

Permanent Hair Reduction With a Home-Use Diode Laser: Safety and Effectiveness 1 Year After Eight Treatments

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Background and Objectives: To evaluate the safety and efficacy of a home-use hair removal diode laser (TRIA Beauty, Inc., Dublin, CA) in a multiple treatment regimen.

Study Design/Materials and Methods: Thirteen indicated adults with naturally brown or black hair and Fitzpatrick skin type I–IV received 8 monthly treatments with the diode laser at three fluences, with a fourth area left untreated as a control. Quantitative hair counts were made at each treatment visit and periodically for 12 months after the last treatment.

Results: The treated sites exhibited statistically significant hair count reduction that generally increased with each treatment and remained stable during the 1 year follow-up period. The mean percent hair count reduction was 47%, 55%, and 73% at 1 month after the last treatment and 44%, 49%, and 65% at 12 months after the last treatment at fluences of 7, 12, and 20 J/cm², respectively, compared to control. Eighty-six percent (86%) of subjects had greater than 30% hair reduction and 38% had >80% hair reduction at 12 months post-treatment. At the same time point, 31% of subjects reported complete (100%) hair removal and 69% reported that the hair that did regrow was less noticeable due to being finer and/or lighter. The only observed side effects were erythema and edema that were mild, transient, and self-resolving usually within a few hours.

Conclusions: The home-use diode laser was safe and highly effective at permanently reducing unwanted hair. *Lasers Surg. Med.* 44:550–557, 2012.

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Key words: home-use; laser hair removal; diode laser; consumer; over-the-counter; permanent hair reduction; hair reduction

INTRODUCTION

High-power pulsed diode lasers are widely used to reduce or eliminate unwanted hair and their safety and effectiveness is well accepted [1–6]. Initially, their use was limited to medical professionals, but now a diode laser device cleared by the US Food and Drug Administration and CE-marked for home-use is available over the counter [7]. The device is currently indicated for permanent reduction

in hair regrowth defined as a long-term stable reduction in hair counts following a treatment regimen. Self-treatment is an attractive option for consumers wishing to remove hair in the privacy of their own home, at a time that is convenient to them, and with less expense and inconvenience of multiple office visits.

Physician-use diode hair removal lasers were among the first commercially successful hair removal lasers and remain a standard for comparison. One example is the LightSheer ST (Lumenis, Inc., Santa Clara, CA) that produces fluences of 10–40 J/cm² with typical pulse durations of 5–100 ms, a spot size of 0.81 cm², and a nominal wavelength of 808 nm [8]. The present home-use device utilizes the same technology with similar outputs adjusted for safe consumer use, producing fluences of 7–20 J/cm² with pulse durations of 150–400 ms, a spot size of 0.81 cm², a nominal wavelength of 808 nm, and Class 1 eye safety.

A previous study was performed with this device which demonstrated safety and effectiveness for indicated users when used three times over a 6-week period [9]. In that simulated consumer use study, the mean percent hair count reduction from baseline was 40%, 35%, and 33% at 6, 9, and 12 months after the third treatment, respectively. The current study has been performed to evaluate the safety and long-term effectiveness when the device is used with a more typical laser hair removal regimen of eight treatments spaced 1 month apart.

MATERIALS AND METHODS

Study Design

This was a controlled prospective, single-center study with independent third-party hair counts.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and have disclosed the following: Dr. Wheeland has been a prior consultant for TRIA Beauty, Inc.

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Subjects

Subjects were eligible for enrollment into the study if they were 18–45 years of age, had Fitzpatrick skin types I–IV, and had naturally brown or black hair in the test areas.

Exclusion criteria included any previous laser hair removal, electrolysis, or other permanent hair removal methods in the test area; any use of topical hair lightening products in the test area in the previous 6 months; any use of plucking, tweezing, waxing, or chemical depilatories in the test area in the previous 12 weeks; any history of keloidal scar formation; and any potentially confounding or non-indicated skin condition in the test area (e.g., pre-existing cuts, abrasions, tattoos).

