Novel Approach to Treating Androgenetic Alopecia in Females With Photobiomodulation (Low-Level Laser Therapy)

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BACKGROUND Photobiomodulation, also referred to as low-level laser therapy (LLLT), has been studied and used for (among other diseases) the promotion of hair regrowth.

OBJECTIVE/MATERIALS AND METHODS/RESULTS A clinical study was developed to define the physiologic effects that occur when the human hair follicle and surrounding tissue structures are exposed to laser light using a novel device that is fitted with an array of laser diode sources operating at 650 nm and placed inside a sports cap to promote discretion while in use. The study demonstrates that low-level laser treatment of the scalp every other day for 17 weeks using the HANDI-DOME LASER device is a safe and effective treatment for androgenetic alopecia in healthy females between the ages of 18 to 60 with Fitzpatrick skin Types I to IV and Ludwig–Savin Baldness Scale I-2 to II-2 baldness patterns. Subjects receiving LLLT at 650 nm achieved a 51% increase in hair counts as compared with sham-treated control patients in this multicenter randomized controlled trial.

CONCLUSION These results suggest that the emerging technology of low-level laser therapy may play a potentially significant role in health care providers' armamentarium for the disease androgenic alopecia.

Supported by Capillus, the manufacturer of the laser cap described. The authors have indicated no significant interest with commercial supporters. Protocol #USC650—ClinicalTrials.gov.

Photobiomodulation, also referred to as low-level laser therapy (LLLT), has been studied and used for the treatment of a variety of clinical indications,[1–21] including the promotion of hair regrowth.[22–38] Each of these applications is based on the biological effects of photobiomodulation in living organisms.[1–21]

The potential application of photobiomodulation to stimulate hair growth can be traced to Endre Mester, a physician practicing in Budapest, Hungary.[22,23] Mester discovered that mice treated with lasers regrew their shaved hair in half the time of non-radiated mice (during experiments conducted while trying to repeat McGuff's experiment to cure cancer in mice with a ruby laser). His 1967 study was the first reference to LLLT and hair growth. Other investigators noted that paradoxical hair growth sometimes occurred at the periphery of areas treated with lasers for hair removal or adjacent to lesions treated with laser sources.[24–26]

These observations led to laboratory and clinical investigations on the effects and applications of LLLT in male and female pattern hair loss.[27–36] In January, 2007, the Food and Drug Administration granted the first clearance for a device indicated for use in treating males diagnosed with androgenic alopecia (AGA) and with Fitzpatrick I to IV skin types.[32,35] In 2010, the category was expanded to treat females diagnosed with genetic hair loss based on the results of a randomized clinical trial.[37]

A clinical study was developed to define the safety and physiologic effects that occur when the human hair follicle and surrounding tissue structures are exposed to laser light using a novel device that is fitted with an

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array of laser diode sources operating at 650 nm and placed inside a sports cap to promote discretion while in use. The present report details the results obtained for the USC650 study.

Materials and Methods

A clinical study was conducted as per the institutional review board–approved USC650 protocol (Essex IRB, Lebanon, NJ). Forty-four healthy female volunteers, aged 18 to 60 years, were recruited at 2 institutional review board–approved treatment sites.

Informed consent was obtained, and patients were screened to verify that they met the inclusion and exclusion criteria for the study (Appendix 1). History and physical examinations were conducted. All 44 patients had Fitzpatrick skin Types I to IV and Ludwig–Savin Baldness Scale I to II hair loss patterns (I-2, I-3, I-4, II-1, and II-2). An area of the scalp was selected in a transition zone at the vertex of the scalp at a site determined by the investigator and based on the individual patient's hair loss pattern. The hairs in the selected site were trimmed to a maximum height of 3 mm in an area that was approximately 2.5 cm in diameter. The area was marked with a medical tattoo using green ink and aseptic technique.

The site was then photographed using a custom camera apparatus specifically configured for this purpose. (The apparatus consisted of a Canon Rebel T3i 18 Megapixel camera system equipped with a Tamron 60 mm f/2 Macro lens with 1:1 magnification. A 55-mm Lens attachment ring was used to affix a Promaster RL60 LED Ring Light.) The camera system was then mounted to a custom-made stand-off device, which was then manually positioned onto the scalp surface by the investigator each time photographs were taken. Images were taken with the tattoo positioned in the center of the frame.

