CLINICAL REPORT

Improvement in Scalp Hair Appearance Following Treatment With a Non-Ablative Fractional Laser: A Retrospective Observational Study

Marc R. Avram[1] | Dawn Queen[2] | Jerry Shapiro[3] | Girish Munavalli[3,4,5]

[1]Weill Cornell Medical School/New York Presbyterian Hospital, Private Practice, New York, New York, USA | [2]Columbia University Irving Medical Center, Private Practice, New York, New York, USA | [3]New York University Grossman School of Medicine, New York, New York, USA | [4]Wake Forest University, Winston Salem, North Carolina, USA | [5]Private Practice, Charlotte, North Carolina, USA

Correspondence: Girish Munavalli (GMunavalli@carolinaskin.com)

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ABSTRACT

Background: Androgenetic alopecia (AGA) affects at least 80% of men and 50% of women by age 70. This study aimed to assess the efficacy of a non-ablative fractional laser (NAFL) in treating AGA and enhancing hair appearance on the scalp in male and female patients.

Methods: This was a single-center, retrospective, observational study. Case files of all subjects, who were treated for improvement of scalp hair appearance using a 1565-nm NAFL at LaserMed Clinic (Lublin, Poland) between February 24, 2020, and January 31, 2023, were reviewed for study inclusion. The authors were not involved in the administration of treatments but reviewed the data that were obtained for the study. Digital images taken before and following laser treatment were gathered and blindly evaluated by non-treating physicians for quality of results. The study's primary efficacy endpoint was the proportion of image sets correctly classified as before and after treatment. Success was defined as correct identification of the posttreatment image as the image demonstrating scalp hair growth and clinical improvement by at least two out of three blinded reviewers. Safety was evaluated based on the incidence of adverse events or safety issues.

Results: A total of 132 patients were included in the study, of whom 98 patients had photos of adequate quality for assessing device efficacy. The overall success rate of correct identification of before and after images among the 98a evaluable patients was 96.9% (95% confidence interval: 91.4%–98.5%) and remained consistently high (> 95%) across the evaluated subgroups (patients with AGA, patients with unknown type of alopecia, males and females). No adverse events were documented in the clinic records for the 132 subjects included.

Conclusions: NAFL is a safe and effective method for promoting visible hair growth and improving the appearance of scalp hair.

1 | Introduction

The majority of the population will experience alopecia, or hair loss, at some point in their life [1]. There are various types of alopecia, including alopecia areata, chemotherapy-induced alopecia, and telogen effluvium, but the most common type is androgenetic alopecia (AGA) or common baldness [1, 2]. AGA is characterized by progressive hair loss that is caused by androgen-mediated miniaturization of hair follicles, resulting in vellus transformation of terminal hair [2]. It affects all genders (male pattern or female pattern hair loss) and gradually increases in incidence with age [1]. AGA can cause emotional distress and have a profound psychological impact [2, 3].

There are various medical and procedural treatment options for AGA. Currently, the two Food and Drug Administration (FDA)-

approved drugs for treating AGA are topical minoxidil and oral finasteride [4, 5]. These medications have proven to be effective for preventing, stabilizing, and regrowing hair in AGA [4]. However, patients need to apply the medications properly to ensure their effectiveness. In addition, these medications need to be continuously used and have noteworthy side effects, with oral finasteride carrying a risk of erectile dysfunction and reduced libido in men, and is prohibited for use in women of childbearing age [4, 6, 7]. These potential side effects may create barriers to use for some people. Additional treatment options for AGA include other topical and oral pharmaceuticals, hormonal therapies, procedural interventions, and nutritional supplements, which may be associated with pain and discomfort or other side effects [5]. Other topical and hormonal medications and over-the-counter supplements have limited supporting evidence [5]. A more recent procedural treatment modality for AGA is platelet-rich plasma (PRP), which requires a blood draw, separation of the PRP, and injection of the plasma preparation into the deep dermis or subcutaneous tissue of the scalp [5, 6]. This treatment is attractive as there are no patient responsibilities, and it is considered to be a "natural" treatment option, but it must be continued long-term at regular intervals to sustain hair growth. Additionally, the standardization of PRP preparation is debated, and some patients may wish to avoid the discomfort associated with scalp injections [5, 6].