The protocol was approved by an institutional review board and conducted in accordance with the principles of the 2004 version of the Declaration of Helsinki. All subjects were recruited locally and signed informed consent.

Treatment

After enrollment, treatment and control areas were identified on the lower leg for each subject. The treatment areas were three separate 3 cm × 3 cm zones on the lower part of one leg. Adjacent to these on the same leg, a fourth area of the same size was left untreated and served as the control area. A transparent template with 3 cm × 3 cm apertures was used to locate and mark each area at each visit based on each subject's natural skin landmarks.

At the screening visit, all four areas were shaved by the study staff, and the subjects were instructed that they should not shave again or remove hair by any other means from the treatment or control areas during the entire study duration. Subjects were requested to return for their first treatment approximately 14 days later, with seven additional treatment visits to follow at intervals of 1 month (28 ± 5 days). Note that shaving was performed at the screening visit to provide a controlled initial condition for the hair counts at baseline and avoid possible shaving bias (caused by unshaven telogen hairs being counted at baseline but being shaved off at the first treatment visit and thus not recounted until the hair follicle changes phase), which can lead to a false measure of treatment effectiveness [10].

At each subsequent treatment visit, study staff cleaned the sites, clipped the hair in all sites to a length of 1–3 mm for accurate hair counting, photographed the sites with a high-resolution digital camera, and then shaved all four sites. To facilitate the later hair counts, a white adhesive label with a 1 cm × 2 cm aperture was placed within each treatment area during the photography. The aperture area of these labels was smaller than the treatment area to avoid edge effects. For consistency, the staff administered the treatments in the laser sites rather than subject self-treatment. The control site was untreated such that it received identical procedures to the other sites except for the laser use.

Laser treatment was performed according to the laser's *Instructions for Use* and consisted of approximately 50 laser pulses per square inch (corresponding to ~75 pulses in each of the 3 cm × 3 cm treatment areas), with the pulses having about 50% overlap from the previous pulse to provide full coverage. The laser was used at low, medium, and high settings in the first, second, and third treatment areas, corresponding to 7, 12, and 20 J/cm² and about 150, 250, and 400 ms pulse durations.

Subjects were assessed for any adverse effects immediately after treatment and the sites were documented photographically post-treatment. Adverse events were categorized as mild, moderate, or severe, and recorded on case report forms.

Identical procedures were performed at the follow-up visits except that no shaving or laser treatments were performed.

Outcome Measures

Quantitative hair counts were made at each treatment visit (thus representing the hair count 1 month after the prior treatment) and at 1, 2, 3, 6, 9, and 12 months after last treatment. The primary effectiveness endpoints were the mean percent hair count reduction ($[\text{count} - \text{baseline}] / \text{baseline} \times 100$) and the incidence of subjects with a >30% reduction from baseline in hair count.

To perform the hair counts, each photograph was rendered in full screen mode on a 19 in. monitor with a resolution of 1,280 × 1,024 pixels per square inch using Mirror medical imaging software version 7.2.8 (Canfield Scientific, Inc., Fairfield, NJ). Using this software in whiteboard mode, a highlighter tool was used to mark hairs as they were counted with an E2 electronic tally counter (Redington Counters, Inc., Windsor, CT). All hair counts were performed by a trained third-party contractor who was experienced in performing hair counts for skin phototypes I–IV and all hair colors.

Subjects were requested to complete a questionnaire at various intervals during the treatment and follow-up periods. The questionnaire included the subject's self-assessment of the hair reduction on a 6-point scale (0%, 1–24%, 25–49%, 50–74%, 75–99%, 100%), their satisfaction with the device (very dissatisfied, not satisfied, slightly satisfied, very satisfied, extremely satisfied), and any changes in the noticeability, thickness, and color (don't know, same, improved, worsened) of the hair regrowth.

