Use of the LightSheer™ Diode Laser System for Hair Reduction: Safety and Efficacy in a Large Series of Treatments

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Summary Provided by Lumenis Inc.

ABSTRACT. An 800 nm high-power, long-pulsed diode laser with contact cooling provides safe and effective reduction of pigmented hair in patients with a variety of skin types. This paper presents the safety and efficacy results of 800 treatments performed on 250 sites in 144 patients with Fitzpatrick skin types II-V.

Over 84% of sites showed a good or excellent response following the second and subsequent treatments. Treatment responses were similar for all skin types treated, with an excellent safety profile. Side effects were noted in only two of the 800 treatments and were transient in nature. Patients were extremely or moderately satisfied with over 96% of their treatments.

Introduction

SEMICONDUCTOR DIODE LASERS are considered the most efficient light sources available and are particularly well suited for clinical applications including hair reduction. This paper reports the use of the LightSheer diode laser system, a high-power, long-pulsed diode laser with a wavelength of 800nm, for laser hair reduction in a large population of patients with a variety of skin and hair types.

Laser hair reduction operates on the principle of selective photothermolyis. This process combines selective absorption of light energy by the melanin in hair follicles with suitable fluences and pulse durations. In order to achieve maximum selectivity, the laser energy is applied in a pulse duration that approximately equals the thermal relaxation time of the target. In practice, the appropriate pulse duration maximizes the temperature rise of the hair follicle and minimizes the conduction of heat to the surrounding tissue, thus sparing adjacent structures from damage.

In order to achieve permanent hair reduction, sufficient light energy must be absorbed by the hair follicle. The melanin in the hair follicle absorbs 3-4 times more energy at 800 nm (the wavelength used in the LightSheer) than at 1064 nm (the wavelength of Nd:YAG lasers)². This increased absorption means that the LightSheer laser can be used at significantly lower fluences to achieve hair

reduction in contrast to the much higher fluences required for a 1064 nm laser.

The effectiveness of laser hair reduction depends on the patient's skin type. Laser hair reduction is typically more effective in lighter-skinned people (Fitzpatrick skin types I-III)². The challenge associated with laser treatment for darker-skinned patients is to avoid surface skin (epidermal and upper dermal) injury due to absorption of light in the pigmented epidermis, while still causing selective destruction of the underlying pigmented hair follicles. This study will examine almost equal numbers of treatments of light and dark skin types.

Recent clinical studies have shown that longer pulse durations combined with aggressive skin cooling provide a greater margin of safety when treating darker skin by allowing higher fluences and fewer side effects^{5,6}. Models of skin optics and heat transfer suggest that the entire hair follicle, including the outermost follicular structures (where the stem cells are located) can be selectively damaged with longer pulse widths than those typically employed (20-40 ms)². The LightSheer can deliver pulse durations up to 100 ms. The thermal relaxation time for the hair follicle is dependent on its diameter; thus longer pulse durations are theoretically best suited for the treatment of medium to thick hairs⁷. These longer pulse durations can be safely used with higher fluences when combined with aggressive

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skin cooling techniques to reduce epidermal damage².

The ChillTipTM handpiece of the LightSheer laser contains an actively cooled convex sapphire lens. When pressed against the patient's skin before and during each laser pulse, this cooling device provides substantial thermal protection for the epidermis⁸. Compression of the target area also places the hair bulb closer to upper dermis where the laser energy is the highest. The combination of longer pulse widths and the unique cooling system minimizes skin damage and allows for higher fluences to be safely used even in darker skinned patients⁴. Other studies have shown that treatment efficacy is directly related to fluence levels⁶.

METHODS

This paper reports on the safety and effectiveness of the LightSheer Diode Laser System in the reduction of pigmented hair in a large patient population with a variety of skin types and hair characteristics. The study monitored 800 hair reduction treatments at 250 sites on 144 patients.

The majority of patients had Fitzpatrick skin type III or IV and medium or coarse dark brown or black hair. Almost 50% of treatments were performed on type IV and V skin. Over two-thirds of treatments were to the face or neck (Table 1).

Over 90% of sites received two or more treatments. The interval between treatments ranged from 2 to 56 weeks, with an average of 10 weeks.

The most frequently used fluence was between 25 and 29 J/cm². Over 94% of treatments used the OptiPulseTM mode for pulse width, while the remaining treatments used a 30 ms pulse width (Table 2). The 30 ms pulse width was most commonly used for skin type V (29% of type V treated sites) and skin type IV (7% of type IV treated sites).

Treatment success was based on apparent clearance and was assessed as no response, moderate, good, or excellent response following each treatment. Patient satisfaction with the previous treatment was assessed as dissatisfied, mildly satisfied, moderately satisfied, or very satisfied.

Treatment responses were classified by skin type, hair color, hair texture, and hair density.