A relatively safe and long-lasting alternative is hair transplantation or surgical hair restoration [4]. However, the relatively high cost, need for long-term anti-AGA therapy, donor suitability, and invasiveness (or minimally invasive at best) of the procedure may preclude access for some patients [4, 8, 9]. In addition, hair transplantation restores hair but does nothing to prevent ongoing hair loss. This makes it critical to concurrently treat with an effective medical therapy to maintain maximum long-term density for hair transplant patients. There is therefore a need for innovative, noninvasive treatments that are effective and safe. Laser and light therapies have been gaining traction in this space, as these therapies are noninvasive and have been shown to be effective for managing alopecia, while minimizing adverse effects compared to conventional treatments [4, 8]. In addition, laser and light therapies do not use external additives or chemicals and work by stimulating the body's natural regenerative processes.

Researchers are beginning to identify the stem cells that can generate new hair follicles in response to skin injury, and to better understand the roles of immune cells, mesenchymal cells, and key signaling pathways involved in this regenerative process [10]. The foremost light-based therapy for treating AGA is low-level light therapy (LLLT) [4], which promotes tissue repair, cell proliferation, and stem cell differentiation, known as photobiomodulation [11]. LLLT devices come in four major designs, namely helmets, sport caps, headbands, and combs [12]. Randomized controlled trials of LLLT have been performed [13–16], demonstrating that most patients with alopecia experience noticeable hair regrowth, with only minor side effects and no major adverse effects [4], and several LLLT devices have now been approved by the FDA [12]. However, with LLLT, compliance is an issue. It needs to be used multiple times a week over an extended period, and treatment success relies on consistent usage. In addition to LLLT, studies have also suggested that the 1550-nm fractional erbium glass (Er: glass) laser and fractional carbon dioxide ($FRCO_2$) laser may stimulate hair growth in AGA [4, 17–20], but these interventions have yet to be approved by the FDA for hair loss treatment.

A non-ablative fractional laser (NAFL) with a wavelength of 1565 nm was developed that contains Er: glass fiber laser technology. Initial evaluations of this technology in a preclinical study and a clinical pilot study have demonstrated promising findings [10, 21, 22]. The present study furthers these findings by evaluating the effectiveness and safety of the NAFL for the treatment of non-scarring hair loss and its potential as a treatment for alopecia. Specifically, the objective of this study was to qualitatively evaluate the efficacy of NAFL for the improvement of hair appearance in the scalp area in male and female patients using real-world data.

2 | Methods

This was a single-center, retrospective, observational study (case file review). The Allendale Investigational Review Board (IRB) of Regulatory and Technical Associates Inc. (Connecticut, United States) was responsible for the review of the study protocol and subject rights. As this was a retrospective data collection using deidentified images and deidentified data that had been collected by the study site, the IRB waived the requirement to obtain informed consent and classified the study protocol as exempt from IRB review. Study procedures were performed in accordance with the IRB's ethical standards, the Declaration of Helsinki, and all applicable regulations.

2.1 | Study Procedures

In this retrospective study, case files of all patients who were treated for improvement of scalp hair appearance using the 1565-nm NAFL device (Lumenis, Yokneam, Israel) at LaserMed Clinic (Lublin, Poland) between February 24, 2020, and January 31, 2023, were screened to determine whether they met the inclusion and exclusion criteria of the study (detailed in Section 2.2). Subjects that failed to pass screening were logged as screen failures. For subjects that did pass screening, the following information was collected—clinical history, medical history and medications, and any history related to hair treatments or adverse events (AEs) during the laser treatments. All data that were collected from patient files were deidentified. Case review and data collection were performed by the study's principal investigator (PI) using case report forms (CRFs) that were inserted into an Electronic Data Capture cloud service. The completed CRFs were reviewed by the PI to ensure that all recorded data were accurate and representative of the patients' clinic records.