Statistical Analysis

Effectiveness analyses were performed using data from all subjects who had a baseline photograph and at least one post-baseline visit. Safety analyses were performed using data from all subjects who received at least one treatment. A paired, double-sided, equal variance student's *t*-test was used to evaluate the statistical significance of observed differences. Hair counts and percentage hair count reduction from baseline were evaluated across energy settings and timepoints. To normalize to control, the difference in hair reduction between the active (laser) and control (shaving only) sites were computed.

RESULTS

Subjects

A total of 21 subjects enrolled with 8 subjects discontinuing, resulting in a final sample size of 13 individuals (with 546 active sites, and 182 control sites across 14 time points). Of the eight dropped subjects, seven were discontinued prior to any treatment (three had insufficient hair density at baseline for accurate hair counts, one had a suspicion of pregnancy, and two were no-shows for the first treatment visit) and one subject discontinued due to reported discomfort after the second treatment. Since the vast majority of dropped subjects occurred prior to treatment and for reasons unrelated to the therapy, the discontinuations are not expected to significantly influence the results.

The sample had a mean age of 32 with 29% 18–25, 14% 26–33, 36% 34–41, and 21% 42–49 years of age. The hair color distribution was 79% brown and 21% black, and the Fitzpatrick skin type distribution was 0% I, 36% II, 43% III, and 21% IV.

Hair Counts

The measured hair count reductions are shown in Table 1 and Figure 1 for the raw hair reduction and in Table 2 and Figure 2 for the normalized hair reduction which shows the difference in reduction between the control and laser sites.

As evident in Figure 1, the laser sites demonstrate a significant improvement in percent hair reduction during the treatment period, generally improving with subsequent treatments to a mean reduction of 23%, 32%, and 50% at 1 month after the 8th and last treatment, for low, medium, and high fluence, respectively. In the follow-up period, the hair count reduction remained stable over the follow-up period being 31%, 36%, and 52% for low, medium, and high settings, respectively, at 12 months post-treatment. These percentage hair count reductions were statistically significant ($P < 0.05$) for all fluences and at all time points after the first treatment except for four (out of 39).

In contrast to the hair reduction seen at the laser sites, the control site showed a slight increase in the number of hairs, especially in the early period, after which hair counts remained relatively stable throughout the study, ending up 13% higher than baseline at 12 months after the last treatment.

The initial increase in the control hair counts is consistent with the fact that the hair count at baseline was made 2 weeks after the most recent prior shaving (the screening visit), whereas for all subsequent visits the count occurred 4 weeks after the most recent prior shaving event (the last treatment visit). Thus, baseline is comparatively undercounted since there was about 2 weeks of additional growth counted for all non-baseline visits. Accordingly, the true laser efficacy is better assessed by normalizing the percent hair count reductions to show the difference in hair reduction obtained from the laser treatment compared to the control.

TABLE 1. Mean Percent Hair Count Reduction

Fluence level	Follow-up period													
	Treatment period													
	1 month post 1st tx	1 month post 2nd tx	1 month post 3rd tx	1 month post 4th tx	1 month post 5th tx	1 month post 6th tx	1 month post 7th tx	1 month post 8th tx	2 months post last tx	3 months post last tx	6 months post last tx	9 months post last tx	12 months post last tx	
N	14	13	13	13	13	13	13	13	13	13	13	13	13	
Mean, 95% CI	-6% ± 12%	-20% ± 12%	-22% ± 12%	-22% ± 12%	-20% ± 21%	-17% ± 15%	-15% ± 20%	-23% ± 21%	-10% ± 23%	-22% ± 15%	-19% ± 18%	-29% ± 22%	-31% ± 18%	
P value	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	0.07	<0.05	<0.05	<0.05	<0.05	
Mean, 95% CI	-12% ± 17%	-12% ± 16%	-12% ± 15%	-15% ± 17%	-14% ± 22%	-12% ± 25%	-28% ± 19%	-32% ± 17%	-24% ± 20%	-18% ± 19%	-18% ± 29%	-34% ± 21%	-36% ± 28%	
P value	<0.05	<0.05	<0.05	<0.05	<0.05	0.11	<0.05	<0.05	<0.05	<0.05	0.08	<0.05	<0.05	
Mean, 95% CI	-2% ± 17%	-14% ± 18%	-30% ± 13%	-17% ± 27%	-32% ± 18%	-30% ± 23%	-42% ± 19%	-50% ± 15%	-40% ± 19%	-33% ± 24%	-34% ± 22%	-51% ± 20%	-52% ± 20%	
P value	0.09	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	
Mean, 95% CI	17% ± 18%	25% ± 24%	23% ± 21%	26% ± 23%	24% ± 18%	15% ± 16%	28% ± 19%	23% ± 16%	14% ± 17%	22% ± 8%	15% ± 19%	15% ± 19%	13% ± 13%	
P value	0.13	<0.05	0.13	0.07	<0.05	0.21	<0.05	<0.05	0.13	<0.05	0.15	0.15	0.07	

