Visible Red Light Laser and LED Sources to Grow Human Scalp Hair in Males and Females
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Background and Objectives: The application of low-level laser therapy has aroused considerable research interest in recent years for the treatment of a variety of clinical indications. These range from pain management to wound healing and most recently to hair regrowth. All have demonstrated biological effects in living organisms. In 1967 Endre Mester, a physician practicing in Budapest Hungary, decided to test the effects of laser radiation on mice and its possible link to resultant cancer. To his great surprise, the mice regrew the shaved hair in half the time of non-radiated mice. This was the first reference to LLLT and hair growth.

Low level laser (light) therapy (LLLT) offers an alternative to systemic treatment of androgenic alopecia that may carry a risk of adverse events, to surgical treatment in the form of hair transplantation, and to topical treatments that require ongoing application. This double-blind, placebo-controlled trial sought to evaluate the efficacy of using LLLT in the management of androgenic alopecia in both males and females.

Methods: Twenty-three females (aged 18 to 60) and 17 males (aged 18 to 48) were recruited to participate in the study. A crown scalp site that was in transition was selected. Hairs of subjects were cut to 2 millimeter height, and the target area was tattooed and photographed. The

experimental group received an actual commercial iRestore Hair Growth System currently sold internationally, containing 21, 5mW diode lasers (650 nanometer plus or minus 5 nm) and 30 LEDs (650 nanometer plus or minus 20 nm). The placebo or sham group were exposed to a red, incandescent light source that appeared identical. Subjects were self-treated at home every other day for 16 weeks, on non-consecutive days (56 treatments, 5 milli-watts of optical energy for a 25-minute treatment -255 milli-watts,). Subjects were photographed at the end of the treatment period. Another blinded investigator assessed a masked 19.5mm circle, photographic area.

Results: A total of 39 subjects completed the study. One patient did not make their final visit. There were no adverse events or side effects reported. Investigators counted incremental terminal hairs but not vellus hairs. Subjects who underwent active treatment experienced an average increase of 43.23% in terminal hairs from baseline to end of treatment while subjects in the sham group experienced an average increase of 5.71% in terminal hair counts from baseline to end of treatment, yielding an overall incremental improvement of 37.52% in the active treatment group as compared to the placebo group.

Conclusions: Treatment of the scalp using 650 nanometer was well-tolerated and resulted in significant improvements in hair counts in men and women with androgenic alopecia.

CLINICAL KEYPOINTS:

- A variety of medical treatments and surgery have been used to treat androgenic alopecia. The condition is more common in men but affects a significant proportion of women in their lifetime.
- Conventional treatment in dermatology offices has been topical minoxidil and the anti-androgen finasteride. Other medical treatments that have been initiated for androgenic alopecia include dutasteride and the anti-fungal agent ketoconazole. Hair transplantation is reserved as a surgical option.
- The iRestore™ Hair Growth System is an FDA-510(k) Cleared, for men and women, non-invasive option to manage androgenic alopecia that can be offered in the

convenience of a patient's home. iRestore is produced by a GMP-certified manufacturer through processes that meet the highest standards for quality, performance and safety– certified to be compliant and audited by Intertek Testing Services.

TABLE 1. Subjects, Treatment Assignments and Hair Counts

Subject	Active	Placebo	Baseline Count	Post-treatment Count
1	x		104	145
2	x		44	48
3	x		78	99
4	x		250	329
5	x		153	208
6	x		107	142
7	x		112	199
8	x		282	301
9	x		157	224
10	x		205	346
11	x		267	409
12	x		75	161
13	x		312	357
14	x		197	226
15	x		57	102
16	x		228	251
17	x		111	151
18	x		316	422
19	x		201	334
20	x		108	185
21		x	146	144
22		x	101	112
23		x	226	221
24		x	196	238
25		x	292	Dropout
26		x	194	242
27		x	153	151
28		x	201	206
29		x	232	238
30		x	263	285
31		x	411	426
32		x	276	252

33		x	123	138
34		x	146	158
35		x	319	333
36		x	167	182
37		x	195	190
38		x	284	299
39		x	301	360
40		x	222	204

Figure 1.

Pre-treatment photograph of scalp on the left. Post-treatment photo of the scalp on the right. A 78.95% increase in terminal hairs occurred from baseline to end of treatment. (see below)

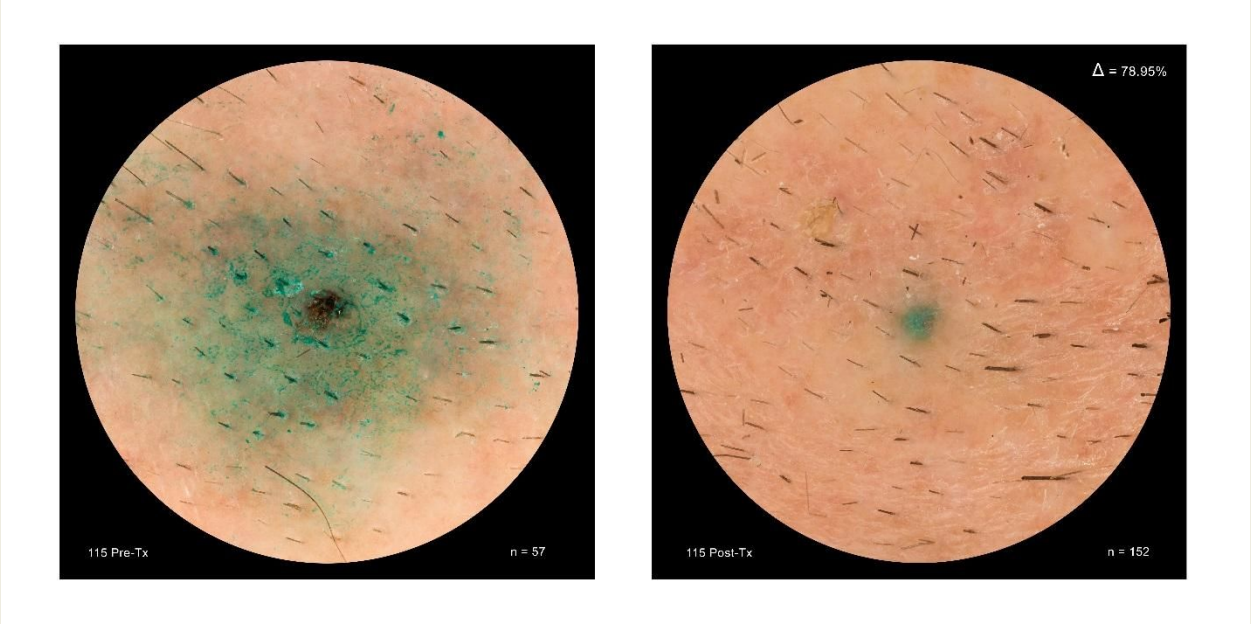


Figure 2.

Pre-treatment photograph of scalp on the left. Post-treatment photo of the scalp on the right. There was a 1.31% decrease in terminal hairs from baseline to end of treatment. (see below).