These baseline images were coded and then forwarded to the photographic consultant. The photographic consultant verified that the images were of acceptable quality and processed the images for transmission to the investigator responsible for conducting the hair counts. The transmitted images were masked using a black mask to produce a 1.9-cm diameter circle centered on the tattoo, which provided a consistent 2.85 cm^2 area for hair counts.

Neither the photographic consultant nor the investigator performing the hair counts was aware of the identity of the subject or the subjects' study group assignment. One baseline photograph per participant was submitted for counting.

Patients were randomly assigned to active or placebo treatment groups. Each subject received a numbered dome laser unit which was distributed to her by the project manager, who also provided the patients with instructions for the care and use of the device.

Neither the patients, the treating physicians at the clinical sites, the photographic consultant, nor the investigator performing the hair counts was aware whether the device was a therapeutic (active) or a functioning placebo (sham) device.

The dome laser is shown in Figure 1. The investigational devices did not have any corporate logos or other identifiers with the exception of a study investigational device number (Figure 1A). An identifying number was assigned to each dome, which was then recorded in a device log that contained the code for placebo and actual test unit reference. This log was not revealed to any investigator, subject, office staff, hair counter, or sponsor employee.

The laser (active) group received a dome laser unit. This is a low-level diode laser device, operating at 650 nm, that contains 272, 5-mW diode lasers, affixed in a low-profile sport style hat. Each subject self-treated at home for 30 min/treatment every other day for 17 weeks (60 treatments [maximum] 1,360 mW total delivered energy over 582 cm^2 or 2.34 mW/cm^2). The device provided pulsed illumination on a 6.92 Hz duty cycle over the scalp covered by the device.

The placebo or sham group received a unit that was identical in appearance and function to the active treatment group devices, with the exception that the light sources were incandescent (painted) red lights that mimicked the appearance and configuration of

Figure 1. Dome laser device: (A) exterior view of device and controller; (B) interior view of an active unit; and (C) interior view of active device during operation.

the functioning device. Again, each subject in the sham group self-treated at home for 30 min/treatment, every other day for 17 weeks (60 treatments with delivered [scattered] light in the visible light range [painted incandescent bulbs] indicating a [maximum] 1,360 mW total delivered energy over 582 cm^2 or 2.34 mW/cm^2). The device provided pulsed illumination on a 6.92 Hz duty cycle over the scalp covered by the device.

The subject's head is self-positioned within the device (which is covered by a sport cap), such that a proximity sensor triggers the start of therapy. The light reaches the subject's scalp through a clear inner liner positioned inside the dome. Treatment duration is approximately 30 minutes. The lasers (lights) automatically shut off, after the treatment session is complete. User function consists of a rocker switch on the hand controller/battery pack that is actuated by the user (press on/off). The battery pack is charged using a charger plugged into a standard 120 V outlet. The user has only to press the on switch. All other functions are automatic. There is no before or after treatment care required, only that subjects' hair must be clean and not contain spray or gel fixative agents. No safety eyewear is required during the treatment session. A complete demonstration of the proper use of the dome was provided to each subject at the time the test units were distributed. Periodic subject monitoring was conducted by telephone. Subjects were queried relative to their use of the device and for any possible side effects or adverse events.

All patients who completed the study exchanged their investigational dome laser unit for a fully functional, production commercial system.

Data analysis was conducted by a consulting statistician, who was provided the raw data and who was blinded as to the identity of the subjects or their individual treatments. The primary endpoint for evaluation was the percent increase in hair counts from baseline at the end of 17 weeks of treatment. The percent increase from baseline is the obtained by the following formula:

TABLE 1. Subjects, Treatment Assignments, and Study

Site	*Sham (Placebo)*	*Active (Laser)*	*Total*
1	7	12	19
2	15	10	25
Total	22	22	44

$$x = 100 \times \frac{(\text{End Count} - \text{Baseline Count})}{\text{Baseline Count}}$$

An analysis of variance was done with site, treatment group, and site treatment group comparisons in the model. The data did not indicate a statistically significant difference in data between the sites. Therefore, the data were pooled across both sites to arrive at an estimate of the effect for the primary endpoint. Univariate tests comparing the sham and laser groups were performed by 2-sided Wilcoxon rank-sum tests, and an unequal variance *t* test was performed.

Results/Statistical Analysis

Study Site Subject Distribution

The study was a blinded multicenter study. The study subjects were allocated to active treatment or sham on a 1:1 basis at each of 2 study sites. The distribution of study subjects by random treatment assignment and study site are given in Table 1 below.