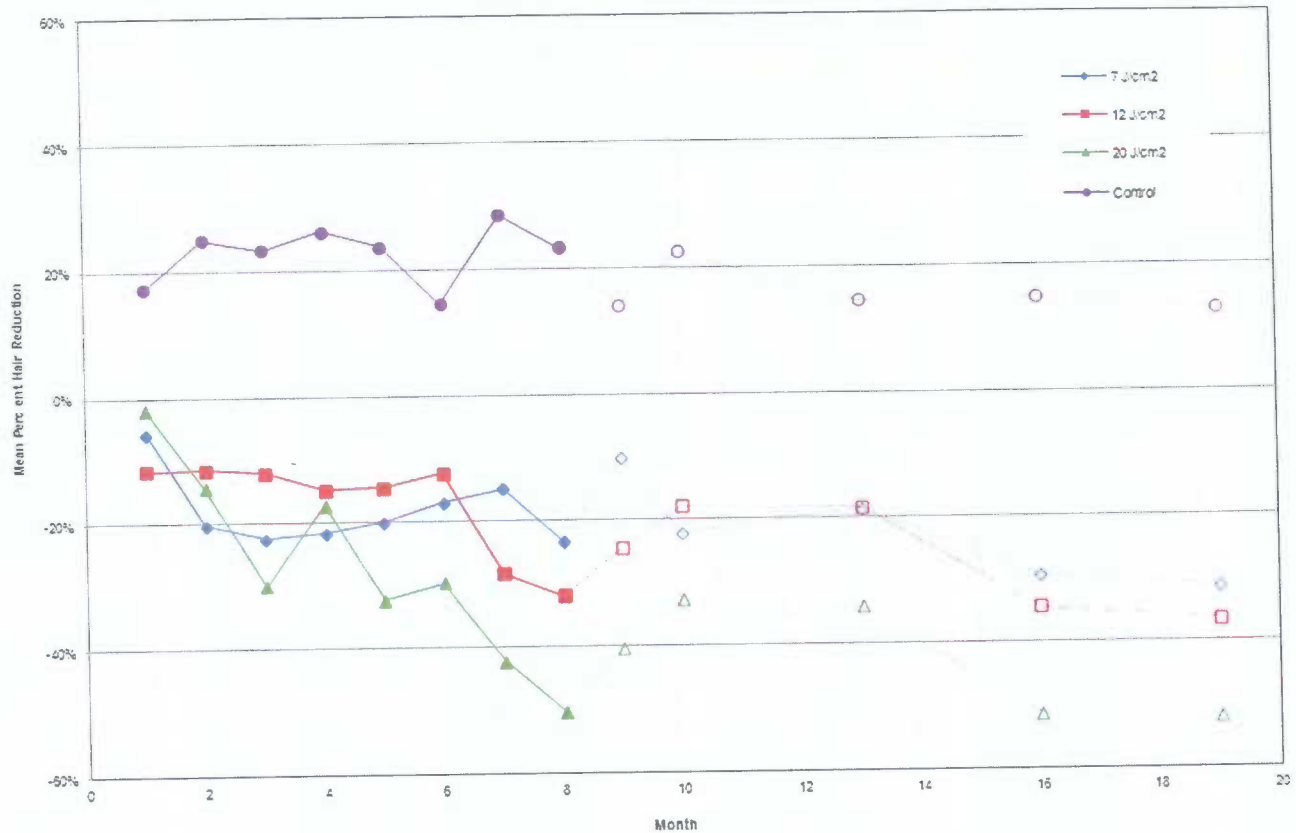


Fig. 1. Mean percent hair count reduction during 8 monthly treatments (solid line) and for 1 year posttreatment (dotted line).

These normalized hair count reductions are shown in Table 2 and Figure 2 which also indicate a significant improvement in percent hair reduction during the treatment period that generally increases with subsequent treatments to a mean normalized reduction of 47%, 55%, and 73% at 1 month after the eighth and last treatment, for low, medium, and high settings, respectively. The result is durable over the 1 year follow-up with a mean normalized reduction of 44%, 49%, and 65%, at the low, medium, and high fluence settings, respectively at 12 months post-treatment. These reductions were statistically significant ($P < 0.05$) for all fluences and time points after the first treatment except for four (out of 39).

To examine variability across subjects, a responder analysis was also performed whereby subjects were classified as responders if they had a reduction in normalized hair count of at least 30% (a clear clinical improvement) at 12 months post last treatment. With this criterion, 46% were responders at low fluence, 69% were responders at medium fluence, and 86% were responders at high fluence. Thus, nearly all subjects had meaningful benefit with at least one of the settings. Furthermore, 38% of subjects had 80% or better hair reduction at 1 year post-treatment, including one subject with complete (100%)

hair removal. Anecdotally, two subjects presented for a voluntary unscheduled 2-year post-treatment visit. These subjects exhibited 100% and 93% reduction in the high fluence treatment area, maintaining their results from the 1 year time point and providing further indication of the permanence of the results.

Subject Evaluations

