

NEW LOW-LEVEL-LIGHT-BASED DEVICE FOR MAXIMAL HAIR REGROWTH EFFICACY

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1 INTRODUCTION

Androgenetic alopecia (AGA) is a common disorder in adult men related to perifollicular inflammation and resulting in hair-loss. High concentration Minoxidil 5% is known to be reference for the treatment of hair loss in AGA. However, the rate of responders is 30-40% of its users, and its performance is limited in inflammatory scalps. In this context we proposed a new approach using a novel anti-inflammatory LLLBD (Low-Level-Light Based Device) with short application time, 70 s in combination with lower concentration of Minoxidil 2%.

2 MATERIALS AND METHODS

LLLBD: LEDs-based device emitting specifically pulsed light at 590 nm as predominant wavelength and 870 nm as secondary wavelength is used once a day for 70 s only. It is an upgraded version of the GentleWaves® technology evaluated for rejuvenation, photo-aging signs and post procedure therapy.

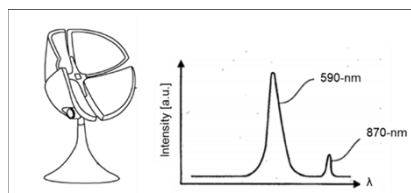


Figure 1. Drawing of the novel Low-Level-Light-Based-Device and its spectrum of emission (cfr. EP2912509B1, EP2861203B1).

CLINICAL STUDY DESIGN: Single-center-controlled, randomized-open study (PhotoTrichoGram, and clinical evaluation of hair-loss in blind), on alopecic male volunteers graded Hamilton II-III vertex. Each treatment with the LLLBD consisted of daily exposure of 0.1 J/cm², during 70 seconds. 120 of 133 healthy male Caucasians (20-50 y.o.) completed the study. 50 received full-head of the new LLLBD once daily and used Minoxidil 2% twice daily; 50 used Minoxidil 5% twice daily, for 5 consecutive days per week, during 6 months, 20 didn't receive any treatment (control group).

EVALUATION: Intra-subject and intergroup comparison were performed.

1. Change in hair density (mean hair density, Telogen and Anagen hair density, Telogen rate and Anagen hair) was measured by PTG method after 1.5, 3, 4 and 6 months.
2. Change in hair-loss parameters was evaluated by clinician and by subjects at the end of the study on photographs using 7-point scale. Tolerance also was monitored during the study.

This concept is based on the results of a previous clinical study where we demonstrated that the GentleWaves®-LLLBD has down-regulation of light on both CD69+ cells and pro-inflammatory genes and miRNA expression is observed following only three successive 70 s daily sessions of GentleWaves®-LLLBD treatment.

4 CONCLUSIONS

We propose a new routine with a short application time (70 s) of Low-Level-Light-Based-Device that in combination with lower concentration Minoxidil 2%

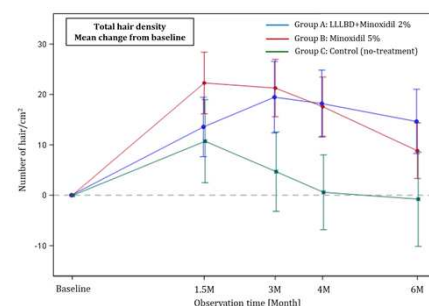
- shortens the application time of LLLBD (up to 25 minutes for other devices).
- reduces the undesired features of Minoxidil using a lower concentration 2%, hence increasing the tolerance of Minoxidil, and
- brings short-term visible performance along with the long-term performance of Minoxidil of at least same level as Minoxidil 5%.

These aspects are all crucially important to ensure users' observance, and such, the combination LLLBD+Minoxidil 2% has a great potential as a cosmetic routine that raises users' compliance. This novel LLLBD with short application time (70 s) can be proposed also for cosmetic face disorders improvement, such as oily skin, texture, shininess.

3 RESULTS & DISCUSSION

Hair density: PTG showed statistical equivalence of hair density between LLLBD+Minoxidil 2% and Minoxidil 5% alone from 3 months (-1.4%) up to 6 months (-1.7%). PTG is in agreement with the efficacy perceived by clinician and volunteers. No adverse effects were reported.

1. PTG evaluation by clinician: Mean change from Baseline of the total number of hair per cm² using PTG. Two groups vs untreated Minoxidil 2% twice daily in combination to LLLBD single daily application, Minoxidil 5% alone twice daily. (Figure 2)



2. PTG volunteers' self evaluation. Mean values of self-assessment using a 7-point scale was used (-3: greatly decreased, -2: moderately, -1: slightly 0: no change, 1: slightly increased, 2: moderately, 3: greatly). (Figure 3)

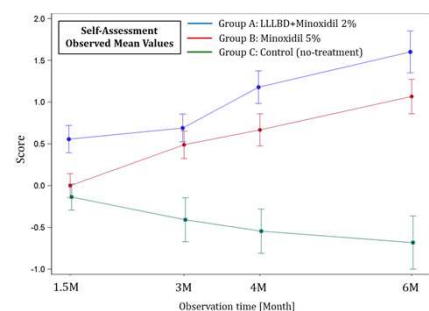


Figure 4. Representative picture of group LLLBD+Minoxidil 2%. Visible increase of hair density of the central line was measured as +4.94% at 1.5 months, +7.33% at 3 months, +6.82% at 4 months, and +5.22% at 6 months.

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