In addition to data collection, all available macroscopic images of scalp hair were collected from all available time points, including images that were taken before treatment initiation ("before" images) and images taken during and after treatment completion ("after" images), and the dates of the image capture were recorded. Once a full database was available, the images

were reviewed for deidentification—where possible, identifying features such as birth marks or moles that could be removed without interfering with the image of the patient's hairline were removed. Images from cases that passed the initial screening were then reviewed for quality according to three criteria: (1) Completeness: each image was required to include at least the full frontal or full vertex aspects of the scalp. Those images that did not contain full aspects were removed from the analysis. (2) Consistency: before and after images needed to be consistent in terms of position/angle and lighting. Images with significant difference in position, angle, or lighting were removed. In addition, patients with significant differences in the before and after photos with respect to hair length (such as patients who shaved or trimmed their hair) or hair color were also removed. (3) Visibility: images were required to have visibility of sufficient quality without editing or manipulation (e.g., images could not be blurred).

Images that met all quality requirements in terms of completeness, consistency, and visibility were blinded for time points (before or after laser treatment) and included in the blinded review process to assess improvement in scalp hair appearance. This process entailed the adjudication of each set of before and after images by three blinded reviewers who determined which image was taken at baseline (the "before" image) and which image was taken at the follow-up visit (the "after" image). Since AGA has a natural course of deterioration, correct identification of the later image as the improved image suggests that treatment altered the natural course of the condition. Where the reviewer concluded that identifying the correct image was not possible, the case was classified as "failed identification" by the specific reviewer. The sets of images were presented in a randomized internal order, with each reviewer receiving the same presentation, with the images ordered the same way.

2.2 | Inclusion and Exclusion Criteria for Initial Screening

Eligibility of cases for inclusion in the study was assessed in terms of the following inclusion criteria: (1) Subjects that completed a series of at least three NAFL treatments to the scalp for the promotion of hair growth between February 24, 2020, and January 31, 2023; (2) male or female subjects between the ages of 21 and 80 years old; (3) patients complaining of hair loss in the scalp area; (4) each set of images was to include at least an image captured at the baseline visit and an image captured during or after the last treatment The after-treatment photos used for comparison were taken as soon as following the third treatment or at a follow-up visit 6 months later.

Cases were excluded according to the following exclusion criteria: (1) The patient set of images did not include an image captured at baseline and an image captured at the follow-up visit; (2) the patient was treated and completed a series of treatments including a follow-up visit outside of the dates February 24, 2020, to January 31, 2023; (3) the patient received less than three NAFL treatments intended for hair growth; (4) subjects in whom hair loss was due to telogen effluvium, scarring alopecia, alopecia areata, alopecia totalis, or post-pregnancy hair loss (or recent pregnancy); (5) patient record described the use of any of the following medications during laser treatment: finasteride (or any other 5α-reductase inhibitor medications) or minoxidil (topical or systemic); (6) documented active skin infection in the scalp or scarring; (7) dysplastic nevi in the treated area; (8) documented current cancer or has had chemotherapy during the laser treatments.

Although exclusion Criteria 4 could not be assessed in cases that did not include a documented diagnosis for the patient's alopecia, it was decided to include these cases in the analysis set. These cases were also analyzed as a separate subgroup that was referred to as the "unknown type of alopecia" subgroup.

2.3 | Study Endpoints

The study's primary effectiveness endpoint was the percentage of image sets that were correctly categorized by at least two out of three blinded reviewers. Correct categorization was defined by correct identification of the baseline ("before") image and the follow-up ("after") image, that is, success was defined as correct identification of the after image as the image with scalp hair improvement by two or more blinded reviewers. Correct identification of improvement in more than 70% of the cases was considered as evidence for significant clinical improvement. Only patients whose images met the requirements of the quality criteria were evaluated for the primary effectiveness endpoint.

The safety endpoint was AEs or any safety concerns that were documented in the patient files that occurred during the NAFL treatments or follow-up period between February 24, 2020, and January 31, 2023. All included patients were evaluated for the safety endpoint.

2.4 | Data Analysis

Descriptive statistics were employed to analyze the data using SAS statistical analysis software (version 9.4). Continuous variables were summarized by mean, standard deviation (SD) and range, and categorical variables by frequency and percentage. For the primary effectiveness endpoint, the percentage of images categorized correctly as before and after by at least two out of three blinded reviewers was calculated and presented with 95% Wilson score confidence intervals (CIs). Data were analyzed with respect to diagnosis subgroups (AGA and unknown type of alopecia), gender (males and females), and age category subgroups.

