

A Single-center Study Evaluating Alma TED™ and a Peptide-based Topical Hair Care Formula for a Variety of Hair Loss Concerns

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Background

Hair loss, whether sudden or insidious, arises from a multitude of clinical etiologies and is broadly categorized as either cicatricial (scarring) or non-cicatricial (non-scarring). While medically benign, hair loss of any type often has a negative effect on self-esteem, emotional state, and social functioning, which can significantly impact health-related quality of life.¹

Scarring hair loss, while less common, is characterized by the active destruction of the hair follicle by inflammatory infiltration.² This irreparable damage to the follicle leads to permanent hair loss.² Some of the more common types of scarring hair loss are lichen planopilaris and central centrifugal scarring hair loss (CCSA).³

Non-scarring hair loss is very common and is primarily characterized by thinning hair.² Common types of non-scarring hair loss include telogen effluvium, characterized by stress-related shedding, and certain autoimmune hair loss; but, the most common type of non-scarring hair loss is female and male pattern hair loss (FPHL/MPHL) which affects approximately 30 million women and 50 million men in the US.⁴ It presents with progressive hair thinning and loss, particularly in the frontal, crown and vertex regions of the scalp.⁵ Initial symptoms can develop as early as the teenage years with 40% of women developing FPHL by age 50, and 50% of men developing MPHL after age 50.⁴ 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.^{5,6} The reduced anagen phase leads to increasingly thinner, shorter hairs that are ultimately unable to penetrate the epidermis.^{7,8}

Treatment options for FPHL/MPHL include medical, surgical, and light-based interventions.⁵ 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.⁵ Platelet-rich plasma (PRP) is an emerging treatment with few side effects, but the harvesting and processing of PRP is time-consuming, the treatment effect is variable, and many patients consider injections painful.^{5,9} Low-level light therapy (LLLT) offers another alternative to standard treatments but has low evidence for efficacy.^{5,10} Immunosuppressant therapies such as intralesional corticosteroid injections for scarring types of hair loss are usually used in combination with other topical

therapies (i.e., anti-dandruff shampoo and topical steroids) often without meaningful effect on hair regrowth.¹¹ Oral janus kinase (JAK) inhibitors, another type of immunomodulatory therapy, are now used for certain autoimmune types of hair loss. While effective, long-term therapy is likely required as hair loss is found to recur in these patients within three months of discontinuing JAK inhibitors.¹² But, the long-term effect of blocking T-cell-mediated inflammatory response is not known.¹² Thus, an unmet clinical need remains for consistent treatment options with few side effects that arrest the progression of hair loss and restore growth.

Here, we present a treatment for various types of hair loss 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 various hair loss types, a single-center, open-label evaluation of 50 participants (45 women and five men) was conducted.

Patients enrolled in the study were treated at Dy Dermatology in Glenview, IL. Eligible participants were 18 years or older with a history of hair loss classified as grade II-IV on the Hamilton Norwood Scale or any grade on the Savin Scale.¹³ Hair loss types included FPHL/MPHL, telogen effluvium, autoimmune, lichen planopilaris, and central centrifugal scarring hair loss. Participants on concurrent therapies were required to be stable for a minimum of six months prior to the evaluation period. Key exclusion criteria included hair loss classified as Hamilton Norwood grade VI-VII, the use of any new prescriptions or OTC products for hair loss during the study period or in the six months prior to the evaluation period, and any dramatic change in hair styling that would make it difficult to evaluate outcomes.¹³ Current use of PRP, history of hair transplantation, immune system disorders, trigeminal neuralgia, and skin disease affecting the scalp were also excluded. Participants 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 days following the last 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 the single treatment zone. Next, the Alma TED™ system was used again for two minutes or until the hair was dry (50% Impact). These three steps were repeated in order 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). Subjective and objective appearance in hair density was evaluated using a 2-point assessment method (improved/not improved). Participants were further evaluated using the 5-point Subject Satisfaction scale. One participant was monitored using the GroTrack hair growth tracking system (GRO Technologies, Santa Monica, CA) at baseline and 30 days following the final treatment. Total hair density per cm² was recorded as part of this assessment. Two participants were monitored for long-term follow-up.

