Clinical Efficacy of an At-Home, 620 and 660 nm Red Light Treatment on Scalp Pruritus and Irritation

Mark S. Nestor[1], Brian Berman[2], Rodney Sinclair[3], Nicholas Medendorp[4], Matt Womble[4], Nathan Stasko[4]

[1] Center for Clinical and Cosmetic Research, Department of Surgery, Division of Plastic and Reconstructive Surgery, Department of Dermatology and Cutaneous Surgery, University of Miami Miller School Of Medicine, Miami, FL [2] Center for Clinical and Cosmetic Research, Department of Dermatology and Cutaneous Surgery, University of Miami Miller School Of Medicine, Miami, FL [3] Department of Dermatology, University of Melbourne, East Melbourne, Australia [4] PhotonMD Inc., Durham, North Carolina (nstasko@photonmd.com)

Introduction

Scalp burning, stinging and pruritus are common patient complaints in the dermatological setting and can be frustrating for both the patient and the Dermatologist. Indeed, the prevalence of pruritus of the scalp is up to 45% of patients with chronic pruritus.[1] These symptoms are often associated with conditions such as seborrheic dermatitis and scalp psoriasis, where up to 80% of patients with psoriasis report scalp itch with a positive correlation between the severity of the lesions and severity of itch,[2] but these symptoms also may appear without any clinical findings. Treatment options for scalp disorders and associated symptoms include topical corticosteroids and, in some cases, anti-fungals, but the wide variety of underlying disease pathologies and limited compliance with dosing regimens hinder their clinical benefit.

Indeed, patients with androgenetic alopecia often complain of scalp itch and irritation and may also have concomitant seborrheic dermatitis. Based on this, the symptoms of pruritus, irritation, burning of the scalp were measured in an ongoing multicenter study evaluating the safety and efficacy of a dual wavelength LED light device in subjects being treated with androgenetic alopecia.

Methods

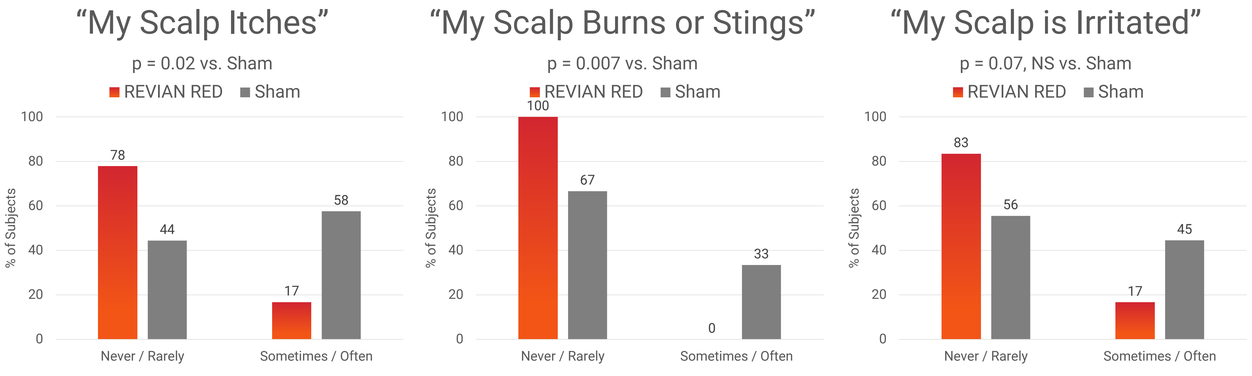
Eighty-one subjects were randomized to either a dual wavelength 620 nm and 660 nm light therapy device paired with a Bluetooth-connected mobile app (REVIAN RED System) or to a sham comparator device with a similar user experience through the mobile app to track daily treatment compliance between both groups. Device usage was fixed at once daily, 10-minute treatment durations for a period of 26-weeks. The trial population consisted of adult men and women between 18 and 65 years of age with a diagnosis of androgenetic alopecia, consistent with males who have Norwood Hamilton Classification IIa to V patterns of hair loss and females who have Ludwig-Savin Scale I-1 to I-4, II -1, II-2 or frontal, both with Fitzpatrick Skin Types I - IV.

The Hair Specific Skindex-29 Quality of Life Questionnaire (HSSQOL) was used to assess Itching, Burning/Stinging, Irritation, and other patient reported outcomes. Participants scored each question on a scale from 1 (never) to 5 (all the time).