3 | Results

A total of 150 cases in the study database were screened, of which 18 (12.0%) did not meet the inclusion or exclusion criteria and were considered screen failures (Figure 1). The screen failures included 10 cases (10/150, 6.7%) in which alopecia was due to an excluded diagnosis, six cases (4.0%) in which patients were not the required age, one case (0.7%) in which images were not available for analysis, and one case (0.7%) in which the patient did not have the minimum number of treatments. Thus, 132 of

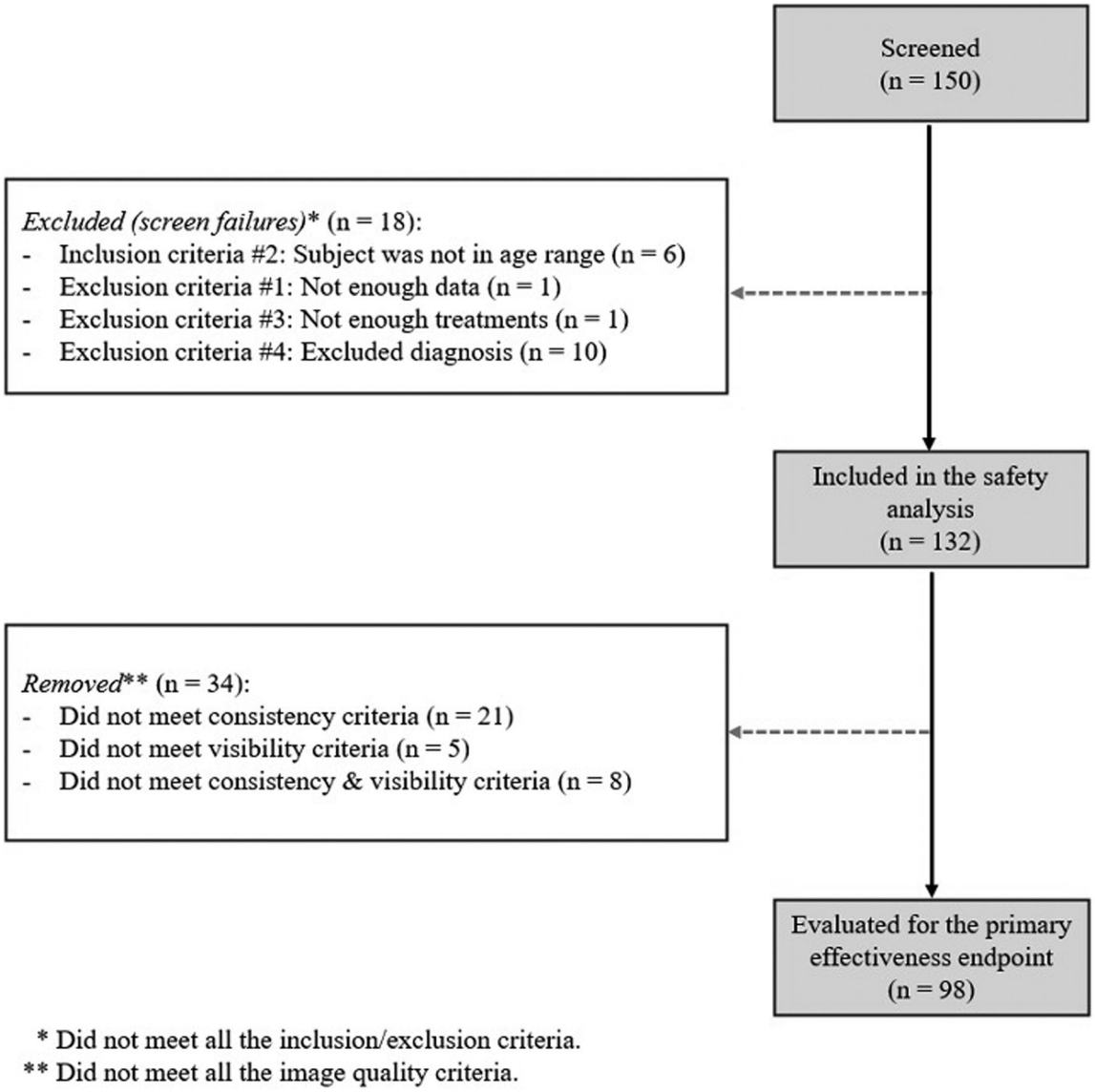

FIGURE 1 | Selection of cases from the study database, yielding 132 cases included in the safety analysis and 98 cases that were evaluated for the primary effectiveness endpoint.

