Low-level laser therapy for the treatment of androgenetic alopecia in Thai men and women: a 24-week, randomized, double-blind, sham device-controlled trial

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Introduction

Androgenetic alopecia (AGA) is a common hair loss disorder in both men and women. Patients with AGA commonly report a negative psychological impact on the quality of life. Only 2 medications currently have US Food and Drug Administration (FDA)–approved indications: oral finasteride and topical minoxidil. However, patients experiencing a poor response or unacceptable side effects are in need of additional treatment options. Low-level laser/light therapy (LLLT) has been increasingly used as an alternative treatment for AGA.

LLLT generally utilizes non-thermal effects of low intensity light at red or near-infrared wavelengths to alter biological activity in cells. Several studies have supported its benefits as a novel treatment option for hair loss. LLLT appears to stimulate anagen reentry of telogen hair follicles and prolong the duration of anagen phase. LLT devices use coherent diode lasers, incoherent LEDs, or a combination of both as the source of light in the wavelength range of 650–900 nm. “RAMACAP” is a new model of portable helmet-type LLLT device with full scalp coverage and working hands free. The purpose of this study was to assess its efficacy and safety for the treatment of AGA in both men and women.

Figure 1. RAMACAP, a helmet-type portable LLLT device containing 224 red diode laser bulbs (660 nm)

Figure 2. Baseline and week 24 global photographs of laser helmet-treated patients

Materials and Methods

Study design

A 24-week, prospective, randomized, double-blind, sham device-controlled clinical trial was conducted. Men with AGA type III vertex, IV, and V, and women with FPHL classified as type I, II, and III by the Ludwig classification were eligible for the study.

The exclusion criteria included use of topical or systemic drugs with hair growth-promoting properties within 6 months, a history of hair transplantation, and patients with a scalp or systemic disease that may affect hair growth.

Intervention

RAMACAP is a combat helmet-shaped device containing single-mode laser diodes, which emit at the wavelength of 660 ± 10 nm (Figure 1). A power density of 3.5 mW/cm^2 with an illumination time of 19.04 min is required to deliver a fluence of 4 J/cm^2 was used in this study.

Subjects were randomized into experimental and control groups. Laser and sham devices were identical in appearance with the exception of the light source. The sham device contained 224 red LED pods emitting 0.5 mW of power at the wavelength of 650 ± 20 nm. Subjects were instructed to use an assigned device at home for 20 min per session, three times per week, over a 24-week period.

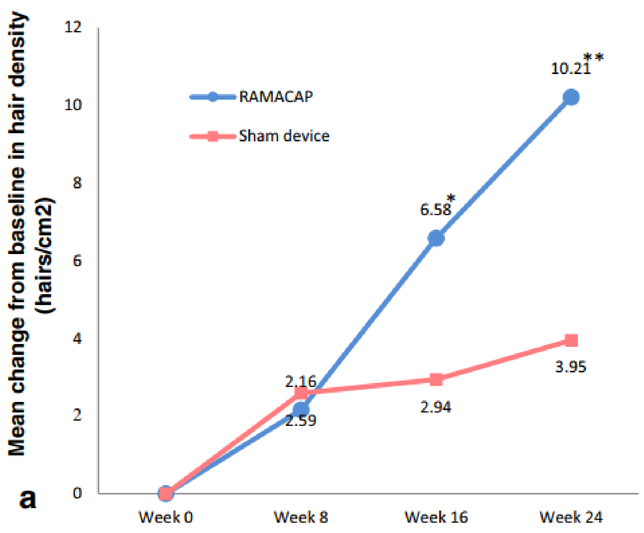
Assessments

The primary endpoint

- The change from baseline in hair density and diameter at weeks 8, 16, and 24, by photographing with a Folliscope® (LeadM Corporation, Seoul, Korea).

Secondary endpoints

- Global photographic assessment (GPA) for hair regrowth by 3 blinded dermatologists and subjects.
- Global photographs were assessed based on 7-point rating scale (- 3 = marked deterioration, - 2 = moderate deterioration, - 1 = mild deterioration, 0 = no change, 1 = mild improvement, 2 = moderate improvement, 3 = marked improvement).
- Adverse events.



Results

A total of 40 subjects (20 men and 20 women) were enrolled to this study. Thirty-six patients completed the study. (experimental group 19 subjects and control group 17 subjects)

Examples of global photographs of laser device-treated subjects are shown in Figure 2. At week 24, the laser device was significantly superior to the sham device for increasing hair density and hair diameter ($p = 0.002$ and $p = 0.009$, respectively; Figure 3).

For GPA after 24 weeks, experimental group showed a significantly greater improvement in hair regrowth compared with control group for both investigators’ evaluation and subjects’ self-assessment.

Reported side effects included temporary hair shedding and scalp pruritus.

Conclusion

This study demonstrated superiority of RAMACAP over the sham device by significantly increasing in hair density and hair diameter after 24 weeks. Analysis of GPA data also showed a significantly greater improvement in laser helmet-treated patients by both investigator and subject scores. No serious adverse events were reported throughout the study period.

The main limitations of this study are the small number of subjects and no long-term follow-up data. A large randomized controlled trial with a longer study period is needed.

To conclude, RAMACAP appears to be an effective treatment option for AGA without age and gender restrictions.

Figure 3. The mean change from baseline in hair density (a) and hair diameter (b) at weeks 8, 16, and 24 of laser helmet-treated patients and sham device-treated patients. *p = 0.001, **p = 0.002; †p = 0.009

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