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

Results

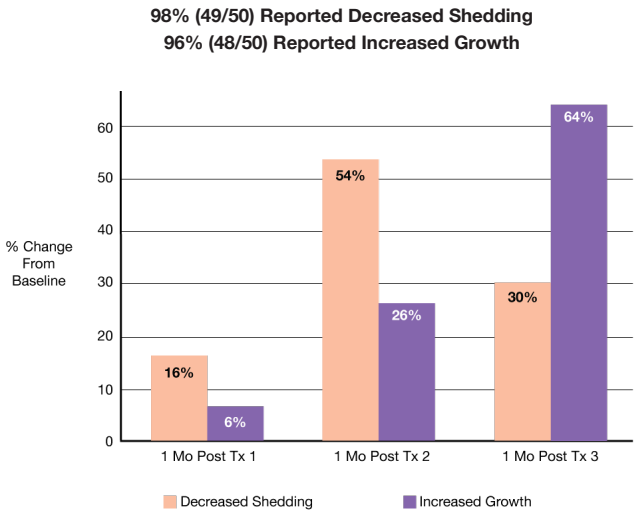
Data from 50 participants (45 women and five men) were evaluated. Except for a single case of non-scarring autoimmune hair loss, all other hair loss types evaluated were responsive to treatment with the Alma TED™ system, resulting in a 98% (49/50) favorable response rate (**Table 2**).

Table 2. Responsiveness by Hair Loss Type

Primary Hair Loss Type	Subjects	Completed	Responded
Female Pattern Hair Loss	35	35	35
Male Pattern Hair Loss	5	5	5
Central Centrifugal Scarring Alopecia (CCSA)	5	5	5
Telogen Effluvium	3	3	3
Lichen Planopilaris	1	1	1
Alopecia Areata	1	1	0
	50	50	49 (98%)

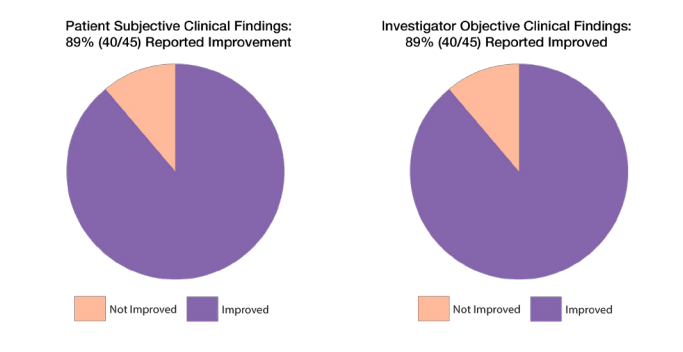
Decreased shedding was reported by 98% (49/50) of participants: 16% after the first treatment, 54% after the second treatment, and 30% after the third treatment (**Table 3**). Increased hair growth was reported by 96% (48/50) of participants: 6% after the first treatment, 26% after the second treatment, and 64% after the third treatment (**Table 3**).

Table 3. Changes in Hair Shedding and Growth



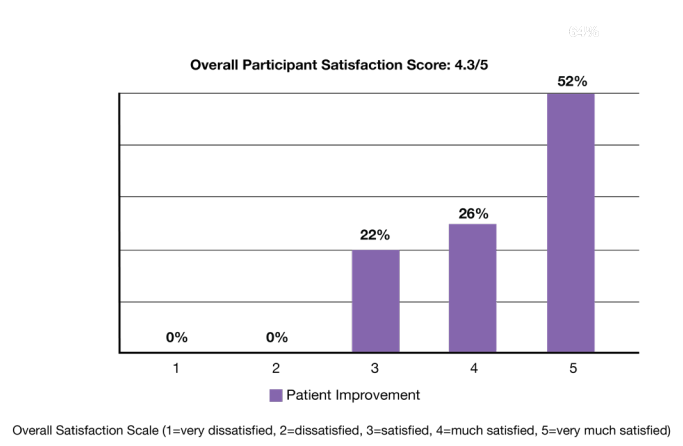
At the 30-day follow-up visit, 89% (40/45) of patients reported visible improvement in hair density appearance (**Table 4**). The investigator's assessment of objective clinical improvement in hair density appearance was aligned at 89% (40/45) (**Table 4**). Of the five patients whose hair density did not appear to improve at the 30-day follow-up, one developed non-scarring autoimmune type of hair loss during the evaluation period; and, the other four went on to show objective clinical improvement after the 30-day evaluation period, as these were active patients of the practice who received continued care.

Table 4. Subjective and Objective Clinical Improvement in Hair Density Appearance



All (100%) participants were either satisfied, much satisfied, or very much satisfied at the 30-day follow-up with an average satisfaction score of 4.3/5 (Table 5).

Table 5. Participant Satisfaction Scores



Importantly, in the 150 treatment sessions administered, there were only four instances of minor discomfort reported (mean pain score=0.057) and there were no adverse events recorded throughout the evaluation period.

Four case examples are presented in Figures 1-4. Case 1 (Figure 1 and Table 6) shows the transformation in hair density for a female patient with FPHL. Case 2 (Figure 2) shows the transformation in hair regrowth for a female patient with CCSA. And cases 3 and 4 (Figures 3-4) show the long-term transformation in hair regrowth with MPHL and FPHL, respectively. Cases 3 and 4 are long-term patients of the practice who went on to receive a fourth treatment following the evaluation period that further enhanced clinical outcomes.

