

# Long-Term Clinical Evaluation of a 800-nm Long-Pulsed Diode Laser with a Large Spot Size and Vacuum-Assisted Suction for Hair Removal

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**BACKGROUND** The long-pulsed diode (800–810-nm) laser is one of the most commonly used and effective lasers for hair removal. Limitations of currently available devices include a small treatment spot size, treatment-associated pain, and the need for skin cooling.

**OBJECTIVE** To evaluate the long-term hair reduction capabilities of a long-pulsed diode laser with a large spot size and vacuum assisted suction.

**METHODS** Thirty-five subjects were enrolled in a prospective, self-controlled, single-center study of axillary hair removal. The study consisted of three treatments using a long-pulsed diode laser with a large spot size and vacuum-assisted suction at 4- to 6-week intervals with follow-up visits 6 and 15 months after the last treatment. Hair clearance was quantified using macro hair-count photographs taken at baseline and at 6- and 15-month follow-up visits. Changes in hair thickness and color, levels of treatment-associated pain, and adverse events were additional study endpoints.

**RESULTS** There was statistically significant hair clearance at the 6 (54%) and 15-month (42%) follow-up visits. Remaining hairs were thinner and lighter at the 15-month follow-up visit, and the majority of subjects reported feeling up to mild to moderate pain during treatment without the use of pretreatment anesthesia or skin cooling.

**CONCLUSIONS** A long-pulsed diode laser with a large spot size and vacuum-assisted suction is safe and effective for long-term hair removal. This is the largest prospective study to evaluate long-term hair removal and the first to quantify decreases in hair thickness and darkness with treatment.

*This study was supported by an equipment and research grant from Lumenis Inc.*

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Laser hair removal (LHR) is among the most commonly requested cosmetic procedures.<sup>1</sup> Anderson and coworkers reported the first demonstration of long-term hair removal,<sup>2,3</sup> which was based on the theory of selective photothermolysis.<sup>4</sup> According to this model, selective damage to pigmented terminal hair follicles is achieved using wavelengths capable of targeting melanin, which results in heating of the hair follicle with the goal of permanently destroying the follicular stem cells in the bulge region, dermal papilla, or both. Although a number of different wavelengths can be

used for LHR, the majority of studies demonstrate only short-term efficacy (<12 months). The long-pulsed diode laser (LPDL) is one of the most popular commercially available wavelengths for LHR. The Food and Drug Administration has approved the device for all skin types, and in our experience, it is safe for the majority of patients (Fitzpatrick skin phototypes I–IV/V).

Despite the popularity and safety of the LPDL for LHR, it has a few limitations. First, the small spot size of most commercially available LPDLs makes

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treatment of large body surface areas time consuming and inconvenient to patients and practitioners. In addition, smaller spot sizes are likely to undergo greater loss of penetrating photons outside of the laser beam because of scattering. This clinically translates to the need for higher fluences for a smaller spot size to achieve a result similar to that of a larger spot size and a greater need for epidermal cooling. Finally, LHR is often associated with discomfort that may require the use of topical anesthetics. Application of these medications requires incubation times of 30 min to 1 h, far longer than the time required to perform LHR for most areas. Furthermore, the application of these topical medications to large body surface areas exposes patients to potentially dangerous side effects such as methemoglobinemia and cardiotoxicity.<sup>1</sup> Pneumatic skin flattening<sup>5</sup> was a recently reported innovation that works by using a vacuum device to draw and flatten the skin against the laser handpiece, which is thought to decrease LHR-associated discomfort by overwhelming sensory receptors in the skin with the sensation of pressure, partially masking the sensation of pain associated with the laser pulse. It is also believed that the suction, which draws the skin into the handpiece, reduces the distance the laser pulse must travel by compressing the skin and bringing the hair follicle closer to the skin surface and temporarily decreases the amount of competing vascular chromophore.

Here, we evaluate the hair reduction capabilities of an 800-nm LPDL with a large spot size (22 × 35 mm) and vacuum-assisted suction (LightSheer Duet HS, Lumenis, Santa Clara, CA) that was designed to address the above limitations of LPDL for LHR.