A total of 44 patients were enrolled in the study and completed baseline screening. There were 19 active treatment patients and 21 sham patients available for analysis at the end of the study after 17 weeks of treatment. There were no reported side effects or adverse events reported by any subject or site at any time during the conduct of the study.

Hair Counts and Photography

The area of treatment was the vertex of the scalp. Photographs of the area being treated were taken

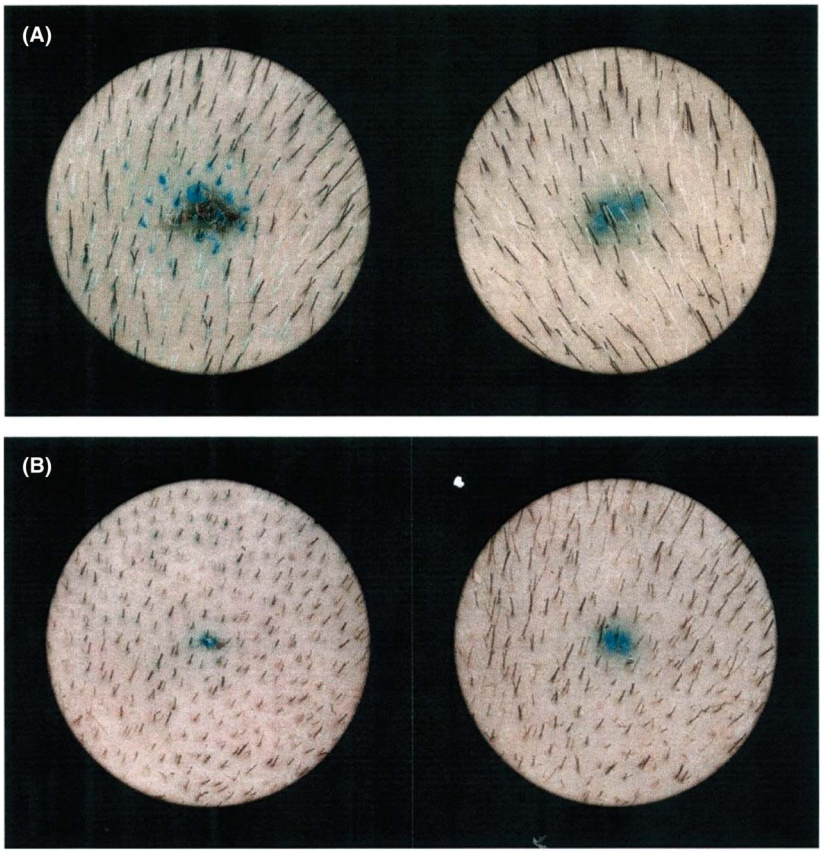

Figure 2. Sham treatment group subject before and after treatment image example: (A) before and after treatment and (B) before and after treatment.

before any therapy treatment being performed by the subject (baseline) and photographs were taken of the treated area after the final light treatment had been performed (final). There were no interim office visits during the 17-week trial. The photographic site was comprised an area on the vertex that was approximately 25 mm in diameter, and all hairs in this area were trimmed to a length not to exceed 3 mm to enhance counting by an evaluator blinded to treatment assignment.

Examples of baseline (before treatment) and final (after treatment) images are presented in Figures 2 and 3. Note that these images are provided for informational and illustrational purposes only and are not intended to be used as evaluative data. Figure 2 demonstrates examples for 2 patients in the placebo or sham group. Note that there is minimal change in the 17-week study interval. Figure 3 demonstrates examples of baseline and final images for 2 subjects in the active treatment group. Note that there is a significant increase in the number of terminal hairs present in these examples.

Hair counts for Subject A were 137 at baseline and 135 after treatment. Hair counts for Subject B were 142 at baseline and 141 after treatment.

Hair counts for Subject A were 108 at baseline and 198 after treatment. Hair counts for Subject B were 123 at baseline and 356 after treatment.

Baseline Demographic Characteristics

There was information gathered on 3 important demographic characteristics, subject age, subject Fitzpatrick skin type, and Ludwig–Savin Baldness Scale. The results of these characteristics by treatment group are presented in Table 2 below.

Note that age was not statistically significant by treatment group nor was it significant by study site ($p = .083$).