The results of the subject evaluations at 12 months after the last treatment are listed in Table 3. When assessed on the 6-point scale, 92%, 92%, and 100% of the subjects reported at least some hair reduction for their low, medium, and high fluence sites, respectively. A hair count reduction of at least 50% was reported by 62%, 70%, and 77% of subjects for their low, medium, and high fluence sites, respectively, and 31% of subjects felt that they had complete (100%) hair removal in the high fluence site. The hair that did regrow in the treatment area was reported to be less noticeable by 69% of subjects, finer by 69% of subjects, and lighter by 38% of subjects. No subject considered that post-treatment regrowth was more noticeable, thicker, or darker. In addition, 100% of subjects reported they were satisfied with the results, including 23% who were "very satisfied" and 38% who were "extremely satisfied."

TABLE 2. Mean Percent Hair Count Reduction Normalized to Control

Fluence level	Treatment period												Follow-up period					
	1 month post 1st tx	1 month post 2nd tx	1 month post 3rd tx	1 month post 4th tx	1 month post 5th tx	1 month post 6th tx	1 month post 7th tx	1 month post 8th tx	2 months post last tx	3 months post last tx	6 months post last tx	9 months post last tx	12 months post last tx	N	P value			
Low	-23% ± 15%	-45% ± 31%	-46% ± 25%	-48% ± 22%	-44% ± 25%	-31% ± 14%	-43% ± 20%	-47% ± 26%	-24% ± 24%	-45% ± 19%	-33% ± 19%	-44% ± 27%	-44% ± 23%	13	<0.05			
Medium	-29% ± 17%	-87% ± 28%	-35% ± 24%	-41% ± 18%	-38% ± 22%	-27% ± 31%	-57% ± 20%	-55% ± 23%	-38% ± 17%	-40% ± 21%	-33% ± 34%	-49% ± 22%	-49% ± 26%	13	<0.05			
High	-19% ± 21%	-39% ± 32%	-53% ± 21%	-43% ± 19%	-56% ± 19%	-44% ± 30%	-71% ± 22%	-73% ± 18%	-55% ± 20%	-55% ± 24%	-49% ± 24%	-66% ± 20%	-65% ± 23%	13	<0.05			
Mean, 95% CI	0.09	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05					
P value																		