Results

SECONDARY EFFICACY Assessment - Hair Specific Skindex-29 QOL At Week 16

The Hair Specific Skindex-29 Quality of Life Questionnaire (HSSQOL) is a 29-item questionnaire with 3 domains: 7 questions for symptoms domain, 10 questions for emotion domain and 12 questions for function domain. The Hair Specific Skindex 29 Quality of Life Questionnaire (HSSQOL) is a 29 item questionnaire with 3 domains: 7 questions for symptoms domain, 10 questions for emotion domain and 12 questions for function domain. Specifically, for the symptom of "my scalp burns or stings", at the end of the 16-week trial 100% of the active treated group showed never or rarely having the symptom versus 66.6% of the sham group and 0% of the active group reported the symptoms sometime or often versus 33.4% of the sham treated group (p= 0.007). For the symptom of "my scalp itches" (pruritus), 77.8% of the active treatment group and 44% of the sham treated group reported the symptom never or rarely versus 16.7% of the active group and 57.6% of the sham treaty group reporting the symptom sometime or often (p=0.02) Finally regarding my scalp is irritated 83.4% of the active treatment group and 55.5% of the sham treated group reported the symptom never or rarely versus 16.6% of the active treated group and 44.5% of the sham treat a group reported the symptoms sometime or often (P=0.07)



P-values calculated using a Chi-Square Test for the between group comparison of combined categories "Never/Rarely" versus "Sometimes/Often."

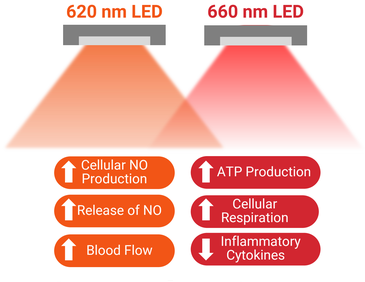
Proposed Mechanism of Action

Red and Infrared Low Level Light Therapy (LLLT) has previously been shown to have anti-inflammatory effects in patients with plaque psoriasis, leading to clearance of recalcitrant lesions[3] and reductions in plaque desquamation, induration, and erythema.[4] The addition of 620 nm LED light results in increased release of nitric oxide (NO) in the skin and provides a complimentary mechanism to reduce inflammation, irritation and pruritus.

Immunomodulatory Modes of Action Associated with Nitric Oxide[5]

- Decreased Production of IL-1β
- Decreased Production of IL-17
- Decreased E-Selection Expression on Endothelial Cells
- Regulation of Matrix Metalloproteinase Activity

Dual Wavelength **620 nm** and **660 nm** Light Stimulates Nitric Oxide Production & Decreases Inflammation



References

1. Matterne et al. (2011) Prevalence, correlates and characteristics of chronic pruritus: A population based cross-sectional study. Acta Dermato-Venereologica 91: 674–679.
2. Kim et al. (2014) Clinical characteristics of pruritus in patients with scalp psoriasis and their relation with intraepidermal nerve fiber density. Ann Dermatol 26: 727-732
3. Ablon G. (2010) Combination 830nm and 633nm light-emitting diode phototherapy shows promise in the treatment of recalcitrant psoriasis: preliminary findings. Photomed Laser Surg 28:141–146
4. Kleinpenning et al. (2012) Efficacy of blue light vs. red light in the treatment of psoriasis: a double-blind, randomized comparative study. J Eur Acad Dermatol Venereol 26: 219–225
5. Del Rosso JQ, Kircik L (2017) Spotlight on the Use of Nitric Oxide in Dermatology: What Is It? What Does It Do? Can It Become an Important Addition to the Therapeutic Armamentarium for Skin Disease? J Drugs Dermatol 16 (1 Suppl 1):s4-10.

Conclusion

The FDA-cleared dual wavelength device (K173729) was found to be safe and well tolerated, with statistically significant differences observed in patient reported pruritus and burning/stinging compared to sham after 16 wks of once daily, at home treatment.

The MOA for improved scalp symptoms are proposed to be a combination of the benefits of traditional anti-inflammatory and antipruritic effects of red (660 nm) LLLT and the anti-inflammatory effects of nitric oxide (NO) released with 620 nm light.

The authors are unaware of any previous reports of a reduction in scalp pruritus with traditional LLLT devices used to treat androgenetic alopecia. Independent, well controlled studies are warranted to confirm these findings for the broader population of individuals suffering from itch and irritation symptoms associated with scalp conditions such as seborrheic dermatitis or psoriasis.

1500-000042

This trial was sponsored by REVIAN, Inc.