## Materials and Methods

A prospective, single-center, self-controlled study was designed to evaluate the long-term hair-reduction capabilities of the LightSheer Duet HS handpiece. The Independent Investigational Review Board, Inc. (Plantation, FL) approved the study

protocol and informed consent documents. Thirty-five subjects meeting the inclusion criteria were enrolled in the study. Inclusion criteria were healthy adult, female, aged 18 and older, skin type I to IV; having at least one suitable axilla treatment area for hair removal with brown hair; being able and willing to provide informed consent and adhere to the study protocol; and using a reliable method of birth control at least 3 months before study commencement and throughout the course of the study treatment if of child-bearing age. Exclusion criteria were showing clinical symptoms of hormonal disorders; use of isotretinoin within previous 6 months; prior treatment of axilla with laser or other devices; history of keloid formation or poor wound healing; having a dermatologic condition affecting the axillae; open laceration, abrasion, active cold sores, or herpes sores on area to be treated; history of immunosuppression or immune deficiency disorder (including HIV infection or AIDS) or use of immunosuppressive medications; history of bleeding disorder or taking anticoagulation medications; having or undergoing any form of treatment for active cancer, a past history of skin cancer or any other cancer in the area to be treated, or any personal history of melanoma; significant concurrent illness, such as diabetes, lupus, epilepsy or cardiac disorders, which might be aggravated as a result of treatment; unable or unlikely to refrain from tanning, including the use of tanning booths, tanning spray, or cream, during the course of the evaluation; tattoos in the treatment areas; dysplastic nevi in the treatment areas; and participation in a study of another device or drug within 3 months before study enrollment or during this study.

Study subjects who met all the above criteria were enrolled in the study. A baseline visit was performed for each subject to establish eligibility for the trial. Up to four spots were tested in the intended treatment area to determine initial treatment settings. The study included three treatment sessions at 4- to 6-week intervals. Before each treatment, macro hair-count photographs were taken using a high-quality digital camera (Nikon D100 with a 60-mm

micro Nikon lens and a macro flash [Melville, NY]) and served as the basis for the hair clearance, thickness, and color analysis. Subjects quantified treatment-associated discomfort using a validated visual analog pain scale ranging from 0 (no pain) to 10 (intolerable pain) immediately after treatment. Total treatment time, including pretreatment preparation time, was recorded for each treatment visit. Six- and 15-month follow-up visits after the last treatment were performed to obtain long-term followup photographs for hair clearance, thickness, and color analyses. Adverse events that appeared or worsened during the study period were documented.

Hair clearance analysis was performed using hair counts from the photographs taken at the baseline visit and at the 6- and 15-month follow-up visits. Each photograph was analyzed using the original image in photo-editing software in which the image was enlarged to facilitate counting. The mean value of each hair count in triplicate was used for the resultant hair count per subject per time point. Both authors, who are board-certified dermatologists, and a PhD research scientist employed by Lumenis performed hair counts. The three evaluators were not blinded to the time points of the hair-count photographs. Hair thickness and hair color were compared at baseline and 15-month follow-up visit by visually rating the thickness and color of hairs on a scale of 1 (very fine or light) to 10 (very coarse or dark) with the same images used for hair clearance analysis.

All statistical tests were two sided. The level of statistical significance for hair clearance, and change in thickness and color analyses was <5%. Subject characteristics at baseline were summarized and included age, sex, race, skin type, and baseline clinical status. Descriptive statistical analysis was performed for demographics.

## Results

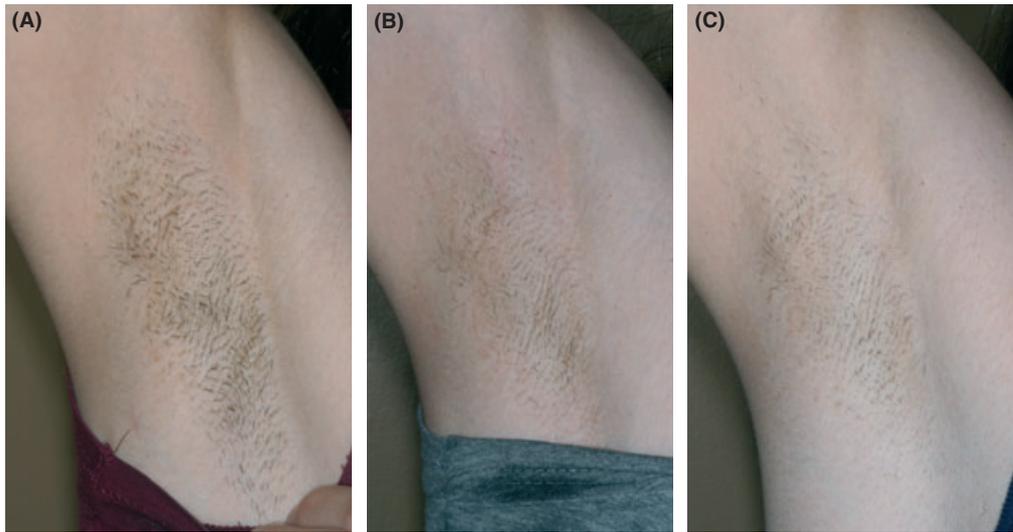
Thirty-five subjects met the study criteria and were enrolled in the study, although one subject dropped

out after the first treatment visit because of a serious adverse event (injured ankle) that was unrelated to the study protocol. Thus, the effective sample size was 34, although 35 subjects were recorded for the demographic characteristics and the safety of the first treatment. The age range of the 35 treated subjects was 19.7 to 52.8 (mean  $30.9 \pm 10$ ). All of these subjects were female with skin types II to IV, and 89% were Caucasian. Seventeen percent of the subjects had undergone previous laser hair removal treatment in anatomical areas other than the ones in which they received treatment in this study. The treatment area of all subjects was the right axilla, and the hair color was dark brown. The demographic characteristics of the 35 treated subjects are summarized in Table 1.