150 cases (88.0%) were included after screening. These 132 cases were assessed for the safety endpoint.

The 132 included cases were then evaluated for image quality. In 34 (25.8%) of these cases, the images did not meet all quality criteria, and the cases were therefore removed from the effectiveness analysis (Figure 1). The cases that were removed comprised 21 (21/132, 15.9%) that did not meet the consistency criteria, five (3.8%) that did not meet the visibility criteria, and eight (6.1%) that did not meet both the consistency and visibility criteria. All images met the completeness criteria. Thus, a total of 98 cases were evaluated for the primary effectiveness endpoint.

3.1 | Patient Demographics and Baseline Characteristics

Patients from the 132 included cases ranged in age from 21 to 80 years (mean ± SD, 38.2 ± 11.5 years), with an equal number of males and females and majority (59.8%) having skin Type III (Table 1). Most patients did not have a medical condition in addition to alopecia (86.4%) and were not taking concomitant medication (96.2%). Only a single patient had previously undergone hair loss treatment. In 57 (43.2%) of the 132 cases, the documented diagnosis was AGA, and in 75 (56.8%), there was no documented diagnosis of the type of alopecia in the clinic records. The demographics and baseline characteristics of these two subgroups (AGA and unknown type of alopecia), as well as the male and female subgroups, were comparable to those in the overall group (Table 1).

The 98 cases that met the image quality criteria included patients who ranged in age from 21 to 66 years (mean ± SD, 37.2 ± 9.9 years), with a roughly comparable number of females and males (52.0% vs. 48.0%, respectively) and majority (61.2%) of patients having skin Type III (Table 1). Like the included cases, most evaluated patients did not have a medical condition (85.7%) and were not taking concomitant medication (95.9%), with only a single patient having previously undergone hair loss treatment. In 44 (44.9%) of the 98 cases, the documented

TABLE 1 | Demographic and baseline characteristics of included and evaluated cases.

Characteristic	Included cases ($n = 132$)	Evaluated cases ($n = 98$)
Age (years)		
Mean (SD)	38.2 (11.5)	37.2 (9.9)
Min, max	21, 80	21, 66
Gender, *n* (%)		
Female	66 (50.0%)	51 (52.0%)
Male	66 (50.0%)	47 (48.0%)
Skin type, *n* (%)		
I	0	0
II	26 (19.7%)	18 (18.4%)
III	79 (59.8%)	60 (61.2%)
IV	3 (2.3%)	1 (1.0%)
V	0	0
VI	0	0
Not specified	24 (18.2%)	19 (19.4%)
Diagnosis, *n* (%)		
Androgenetic alopecia	57 (43.2%)	44 (44.9%)
Unknown type of alopecia	75 (56.8%)	54 (55.1%)
Medical conditions in addition to alopecia, *n* (%)		
Endocrine: Hashimoto	6 (4.5%)	4 (4.1%)
Endocrine: Insulin resistance	5 (3.8%)	5 (5.1%)
Endocrine: Hypothyroidism	4 (3.0%)	3 (3.1%)
Endocrine: PCOS	2 (1.5%)	2 (2.0%)
Dermatological: Psoriasis	1 (0.8%)	0
None	114 (86.4%)	84 (85.7%)
Concomitant medications, *n* (%)		
Euthyrox 50 mg	3 (2.3%)	2 (2.0%)
Glucophage 1500 mg	1 (0.8%)	1 (1.0%)
Letrox, metformin	1 (0.8%)	1 (1.0%)
None	127 (96.2%)	94 (95.9%)
Previous treatments, *n* (%)		
Hair transplant	1 (0.8%)	1 (1.0%)
None	131 (99.2%)	97 (99.0%)

Note: Included cases are cases that met all the inclusion/exclusion criteria and were assessed for the safety endpoint. Evaluated cases are cases that met the image quality criteria in addition to the inclusion/exclusion criteria and were analyzed for the primary effectiveness endpoint.
Abbreviations: mg, milligrams; PCOS, polycystic ovary syndrome; SD, standard deviation.

diagnosis was AGA, and in 54 (55.1%), there was no documented diagnosis of the type of alopecia in the clinic records. The demographics and baseline characteristics of these two subgroups (AGA and unknown type of alopecia), as well as the male and female subgroups, were comparable to the overall group (Table 1).