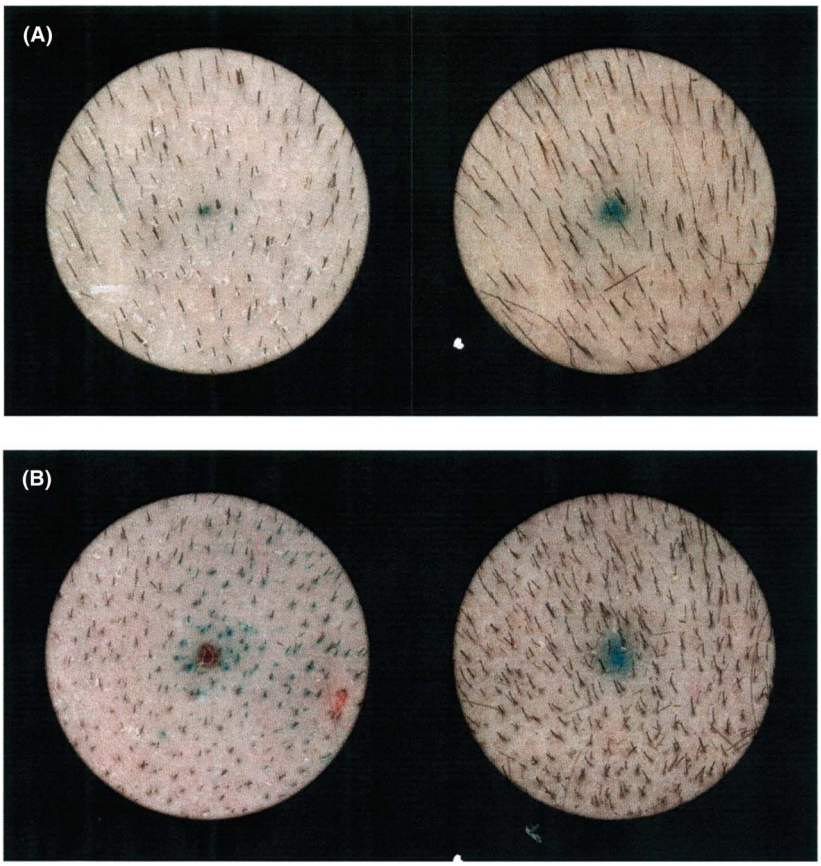

Figure 3. Active treatment group subject before and after treatment image example: before and after treatment and (B) before and after treatment.

TABLE 2. Baseline Demographic Characteristics by Treatment Group

Characteristic	*Sham*	*Active*	*p*
Age			.656
Mean (SD), *N*	47.05 (11.62), 22	48.41 (5.25), 22	
Med (min, max)	49 (28, 60)	49.5 (28, 58)	
Hair color x/*n* (%)			.058
Black	2/22 (9.09)	0/22 (0.00)	
Blonde	1/22 (4.55)	0/22 (0.00)	
Brown	13/22 (59.09)	11/22 (50.00)	
Dark brown	1/22 (4.55)	5/22 (22.73)	
Light brown	2/22 (9.09)	6/22 (27.27)	
Medium brown	1/22 (4.55)	0/22 (0.00)	
Red brown	2/22 (9.09)	0/22 (0.00)	
Fitzpatrick skin type x/*n* (%)			1.000
1	0/22 (0.00)	0/22 (16.67)	
2	4/22 (18.18)	5/22 (22.73)	
3	17/22 (77.27)	17/22 (77.27)	
4	1/22 (4.55)	0/22 (8.33)	
Ludwig–Savin Baldness Scale x/*n* (%)			.227
I	8/22 (36.36)	13/22 (59.09)	
II	14/22 (63.64)	9/22 (40.91)	

Max, maximum; Min, minimum; SD, standard deviation.

Neither Fitzpatrick skin type nor the Ludwig–Savin Baldness Scale differed by treatment group. Study sites did not differ by hair color ($p = .275$) but differed by Fitzpatrick skin type ($p < .013$) and by Ludwig–Savin Baldness Scale ($p < .001$). In pooling analysis below, study site is put into a multivariable model to see if it affects the primary endpoint.

Baseline Hair Counts

The analyses reported below were conducted in Minitab 16. The raw data for these analyses appear in Appendix 2. The baseline hair counts by treatment group and study site are presented in Table 3 below.

The study sites do not differ in baseline hair counts and the treatment groups do not differ.

Primary Analysis

The primary endpoint is the percent increase in hair counts from baseline at the end of 17 weeks of treatment. The percent increase from baseline is the obtained by the following formula.