A total of 34 axilla, 102 treatment sessions, and 57 follow-up visits (34 and 23 follow-up visits at 6 and 15 months, respectively) were conducted as part of this study. During the first treatment, 13 patients were treated with fluences of 11.1 to 12 J/cm<sup>2</sup>, 18 were treated with fluences of 10.1 to 11 J/cm<sup>2</sup>, one was treated with fluences of 9 to 12 J/cm<sup>2</sup>, and two were treated with a fluence of <10 J/cm<sup>2</sup>. At the second treatment, 18 patients were treated with a fluence of 11.1 to 12 J/cm<sup>2</sup>, 13 were treated with a fluence of 10.1 to 11 J/cm<sup>2</sup>, and three were treated with a fluence of <10 J/cm<sup>2</sup>.

**TABLE 1. Demographic Characteristics**

<i>Characteristic</i>	<i>Value</i>
Age, mean $\pm$ standard deviation (range)	30.9 $\pm$ 10 (19.7–52.8)
Race, n (%)	
Caucasian	31 (89)
Asian or Pacific Islander	3 (9)
Hispanic	1 (3)
Fitzpatrick skin type, n (%)	
II	6 (17)
III	19 (54)
IV	10 (29)
Hair removal method before study, n (%)	
Shaving	32 (91)
Shaving and waxing	2 (6)
Tweezing	1 (3)



**Figure 1.** Representative photographs of a study subject at (A) baseline, (B) 6-month, and (C) 15-month follow-up visits.

During the third treatment, 19 patients were treated with a fluence of 11.1 to 12 J/cm<sup>2</sup>, 12 were treated with a fluence of 10.1 to 11 J/cm<sup>2</sup>, and three were treated with a fluence of <10 J/cm<sup>2</sup>. All treatments consisted of a single pass with 10% overlap between treated areas. In 94% of the treatments, a medium vacuum level was used, and in the remaining 6%, a low vacuum level was used. Pulse widths ranged from 30 to 70 ms. Representative photographs of a study subject at baseline and at the 6 and 15-month follow-up visits are shown in Figure 1.

The average hair clearance as measured 6 months after three treatments for all subjects ( $n = 34$ ) was  $54 \pm 24\%$  ( $p < .001$ ). One subject was noted to have higher hair counts at follow-up visits than at baseline (92 at baseline, 139 at 6-month follow-up, and 110 at 15-month followup). This subject was noted to have wax epilated her axillae before enrollment into the study, and it is possible that a large portion of the subject's hair follicles escaped damage from the laser treatment because there may not have been a hair shaft present to absorb the laser energy and subsequently re-entered anagen phase after the treatment period. Alternatively, the subject may have developed laser-induced paradoxical hypertrichosis,<sup>6</sup> a rare but documented

**TABLE 2. Hair Clearance at 6- and 15-Month Follow-Up Visits**

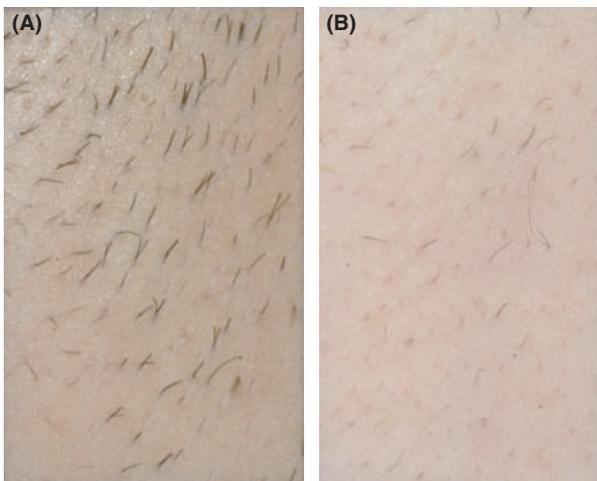
<i>Change in Hair Count, %</i>	<i>6-Month Follow-Up (n = 34) n (%)</i>	<i>15-Month Follow-Up (n = 23)</i>
Worsening	1 (2.9)	1 (4.3)
<25	2 (5.9)	6 (26.1)
25–49	7 (20.6)	5 (21.7)
50–74	21 (61.8)	10 (43.5)
>75	3 (8.8)	1 (4.3)

phenomenon that predominantly occurs on the lateral face of Mediterranean and South Asian women but has been reported in other anatomic areas.<sup>7</sup> The other subjects all had some level of hair clearance. When divided into distinct clearance subsets (Table 2), at the 6-month follow-up visit, 21 (61.8%) subjects had 50% to 75% hair reduction, and three (8.8%) had more than 75% hair reduction.