Safety

No adverse events were reported in the control area or in the low fluence treatment area. In the medium and high fluence sites, the most common adverse event was transient erythema, each occurrence being graded as mild severity and resolving spontaneously without intervention, often while the subject was still at the study site. Mild erythema occurred after the medium fluence treatment in 47% of subjects and after the high fluence treatment in 100% of subjects. Mild edema was observed in 8% of subjects in the high fluence treatment area. One subject discontinued after the second treatment due to reported discomfort/pain from the high fluence dose. Other adverse events recorded were eczema (one subject) and nausea (one subject), although there is no evidence that such effects resulted from the laser treatment. No serious adverse events were reported. Thus, the only observed side effects were typical of routine laser hair removal, namely erythema and edema that were mild, transient, and self-resolving usually within a few hours.

DISCUSSION

The results of this study confirm the effectiveness of this home-use diode laser device in achieving long-term benefits for indicated users concerned with unwanted hair.

Firstly, the quantitative hair counts showed a significant permanent reduction in the number of hairs present after a treatment regimen (e.g., 44%, 49%, and 65% fewer hairs on average than the control at low, medium, and high fluence, respectively, at 12 months post-treatment). This was corroborated by the subjects themselves with, for example, 62%, 70%, and 77% reporting at least 50% hair reduction in their low, medium, and high fluence sites, respectively, and 31% reporting that they had complete (100%) hair removal in the high fluence site.

Secondly, the hairs that did regrow after the treatment regimen were reported by the subjects to be generally less noticeable because they were finer in diameter and/or lighter in color than before treatment. This is consistent with (a) the results of other light-based hair removal studies [9,11-13] and, (b) with the fact that subjects judged their subjective hair count reduction somewhat greater than the objective count because a reduction in "noticeability" would provide additional visual and tactile benefit and reduce the apparent hair density.

Thirdly, this study suggests that consumers will get additional benefit from additional treatments. In a previous study of this device with only three treatments over a 6 week period, a lower percentage of hair follicles were permanently disabled (e.g., mean hair count reduction of 33% at 12 months after the third treatment) [9]. While it is not possible to make direct comparisons because of somewhat differing methodologies in the studies, the greater long-term efficacy in the present study (about two-fold better) is believed to be due primarily to the increased number of treatments (about threefold more). Treating monthly over 8 months exposes a much higher percentage