3.2 | Hair Loss Treatments

All hair loss treatments utilized irradiance up to 2.76e7 W/cm^2 and shape size up to 52.6 mm^2. Most of the 132 included patients underwent either three ($n = 74$, 56.1%) or four ($n = 39$, 29.5%) treatments, whereas a smaller number received five ($n = 9$, 6.8%) or six ($n = 10$, 7.6%) treatments.

In the AGA subgroup, 27 (27/54, 50%) of the patients underwent 3 treatments, 20 (20/54, 37%) underwent 4 treatments, and a smaller number received 5 (4/54, 7.4%) or 6 (6/54, 11.1%) treatments. Similarly, in the unknown type of alopecia subgroup ($n = 75$), most patients underwent three ($n = 47$, 62.7%) or four ($n = 19$, 25.3%) treatments, with only five patients (6.7%) and four patients (5.3%) undergoing five and six treatments, respectively. Likewise, most male patients underwent three treatments (32/66, 48.5%) or four treatments ($n = 24$, 36.4%), with four (6.1%) undergoing five treatments and six (9.1%) undergoing six treatments (Figures 2 and 3). Among females, 42 of 66 (63.6%) patients underwent three treatments, 15 (22.7%) underwent four treatments, five (7.6%) underwent five treatments, and four (6.1%) underwent six treatments (Figure 4).

3.3 | Effectiveness Assessment

The rate of correct categorization of "before" and "after" images in the evaluated cases was high, with Reviewer 1 being correct in 94.9% (93/98) of cases and Reviewers 2 and 3 being correct in 87.8% (86/98) of cases each. There were only three cases with incorrect categorization, resulting in an overall success rate of 96.9% (95% CI: 91.4%–98.5%) (Table 2).

In the evaluated cases in the AGA subgroup, only a single case was not correctly categorized, yielding a success rate of 97.7% (95% CI: 87.8%–99.7%) (Table 2). A similar success rate of 96.3% (95% CI: 84.7%–99.2%) was evident in the unknown type of alopecia subgroup. Likewise, success rates over 95% were found in the male and female subgroups (97.9% [95% CI: 91.1%–99.7%] and 96.1% [95% CI: 82.5%–99.2%], respectively). The lowest success rate was obtained in the youngest age group 21–30 years with 86.9% (95% CI: 66.4%–97.2%), for all other age groups success rate was 100%.

3.4 | Safety Assessment

There were no recorded AEs or safety concerns in the clinic records among all 132 included cases during the study period (February 24, 2020, to January 31, 2023).

4 | Discussion

This single-center, retrospective, observational study evaluated the effectiveness and safety of a 1565-nm NAFL for the improvement

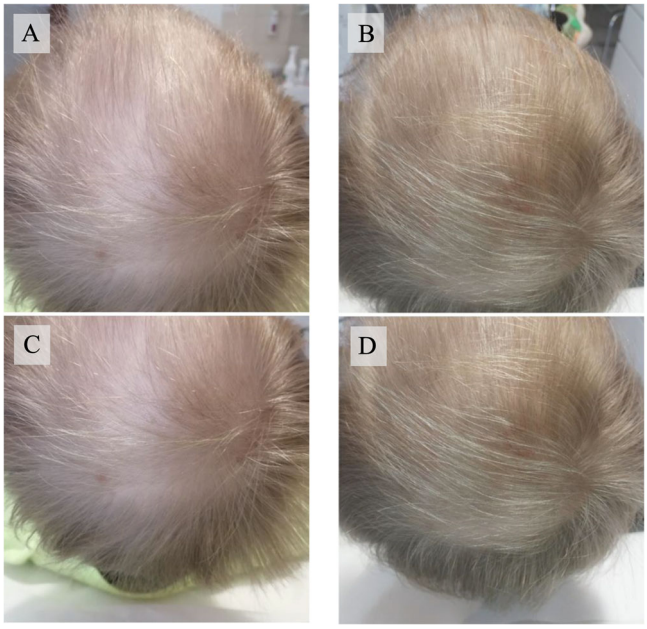

FIGURE 2 | (A, C) Global photography of a male patient before NAFL laser treatment. (B, D) Global photography following three sessions of NAFL laser treatment demonstrating visible hair growth. In this case, the image marked as (C) is the same as the image marked as (A), only at a magnified perspective. The same goes for (D) and (B), respectively.

