650 NM PULSED DIODE LASER ARRAY, CAPILLUS272®, LOW LEVEL LASER THERAPY DEVICE FOR THE TREATMENT OF ANDROGENETIC ALOPECIA IN FEMALES: A CASE REPORT OF TWO SUBJECTS

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Case report selected from an ongoing prospective study that is evaluating the application of a LLLT device for the treatment of Androgenetic Alopecia.

INTRODUCTION

The objective of this study was to evaluate the effectiveness of the Capillus 272, pulsed, diode laser system for the treatment of Androgenetic Alopecia. This is a prospective, randomized, placebo-controlled, double blind study with 44 subjects enrolled. Two subjects were selected from the first group to complete the 17 weeks of therapy, for preliminary reporting of outcome data. The following is the report of this activity. The Capillus 272 is a laser diode device, that incorporates 272 , 5-milliwatt laser diodes into the design. This laser class is IIIR by international and FDA standards. The red light diodes operate at 650 nanometers, +/- 5 nanometers.

TREATMENT PROTOCOL

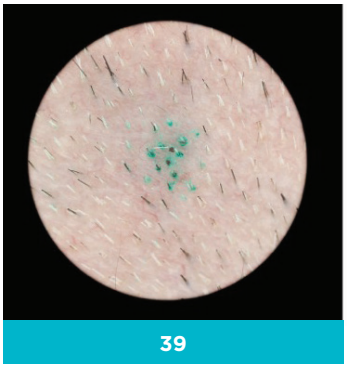
The area selected for treatment and monitoring, was the central vertex area of the scalp. After enrollment was completed by the physician investigator, a designated area of approximately 19mm was clipped uniformly to a length of 3 mm and the center of the area was tattooed with a permanent green ink, utilizing a commercially available decorative tattoo gun. Each subject was provided with a test device, unspecified as to active or placebo. Pre-treatment photographs were taken by a professional photographer, with a proprietary SLR camera, macro lens and standardized formatting lens adapter. The subject was instructed on the proper use and care of the device and directed to use it every other day, at home, for 30 minutes, for 17-weeks. The fluence delivered is 1.775j/cm2 and the total energy delivered in 30 minutes is 1379.04 joules. Monitoring for compliance was managed by an independent third party. The subject was called once per month. At the completion of the 17th week of treatment, the subject returned to the investigation site for clipping and post- treatment photography.

SUBJECT 1. GREAT NECK SITE

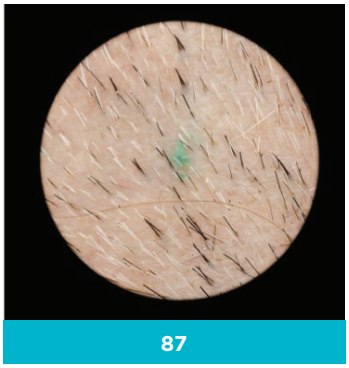
A 53 year-old Caucasian female, Fitzpatrick skin phototype III, Ludwig-Savin 1-3, with a history of androgenetic alopecia hair loss that has been associated with peri-menopausal activity, was entered into the study. This subject was enrolled into the active test device group. After 17-weeks of compliant home use, treatments she returned for her final photography and release from the trial.

PRIMARY RESPONSE

The formatted photographs were submitted for terminal hair counting. In the pre-treatment image, 39 terminal hairs were counted. In the post-treatment image 87 terminal hairs were counted. This demonstrates a 123% increase in terminal hairs, from baseline.



39



87

SUBJECT 2. WOODBURY SITE

A 49 year-old Caucasian female, Fitzpatrick skin phototype II, Ludwig-Savin 1-1, with a history of androgenetic apolecia that has been associated with peri-menopausal activity, was entered into the study. This subject was enrolled into the active test device group. After 17-weeks of compliant home use, treatments she returned for her final photography and release from the trial.

PRIMARY RESPONSE

The formatted photographs were submitted for terminal hair counting. In the pre-treatment image, 97 terminal hairs were counted. In the post-treatment image 153 terminal hairs were counted. This demonstrates a 57% increase in terminal hairs, from baseline.

97

153

CONCLUSION

These results suggest that the emerging technology of Low Level Laser Therapy may play a potentially significant role in the physicians' armamentarium of therapies for the disease Androgenetic Alopecia. The full report on the clinical study of 44 subjects will provide further and more detailed data on this technology.

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