TABLE 3. Baseline Hair Counts of Vertex Scalp Site

Site	*Sham*	*Active*	*p*
1			.373*
Mean (SD), *N*	220.0 (74.42), 7	188.5 (71.26), 12	
Med (min, max)	195 (137, 335)	200.0 (39, 305)	
2			.605*
Mean (SD), *N*	215.4 (124.38), 15	190.3 (104.78), 10	
Med (min, max)	196.0 (21, 502)	181.5 (39, 379)	
p	.929*	.962*	—

*Two-sided unequal variance *t* test.
Max, maximum; Min, minimum; SD, standard deviation.

$$x = 100 \times \frac{(\text{End Count} - \text{Baseline Count})}{\text{Baseline Count}}$$

A data pooling analysis was done to determine whether there is a site by treatment interaction in the percent increase. If the interaction between site and treatment was significant with a $p < .15$, there would be evidence of a site by treatment interaction that would require weighting the site results to obtain an estimate of the study effect. An analysis of variance was performed with only site, treatment group, and site by treatment group interaction in the model, and the interaction was not statistically significant ($p = 0.190$). Note that 3 subjects in the active arm and 1 in the sham arm were found to never have begun therapy or were not forthcoming with the monitor about the use of the device and would not return for final clipping and photography. These subjects were deleted from the analysis.

Univariate tests comparing the sham and laser groups were intended to be by Wilcoxon rank-sum tests unless the variance between the 2 groups was statistically significantly different. In that case, the comparison was conducted by an unequal variance *t* test. The relevant data for this analysis appears in Table 4 below.

These data indicate that the univariate result comparing the increase in hair counts was statistically significant ($p < .001$). Thus, the results indicate that low-level laser treatment for 17 weeks increases mean hair counts by approximately 51%.

A multivariable analysis accounting for baseline differences in study site and treatment group without interaction indicated that the study site had a significant impact on the percent change from baseline ($p = .036$) but the treatment effect was still statistically significant ($p < .001$). So, the study site differences in percent change from baseline did not modify the effect of treatment on the percent increase in hair counts after treatment.

A second supportive multivariable analysis used baseline count as a covariate and in that analysis, the baseline term was significant ($p = .003$), treatment was highly significant ($p < .001$), and study site was statistically significant ($p = .024$). Furthermore, when age, Fitzpatrick type, and Ludwig–Savin Baldness Scale were included in a third sensitivity model, none were statistically significant with *p* value of .268, .397, and .268, respectively, with site, baseline count, and treatment included in the model. Thus, the univariate result is confirmed by the multivariable analysis with laser treatment term in the model with statistical significance unchanged from the univariate analysis ($p < .001$). These data indicate that low-level laser

TABLE 4. Baseline Hair Counts, End of Study Hair Counts, and Percent Increase by Treatment Group

Variable	*Sham*	*Active (Laser)*	*p*
Baseline			.500*
Mean (SD), *N*	216.9 (109.1), 22	189.3 (85.8), 22	
Med (min, max)	195.5 (21, 502)	195.5 (39, 379)	
After treatment			.377*
Mean (SD), *N*	235.3 (105.8), 21	268.3 (117.7), 19	
Med (min, max)	225.0 (28, 499)	275.0 (87, 559)	
Difference from baseline			.001†
Mean (SD), *N*	18.5 (24.4), 21	89.9 (63.3), 19	
Med (min, max)	22.0 (−23, 62)	65.0 (28, 234)	
Percent increase			.001†
Mean (SD), *N*	12.48 (13.76), 21	63.67 (50.9), 19	
Med (min, max)	12.69 (−6.87, 37.2)	48.4 (11.2, 189.4)	

*Two-sided Wilcoxon rank-sum test.
†Two-sided unequal variance *t* test.
Max, maximum; Min, minimum; SD, standard deviation.

treatment of the scalp every other day for 30 minutes for 17 weeks improved the percent increase from baseline by 51% in females.

Adjustment for differences in baseline counts by study site and demographic variables by treatment did not change the statistical significance observed in the univariate analysis of the primary endpoint. The increase in percent hair growth in women using the active device was confirmed. No adverse events were reported by study participants. Factoring the results and the absence of reported adverse events, the device is considered safe and effective.

Results

Specifically, there was a 51% increase in terminal hair counts in the laser group as compared to the control or sham treatment group ($p < .001$) in female patients who were aged 18 to 60 years and had I-2 to II-2 Ludwig–Savin Baldness Scale baldness patterns and were of Fitzpatrick skin Types I to IV.

This study demonstrates that the use of LLLT at 650 nm as applied to the scalp every other day for 17 weeks (60 treatments) using the dome laser device resulted in a significant improvement in female patients who used the device. Representative active treatment group subject before and after treatment images are presented in Figures 4 and 5.