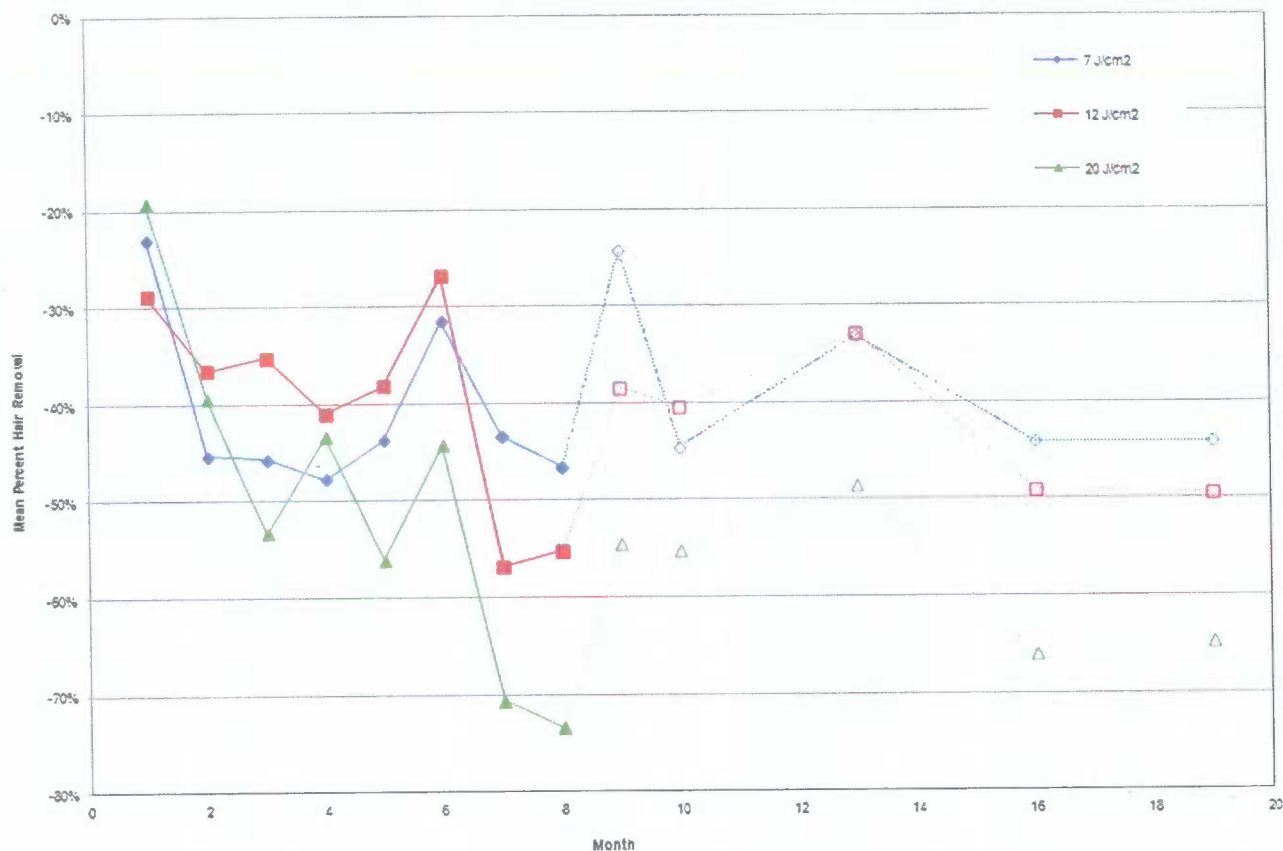


Fig. 2. Mean percent hair count reduction during 8 monthly treatments (solid line) and for 1 year posttreatment (dotted line) normalized to control.

of hairs to treatment in the anagen phase (during which it is commonly thought that the hair is most susceptible to treatment [9,14,15]) than the prior study. Furthermore, performing more treatments increases the probability that all skin regions are treated (i.e., that areas are not missed by chance) and thus should also improve efficacy. The fact that additional treatments provide additional benefit is well-established in the physician-administered laser hair removal literature [16,17] and in the professional hair removal industry where a course of light-based treatments is the standard offering. But this point is of particular importance for home-based treatments since regular, repeated use (with its additional incremental efficacy benefits) is more convenient and less expensive (essentially free other than the time involved) than repeated clinic visits, and thus consumers can continue to more practically treat themselves until they receive the maximum benefit.

In regard to the initial increase of hair in the control site after the first visit, this effect is consistent with the fact that the baseline hair counts were based on a 2 week interval between visits whereas subsequent visits had a 4 week interval. In other words, the hair count at baseline was taken after only 2 weeks of hair regrowth following

shaving, while the subsequent counts were taken with 4 weeks of hair regrowth. Since a greater number of hairs would transition from telogen to anagen and therefore emerge as countable stubble for subsequent visits compared to baseline, this means that the hair count at baseline was comparatively undercounted, and the hair count reduction from baseline at subsequent visits was underestimated. Therefore, the normalized results (which are the difference in hair count reduction from the laser therapy compared to the control) are considered the best measure of the true laser efficacy. It is also worth noting that if the increase in the control hair counts were instead due to stimulation of hair by shaving or by seasonality effects (two effects sometimes cited in the literature, for example [10]) these effects would similarly apply equally to the control and laser sites, so the normalized results would still be the best measure of laser effectiveness.