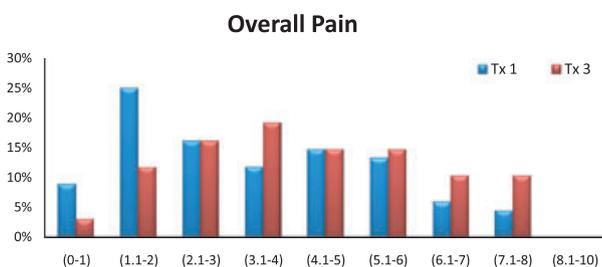
Twenty-three of the 34 subjects who completed the three study treatments (68%) returned for a 15-month follow-up visit. The average hair clearance measured 15 months after three treatments for all subjects ( $n = 23$ ) was  $42 \pm 25\%$  ( $p < .001$ ). When divided into distinct clearance subsets (Table 2), the majority of subjects at 15-month follow-up

(10/23, 43.5%) had 50 to 75% hair reduction. In addition to the long-term clearance of hair, we also noted by visual analysis a decrease in the thickness and color of remaining hairs. There was a mean decrease in thickness of  $19 \pm 18\%$  ( $p < .001$ ) and a mean lightening of color of  $10 \pm 13\%$  ( $p < .001$ ) of remaining hair at the 15-month follow-up visit (Figure 2).

Pain and discomfort were assessed by asking subjects to quantify their pain level on a visual analog pain scale ranging between no pain (0) and intolerable pain (10). The distance from no pain was recorded for each subject after the first and last treatment. The distribution of the subjects' pain assessments is presented in Figure 3. Subjects



**Figure 2.** Visual decrease in hair thickness and color in a study subject. (A) baseline, (B) 15-month follow-up visit. This subject had a 60% decrease in hair thickness and a 40% decrease in hair color.



**Figure 3.** Distribution of study subjects' pain assessments according to the visual analogue pain scale.

reported feeling no pain or up to moderate pain at most of the treatments.

None of the subjects reported experiencing severe or intolerable pain. The pain levels were slightly worse at the third treatment than at the first treatment ( $p < .05$ ). This may be related to the higher fluences used in the third treatment. The average treatment time (including all preparation for the treatment) was  $3.5 \pm 2.7$  minutes for each axilla treated.

## Discussion

Published studies of LHR with a varying number (1–5) of LPDL treatments and at least 6 months of follow-up after the final treatment demonstrate hair clearance ranging between 25 and 91%.<sup>8–13</sup> The current study demonstrated hair clearance of 42% at 15 months and 54% at 6 months with three treatments, which falls in the middle range of these previously reported values and number of treatments. The slight decrease in hair clearance from 6-month follow-up to 15-month follow-up supports the long-held notion that not every hair follicle that is damaged undergoes long-term involution. We could find only five studies that analyzed long-term (>12 months) hair clearance.<sup>3,8,9,13,14</sup> Thus, this study is also notable in that it serves as the largest prospective study to evaluate the long-term efficacy (>12 months) of LHR and the first to demonstrate that remaining hairs also undergo decreases in thickness and color with treatment.

These results suggest that a LPDL with a large spot size and vacuum-assisted suction has similar efficacy to other LPDL devices used for LHR. Histopathologic specimens from subjects treated with a LPDL with a large spot size and vacuum-assisted suction show qualitatively similar levels of thermal damage to specimens from subjects treated with a traditional chilled sapphire tip LPDL,<sup>15</sup> but the device evaluated in this current study has several advantages over other LPDL devices. First, the large spot size of the device evaluated in this study

translates to lower fluences used for LHR while retaining similar efficacy to LPDL devices with a smaller spot size. The use of lower energies is also thought to diminish the risk of adverse events, obviate the need for skin cooling, and expand the spectrum of Fitzpatrick skin phototypes that can be safely treated with this device. Furthermore, a larger spot size translates to fewer pulses needed to cover a given anatomic area and probably translates to faster treatment times. Finally, the use of vacuum-assisted suction in the LDPL device evaluated in this study eliminated the need for pretreatment anesthesia, with 39% of patients reporting no (0) to slight (2) pain while also bringing the target chromophore closer to the skin surface. We hypothesize that these advances in device design correlate to greater patient and physician satisfaction. Limitations of this study include the lack of a treatment arm with a traditional LPDL that would allow direct comparisons of treatment efficacy, treatment times, and treatment-associated pain with those of a LPDL with large spot size and vacuum-assisted suctioning.

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