Primary Response (Subject A, Site 1)

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

Primary Response (Subject B, Site 2)

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

All the patients in this female study were able to apply and use the device as directed to self-administer their treatments at home. There were no side effects or adverse events reported by any of the study subjects at any time during the conduct of the study. This indicates that the device is safe for the unsupervised environment of home use.

This study, conducted by a neutral third party for Capillus, LLC, demonstrates that low-level laser treatment of the scalp every other day for 17 weeks using the Capillus272 Pro device is a safe and effective treatment for androgenetic alopecia. ClinicalTrials.gov Identifier: NCT01967277.

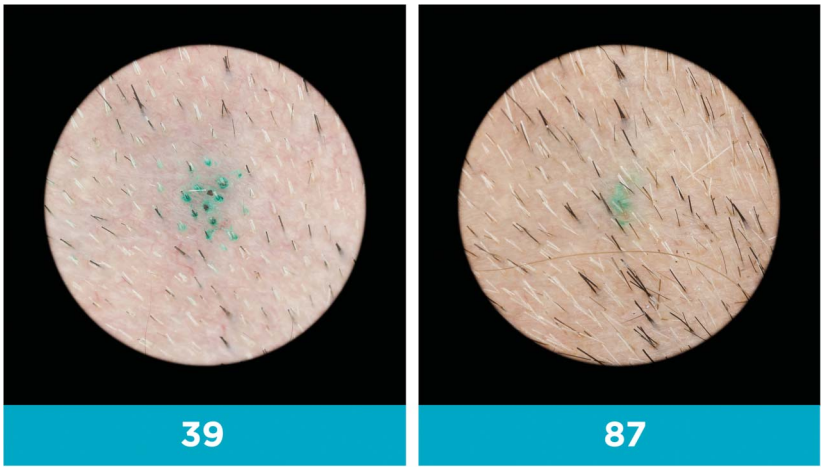

Figure 4. A 53-year-old white female, Fitzpatrick skin phototype III, Ludwig–Savin Baldness Scale 1-3, with a history of androgenetic alopecia. This subject was enrolled into the active test device group. After 17 weeks of compliant home-use treatments, she returned for her final photography and release from the trial (Subject A, Site 1).

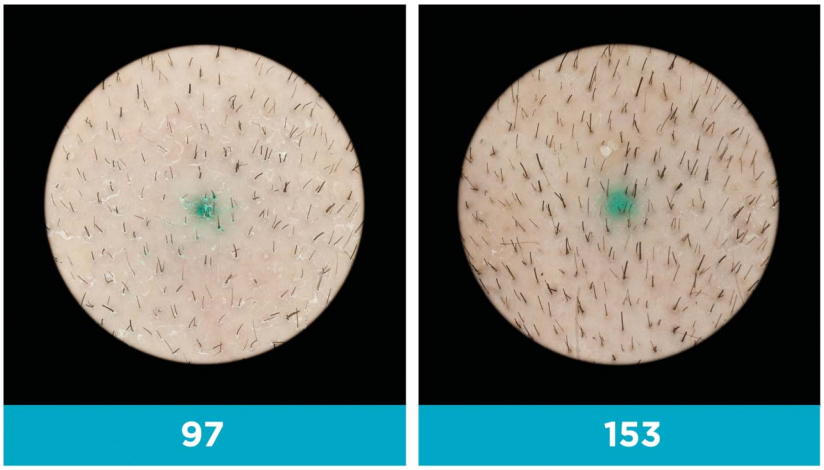

Figure 5. A 49-year-old white female, Fitzpatrick skin phototype II, Ludwig–Savin Baldness Scale 1-1, with a history of androgenetic alopecia. This subject was enrolled into the active test device group. After 17 weeks of compliant home-use treatments, she returned for her final photography and release from the trial (Subject B, Site 2).

Discussion

Various investigators have studied a variety of light sources, wavelengths, and treatment parameters for the treatment of alopecia with LLLT.[27–30,32,33,35–38] Most of these reports on the efficacy of LLLT for alopecia have been prospective, uncontrolled, open-label studies and have not been confirmed by multicenter, randomized, double-blind, controlled trials.[27–30,33,35–38]

This study used a randomized, double-blind design and used a true placebo using a device that was identical in appearance to the active device, with incandescent sources that glowed red but did not deliver coherent light to the subject's scalp. Treatments were passive and did not depend on the user for delivery, aside from the subject placing the unit on the scalp and activating the controller. This differs from the device studies that required the user to comb the scalp for a specified treatment time and used a placebo device that was readily distinguished by the fact that it was a white light source.[27–29,32,35,38]

Hair growth after exposure to LLLT alone is not sufficient to document that photobiomodulation has occurred. Increases in hair counts were also observed in the sham or placebo group in this study. These observations may represent a true placebo effect because the sham device did not deliver thermal energy or collimated light at scalp level. However, other explanations might also include seasonal variations in hair growth or other factors. This makes it important to include placebo and sham treatments in the study design and to conduct the investigation in such a manner as to minimize selection bias.