Although the subject sample size in the current study is small in absolute numbers, the efficacy results are statistically significant. This derives from the fact that the present device (and laser hair removal in general) is highly efficacious and thus a comparatively small sample size relative to studies of less dramatic therapies is adequate for significance. In addition, the power of the study is

TABLE 3. Subject Observations at 12 Months Post-Treatment

	Fluence setting	No improvement	1-24%	25-49%	50-74%	75-99%	100%
Hair reduction	Low	8%	23%	8%	31%	31%	0%
	Medium	8%	8%	15%	31%	31%	8%
	High	0%	8%	15%	15%	31%	31%
Overall satisfaction	Very dissatisfied	Not satisfied	Slightly satisfied	Very satisfied	Extremely satisfied		
	0%	0%	38%	23%	38%		
	Characteristic	Improved	Same/Don't know	Worsened			
Overall regrowth	Noticeability	69%	31%	0%			
	Thickness	69%	31%	0%			
	Color	38%	62%	0%			

enhanced by three sites (plus control) for each subject and the aggregation and trend analysis that can be performed across the dataset. Further, variability was minimized in this study by administering the treatment by the study staff to ensure a consistent treatment performed according to the device instructions.

Lastly, it is interesting to compare the current results for this home-use device to published results for prescription-use devices. To this end, Table 4 summarizes some of the published results for diode lasers, in which it can be seen that a wide range of results are reported with long-term hair removal (6 months or more) ranging from at least 34% to 65% under a variety of conditions [2,3,9,18-24]. In light of this, the present study demonstrates that the home-use laser of the current study can produce results that are generally comparable to professional prescription-use diode lasers when used in a series of

treatments on indicated users and according to its instructions for use.

CONCLUSION

The present home-use diode laser is safe and effective in achieving a stable, long-term reduction in the number of hairs that meets the FDA and industry definition of permanent hair reduction [25]. A significant proportion of subjects had sufficient benefit as to likely eliminate or reduce the need for other hair removal methods such as shaving and waxing because of (a) the high degree of reduction, namely, 65% normalized mean reduction and 38% of subjects with >80% hair count reduction after eight high fluence treatments, (b) the permanent nature of this reduction, (c) the fact that subjects reported that the hair that did regrow was finer, lighter, and less noticeable, and (d) the ability to conveniently perform ad-

TABLE 4. Comparison With Reported Results for Professional Diode Laser Hair Removal

Author	Fluence (J/cm ²)	# Tx	Tx site	1 month after 2 txs	Months post-treatment		
					6 (5-7)	9	12
Home-use diode laser of this study							
Wheeland (2007)	13-22	3	Axilla, leg, arm abdomen, chest, upper lip, bikini, neck	70%	41%	30%	33%
Present study	20	8	Leg	45%	49%	66%	65%
Prescription devices							
Handrick	25	3	Axilla	74%	46%	—	—
Fiskerstrand	35	3	Upper lip	—	49%	—	—
Amin	28	2	Leg	—	36%	—	—
Royo	5-10	5	Axilla, bikini, abdomen, pubis, thorax	—	40-65% (53)	—	—
Eremia	40	4	Axilla	—	—	—	84%
Williams	20-100	4	Bikini, back, leg, axilla, chest, upper lip, chin, neck	39%	40%	30%	—
Lou	10-40	2	Leg, arm, back	70%	36%	42%	42%
Sadick	25-35	3	Bikini, axilla, chin, moustache, facial temples	—	70%	—	—
Baumler	33	3	Leg	87%	—	—	—