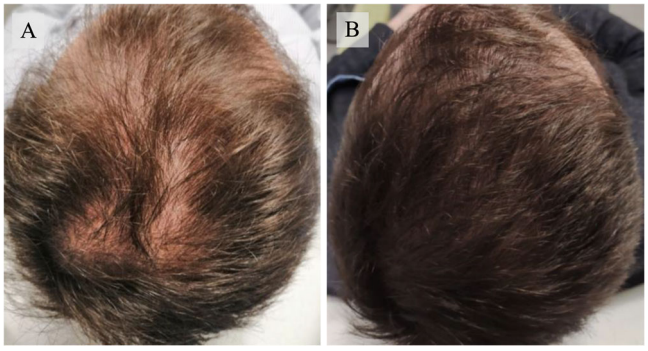

FIGURE 3 | (A) Global photography of a male patient before NAFL laser treatment. (B) Global photography following four sessions of NAFL laser treatment demonstrating visible hair growth.

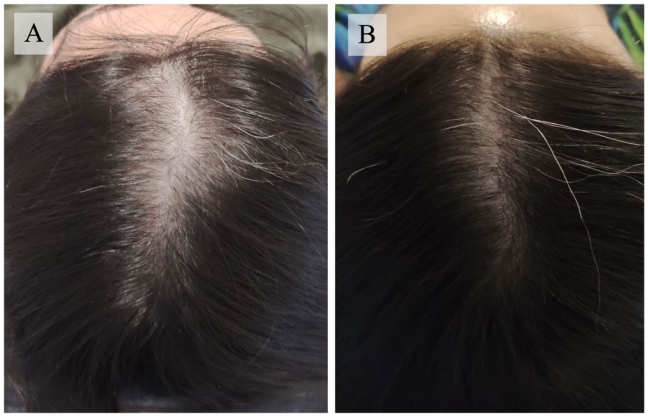

FIGURE 4 | (A) Global photography of a female patient before NAFL laser treatment. (B) Global photography following three sessions of NAFL laser treatment demonstrating visible hair growth.

TABLE 2 | Primary effectiveness endpoint—The percentage of images categorized correctly as before and after by at least two out of three blinded reviewers.

	% (*n*/*N*)	95% CI (Wilson score)
Overall	96.9% (95/98)	[91.4%–98.5%]
Diagnosis		
Androgenetic alopecia	97.7% (43/44)	[87.8%–99.7%]
Unknown type of alopecia	96.3% (52/54)	[84.7%–99.2%]
Gender		
Female	96.1% (49/51)	[82.5%–99.2%]
Male	97.9% (46/47)	[91.1%–99.7%]
Age group		
21–30	86.9% (20/23)	[66.4%–97.2%]
31–40	100% (36/36)	[90.2%–100%]
41–50	100% (33/33)	[89.4%–100%]
51–60	100% (2/2)	[15.8%–100%]
61–70	100% (4/4)	[39.7%–100%]

Abbreviation: CI, confidence interval.

of hair appearance in the scalp area. The overall success rate of identification of hair density improvement following NAFL laser treatment in 98 evaluated patients was 96.9% and was similarly high (> 95%) among the evaluated subgroups (AGA, unknown type of alopecia, males, and females). The lower limit of the two-sided CIs overall and for all evaluated subgroups was above 70% (Table 2), providing evidence for significant clinical improvement. With regard to safety, no adverse reactions were reported among the 132 included patients during or following the laser treatment. Thus, the 1565-nm NAFL appears to be effective and safe for the treatment of alopecia, improving scalp hair appearance for both genders.