Several investigators have studied the effects of LLLT on hair growth in animal models.[22,23,32,35,38] Paradoxical hair growth after light-based hair removal and other treatments in human subjects has also been observed with various laser and intense pulsed light sources.[24–26,30]

The theory that is widely accepted is that LLLT, particularly at wavelengths in the red range as was used in this investigation, affects the functioning of the stem cells that cause hair growth. Photobiomodulation activates cytochrome c oxidase and increases mitochondrial electron transport,[11–17] which leads to an increase in adenosine triphosphate and subsequent reversal of hair follicles from the dormant telogen stage of growth, to the active growth or anagen stage.[27,28,30–32,34,35,38] However, the optimal wavelengths and treatment parameters remain indeterminate at this time. This shortcoming has been underscored in the recent review of LLLT to promote hair growth by Avci and colleagues.[38] This study was not designed to investigate alternative treatment regimens or parameters.

Are Men and Women Created Equal?

The final part of this discussion addresses sex; specifically, the question whether there is a difference between men and women with regard to the physical function of hair regrowth. This study recruited women; however, there is no published empirical evidence or reference regarding hair regrowth as a sex-specific function, other than pattern; i.e., the form in which hair is lost. (No articles or evidence was discovered during research and investigation for this article.) There is no scientific article postulating that there is a difference in the physical function of hair growth for men versus that for women. Industry opinion indicates that overall thinning is more prevalent in women, and "receding hairline" or "monk's spot" are more common in men; however, for external strategies for regrowth (i.e., LLLT), there are no published differences in industry literature. Finally, in the clinical trials for LLLT devices reviewed for this article, the treatment regimen between sexes is the same.

There is also a lack of published data specifically regarding the treatment (or difference in treatment) of androgenetic alopecia in women versus men; this very lack of such discussion gives credence to the argument that there is no difference. The discussions regarding sex are generally focused on the differences between the patterns of hair loss, and the increased likelihood that for women, hair loss is often attributable to reasons other than genetics (e.g., underlying medical cause such as thyroid disease).

References identified during research for this article regarding treatment difference between men and women were limited to the use of drugs and topicals which target specific hormones; the use of these drugs and/or topicals do present differently between the sexes. When asked, hair restoration physicians and specialists stated that with regard to LLLT, they prescribe essentially the same treatment regimen for men and women who present with androgenetic alopecia. There is no difference with regard to the physical function of hair regrowth, other than the normal differences found in individuals; that is, treatment regimen is adjusted by physician prescription based on each individual's needs, not specific to sex.

Conclusion

This study demonstrates that low-level laser treatment of the scalp every other day for 17 weeks using the dome laser device is a safe and effective treatment of androgenetic alopecia in healthy females between the ages of 18 to 60 with Fitzpatrick skin Types I to IV and Ludwig–Savin Baldness Scale I-2 to II-2 baldness patterns. Subjects receiving LLLT at 650 nm achieved a 51% increase in hair counts as compared to sham-treated control patients in this multicenter randomized controlled trial.

These results suggest that the emerging technology of low-level laser therapy may play a potentially significant role in health care providers' armamentarium for the disease AGA.

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Appendix 1. Subject Selection Criteria for USC650 Study

- Female subjects experiencing any type of hair loss, thinning hair, or androgenetic alopecia, who have a diagnosis of Ludwig–Savin Baldness Scale I or II grade of hair loss.
- Subjects having a Fitzpatrick skin phototypes of I to IV will be included.
- The total number of subjects being recruited is 44 females.
- Age range is 18 to 60 years.
- Apparent good health.
- No previous involvement in other hair studies.
- No use of any hair growth agent within the last 4 weeks.
- Subjects may continue with normal haircuts, coloring, and permanents.
- No evidence of any current viral, fungal, or bacterial infection.
- Hair must be clean and not contain spray or gel fixative agents.
- Subjects may not be pregnant or breastfeeding. No urine pregnancy test will be required.
- Must be willing to have a small section of hair cut to approximately 1/8 inch (3 mm height).