Figure 1. Case 1: Diffuse Female Pattern Hair Loss. At 30 days following three treatments, crown hair density improved by 75%.



Total hair density measurements per cm² as determined by GroTrack analysis (confirmed by manual count) increased on average by 58% demonstrating significant improvements in hair density at 30 days across all locations measured—frontal, crown, and vertex (Table 6).

Table 6. Case 1: Change in Total Hair Density per cm² in FPHL

Location	Baseline	30-Day Follow-up	Change
Frontal	82	120	46%
Crown	82	144	75%
Vertex	96	148	54%

Figure 2. Case 2: Central Centrifugal Scarring Hair Loss. Early hair regrowth is visible following treatment initiation, with significant regrowth achieved 30 days following three treatments.



Figure 3. Case 3: Diffuse Male Pattern Hair Loss. Early hair regrowth is visible following treatment initiation, with significant regrowth achieved 30 days following four treatments.



Figure 4. Case 4: Diffuse Female Pattern Hair Loss. Shedding was triggered following a stressful event five months post three treatments with a fourth treatment restoring hair growth.



Discussion

The Alma TED™ system + Hair Care Formula is safe and efficacious at increasing hair growth in many types of hair loss. This treatment demonstrated strong improvement via all evaluated metrics which included subjective and objective clinical assessment of hair density appearance, hair density measurement, as well as hair growth/shedding surveys, and participant satisfaction. Positive results were apparent early after initiating treatment and durable through 30 days. The only type of hair loss that did not respond to treatment was one case of non-scarring autoimmune hair loss; this is an expected outcome as the Alma TED™ system + Hair Care Formula is not intended to address underlying autoimmune conditions resulting in hair loss.

While some participants were naïve to hair loss treatments, the majority were receiving concurrent therapy. To clearly evaluate the potential additional benefit of treatment with the Alma TED™ system + Hair Care Formula, these participants were required to be stable (i.e., no change in therapies used or changes in hair shedding or growth pattern) for a minimum of six months prior to the evaluation period.

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.¹⁴ 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.⁵ Minoxidil can also cause transient hair shedding, potentially heightening a patient's anxiety level; and, the hair gained during treatment falls out upon discontinuation.¹⁵ Additionally, the controversial irreversible male sexual dysfunction occurring with finasteride may prevent its widespread usage among men, and its efficacy has not been established in women.^{5,16} In contrast, the Alma TED™ system + Hair Care Formula appears to be an effective treatment option for hair restoration with no observed adverse effects.

Similarly to minoxidil, JAK inhibitors also see that hair gained

during treatment falls out upon discontinuation.¹² The additional immunomodulatory effects may be a deterrent for others to adopt this therapy for either short or long-term duration. However, the Alma TED™ system + Hair Care Formula may be a unique adjunctive therapy to help maintain hair growth achieved by JAK inhibitors.

When compared with PRP and LLLT, the Alma TED™ system + Hair Care Formula is distinguished by its convenience and patient comfort. The minimal discomfort noted in this evaluation was likely due to the novelty of the technique and associated sound, and one instance of the tip being applied to the scalp while the device was tuning. While tuning, the tip temperature increases which may cause mild discomfort; therefore, skin contact with the tip during device calibration should be avoided. Other clinical evaluations have noted a pain score of zero. This high degree of patient comfort may be an additional 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 visible results.^{5,9,17} In contrast, the Alma TED™ system + Hair Care Formula is an easy and convenient procedure capable of achieving meaningful results over three short sessions.

Hair loss is increasingly affecting younger individuals, surprising many who are only aged in their 20s, 30s, or 40s. Environmental influences such as higher reported levels of stress, diet-related nutrient deficiencies, common medications, and certain infections are likely contributing to hair loss in younger adults.^{18,19,20} Thus, the Alma TED™ system + Hair Care Formula has wide clinical utility for those aged 18 years and older who are experiencing hair loss.

Maintenance therapy varied among participants depending on their hair loss type and progression. Maintenance therapy was performed once every three months for those using the Alma TED™ system + Hair Care Formula as a monotherapy. Maintenance therapy was performed once every three to six months for those receiving a multimodality treatment approach. Adjustments were made according to the patient's personal medical needs and goals.

Conclusion

In this single-center evaluation, treatment of various hair loss types using the Alma TED™ system + Hair Care Formula improved the appearance of hair density by decreasing shedding and improving hair growth. Importantly, participants recognized these treatment benefits 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 through 30 days. To support the promising data presented here, longer-term follow-up and further hair metrics analysis are warranted.

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