Management of AGA remains challenging due to its chronic nature, multifactorial etiology, and the wide array of treatment options—many of which lack FDA approval [23]. Current therapies include topical and oral medications, procedural interventions such as PRP and LLLT, and surgical options like hair transplantation [24]. However, these modalities have notable limitations. For example, oral and topical agents require continuous use and may cause systemic or local side effects, while PRP and LLLT demand consistent compliance and may involve discomfort or variability in preparation protocols.

The 1565-nm NAFL presents a promising alternative. Compared to existing modalities, it offers an improved side effect profile, minimal discomfort, and lower patient burden due to the absence of daily treatment requirements [25]. Compared to PRP, NAFL does not involve injections or blood draws, and unlike LLLT, it does not require ongoing, frequent at-home sessions. In contrast to ablative fractional lasers, NAFL preserves the epidermal surface and minimizes tissue disruption, combining the safety of non-ablative technologies with the efficacy benefits of fractional delivery [26, 27]. Of note, like

other in-office treatments, it would be expected for patients to receive ongoing maintenance with one laser treatment every 6–9 months if responding positively.

The biological mechanisms underlying the observed improvements remain under investigation. It is hypothesized that NAFL may exert its effects through low-grade thermal injury that induces dermal remodeling, enhances local blood flow, or activates follicular stem cell populations [25]. Although these mechanisms remain speculative, they align with growing evidence suggesting that controlled dermal injury can trigger regenerative pathways relevant to hair follicle stimulation.

A key strength of this study is its relatively large sample size (98 patients in the effectiveness cohort and 132 in the safety cohort) compared to other NAFL studies of alopecia or other esthetic indications, which typically have fewer than 30 study participants [28–31]. This study thus contributes to valuable real-world evidence for the clinical use of this technology. Indeed, the device received FDA clearance after the study's completion, and the 1565-nm NAFL is now the first and only cleared fractional laser technology for the treatment of hair loss [32].

That said, several limitations warrant consideration. This study was retrospective in design and relied on available clinic data. Additional limitations include the absence of a control group, reliance on subjective image-based assessments rather than objective trichoscopic measurements, and the lack of long-term follow-up data to assess the durability of results. As well, patients using minoxidil and finasteride were explicitly excluded from the study, but alternative treatments were not necessarily excluded (PRP, LLLT, etc.). Although the role of these alternative treatments was not a focus of this retrospective review, future studies could explore these aspects in more detail. Notably, a significant proportion of patients lacked a documented diagnosis of alopecia type. Given that AGA is the most common form of alopecia in both men and women [3, 23], it is likely that many of these patients were experiencing AGA. The primary endpoint was met both in the overall cohort and within subgroups, further supporting the robustness of the findings.

5 | Conclusions

This study demonstrates that the 1565-nm NAFL is a safe and effective modality for promoting an overall global increase in hair density and improving overall scalp hair appearance, particularly in patients with AGA. The absence of AEs supports the favorable safety profile of NAFL, while the high rate of accurate identification of posttreatment images by blinded reviewers validates its clinical efficacy. In comparison to existing treatment options, NAFL offers distinct advantages—including minimal discomfort, no need for daily adherence, and the absence of systemic side effects—positioning it as a compelling noninvasive alternative in the management of hair loss.

Ethics Statement

The Allendale Investigational Review Board (IRB) of Regulatory and Technical Associates Inc. (Connecticut, United States) was responsible for the review of the study protocol and subject rights. As this was a retrospective data collection using deidentified images and deidentified data that were previously collected by the study site, the IRB waived to the requirement to obtain informed consent requirements and classified the study protocol as exempt from IRB review. Study procedures were performed in accordance with the IRB's ethical standards, the Declaration of Helsinki, and all applicable regulations.

Conflicts of Interest

Dr. Munavalli is a clinical investigator for Lumenis Inc. Dr. Shapiro is a consultant and investigator for Pfizer, Lilly, Eirion, and 30 Madison. Dr. Avram is a consultant for Lumenis Ltd. Dr. Dawn Queen declares no conflicts of interest. No other financial relationships or personal connections relevant to the content of this manuscript exist among the authors. No external funding was received for this work. All authors had full access to the data and accept responsibility for the integrity of the analysis and reporting.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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