Appendix 2. Raw Hair Counts by Study Site and Treatment Group

*Subject**	*Site*	*Site ID*	*Trtmt*	*BL-Count*	*Pst-Count*	*Diff*	*Pct-diff*	*Age, yrs*	*Hair Color*	*Ftptrck Tpe*	*Ldwg Scl*
1	1	1-1	Active	224				47	Brown	II	II
2	1	1-2	Active	179	325	146	81.56	41	Brown	III	II
3	1	1-3	Active	39	87	48	123.08	53	Med Brown	II	II
4	1	1-4	Active	96	148	52	54.17	52	Red Brown	II	II
5	1	1-5	Active	218	287	69	31.65	47	Lt Brown	II	II
6	1	1-6	Active	247				55	Brown	III	I
7	1	1-7	Active	305	358	53	17.38	47	Brown	III	I
8	1	1-8	Active	141	170	29	20.57	53	Blonde	III	I
9	1	1-9	Active	185	234	49	26.49	57	Brown	III	II
10	1	1-20	Active	174	245	71	40.80	48	Black	III	I
11	1	1-21	Active	215	275	60	27.91	58	Brown	III	I
12	1	1-22	Active	239	298	59	24.69	53	Dk Brown	III	I
13	2	2-10	Active	97	146	49	50.51	28	Brown	III	II
14	2	2-11	Active	39	104	65	166.67	58	Brown	III	I
15	2	2-12	Active	249	277	28	11.25	32	Brown	III	I
16	2	2-13	Active	123	356	233	189.43	46	Lt Brown	III	I
17	2	2-14	Active	108	198	90	83.33	45	Brown	III	I
18	2	2-15	Active	304				57	Brown	III	I
19	2	2-16	Active	206	440	234	113.59	56	Brown	III	I
20	2	2-17	Active	379	559	180	47.49	44	Brown	III	I
21	2	2-18	Active	241	358	117	48.55	37	Brown	II	II
22	2	2-19	Active	157	233	76	48.41	51	Brown	III	II
23	1	1-23	Sham	178	203	25	14.044	60	Med Brown	II	II
24	1	1-24	Sham	137	135	−2	−1.460	51	Red Brown	II	II
25	1	1-25	Sham	219				55	Lt Brown	II	II
26	1	1-26	Sham	167	192	25	14.97	51	Brown	III	I
27	1	1-27	Sham	335	312	−23	−6.87	27	Brown	III	I
28	1	1-28	Sham	195	229	34	17.44	47	Blonde	III	I
29	1	1-29	Sham	309	305	−4	−1.29	59	Brown	III	II
30	2	2-30	Sham	219	215	−4	−1.83	53	Black	III	I
31	2	2-31	Sham	187	224	37	19.79	46	Brown	III	I
32	2	2-32	Sham	164	225	61	37.20	46	Dk Brown	III	I
33	2	2-33	Sham	163	213	50	30.67	54	Brown	III	II
34	2	2-34	Sham	247	244	−3	−1.21	28	Brown	III	I
35	2	2-35	Sham	323	364	41	12.69	23	Brown	III	I
36	2	2-36	Sham	196	258	62	31.63	52	Lt Brown	III	I
37	2	2-37	Sham	34	37	3	8.82	60	Brown	III	I
38	2	2-38	Sham	21	28	7	33.33	49	Brown	III	I
39	2	2-39	Sham	221	243	22	9.95	49	Brown	III	I
40	2	2-40	Sham	142	166	24	16.90	22	Brown	III	I
41	2	2-41	Sham	273	279	6	2.20	48	Brown	II	II
42	2	2-42	Sham	392	381	−11	−2.81	46	Brown	III	II
43	2	2-47	Sham	502	499	−3	−0.60	49	Med Brown	II	II
44	2	2-44	Sham	147	189	42	28.57	60	Red Brown	II	II

Pct-diff is the percent hair increase (decrease) at 17 weeks as a percent of baseline as defined in the report. Three subjects refused to return for the 17-week assessment at Site 2. Diff = Pst-Count − BL-Count.

*Patient numbers were grouped for convenience not by the order of presentation.

BL, baseline count; Diff, difference = postcount minus baseline count; Dk, dark; ID, identification assigned; Ldwg Scl, Ludwig–Savin Baldness Scale; Lt, light; Med, medium; Pct-diff, percent hair increase (decrease); Pst-Count, hair count after 17 weeks of treatment; Trtmt, treatment.