three months. To support the promising data presented here, longer-term follow-up with larger sample sizes at multiple sites is warranted.

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