Treated areas were visually assessed for skin responses, including edema, erythema, hypopigmentation, hyperpig-

Table 1: Characteristics of Treated Sites

Skin Type	Number (%) of Sites	
II	15	(6.0%)
III	112	(44.8%)
IV	109	(43.6%)
V	14	(5.6%)
Tan		
No	224	(89.6%)
Yes	26	(10.4%)
Treatment Site		
Face/neck	172	(68.6%)
Trunk	27	(10.8%)
Axilla	11	(4.4%)
Bikini/legs	33	(13.2%)
Other	7	(2.8%)
Hair Color		
Light Brown	10	(4.0%)
Dark Brown	96	(38.4%)
Black	144	(57.6%)
Hair Texture		
Fine	31	(12.4%)
Medium	73	(29.2%)
Coarse	146	(58.4%)
Hair Density		
Low	46	(18.4%)
Medium	116	(46.4%)
Heavy	84	(33.6%)
Not specified	4	(1.6%)

Table 2: Treatment Parameters

No. of Treatments/Sit	<u>:e Numbe</u>	Number (%) of Sites	
1	19	(7.6%)	
2	74	(29.6%)	
3	57	(22.8%)	
4	38	(15.2%)	
5 or more	62	(24.8%)	
Fluence (J/cm²)	Number (Number (%) of Treatments	
<20	44	(5.5%)	
20-24	104	(13.0%)	
25-29	379	(47.4%)	
30-34	184	(23.0%)	
35-39	76	(23.0%)	
>40	13	(1.6%)	
Pulse Width			
OptiPulse™ mode	754	(94.3%)	
30 ms	46	(5.7%)	

mentation, and textural changes following each treatment. Patients also noted their level of pain and the use of topical anesthesia was recorded.

RESULTS

Treatment response was rated as good or excellent for approximately 65% of all treatments. Figure 1 (A-H) illustrates several examples of treatment results. Favorable responses increased substantially after multiple treatments. Over 84% of sites showed a good or excellent response following the second and subsequent treatments (Figure 2). Multiple treatments are important for the patient to achieve the desired response.

In general, the percentage of treatments that resulted in good or excellent response was similar regardless of skin type or hair color. Treatment responses for second and subsequent treatments by skin type and hair color are shown in Figures 3 and 4.

The average number of treatments required for good or excellent response was similar for all body areas treated (Figure 5).

Treatment satisfaction was similar for patients with different hair colors and skin types, although patients with skin type V were slightly less satisfied than those with skin types II-IV (Figures 6 and 7). The use of a 100 ms pulse width, which was not available in this study, would likely improve the effectiveness of treatment for patients with skin type V.



Overall, patients were moderately or very satisfied with 96% of their treatments (Figure 8).

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Safety

Any untoward event at the treatment site (e.g., edema, erythema, hypopigmentation, hyperpigmentation, textural changes) that lasted 30 days or more was considered to be a side effect. Side effects were reported for only two out of 800 total treatments (0.25%). These were both cases of transient hyperpigmentation.

One incident of transient hyperpigmentation occurred after the second treatment of a patient with skin type IV. The patient's axilla was treated using a fluence of 28 J/cm² and a 30 ms pulse duration. This hyperpigmentation lasted slightly over one month. The patient underwent two further treatments at that site and no further hyperpigmentation was noted.

The second incident of transient hyperpigmentation occurred following the second treatment in a patient with skin type III and black, medium texture, medium density hair. Treatment fluence was 28 J/cm² in Optipulse mode (pulse width of 14 ms). The patient did not undergo any further treatments at this site, but had a total of 17 other treatments on the neck, back, and cheeks with no reported side effects.

The majority of patients experienced some pain during the procedure. The pain was usually mild (42% of treatments) or moderate (49% of treatments) and only 2% of treatments were associated with severe pain. Topical



Figure 1. A female patient with Fitzpatrick Type III skin (A) before treatment of bikini line, and (B) 18 months after third treatment with the LightSheer diode laser using 26 J/cm² in OptiPulse mode.

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A male patient with pseudofolliculitus barbae, Fitzpatrick Type V skin (C) before treatment of neck, and (D) 8 months after fourth treatment with the LightSheer diode laser using 15 J/cm² and a pulsewidth of 30 ms.





A female patient with Fitzpatrick Type III skin (E) before treatment of axilla, and (F) 10 months after third treatment with the LightSheer diode laser using 38 J/cm² in OptiPulse mode.



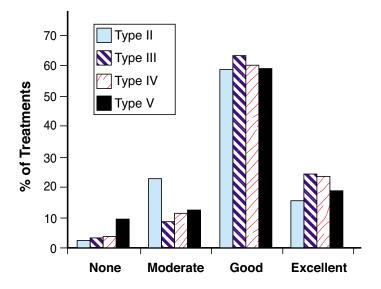


A female patient with Fitzpatrick Type IV skin (G) before treatment of chin, and (H) 6 months after sixth treatment with the LightSheer diode laser using 27J/cm² in OptiPulse mode.

80 -None Moderate 70 Good 60 Excellent % of Treatments 50 40 30 20 10 0 -3 > 4 **Number of Treatments**

Figure 2: Treatment Response by Treatment Number





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Figure 4: Treatment Response by Hair Color

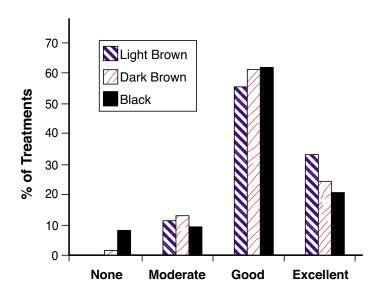
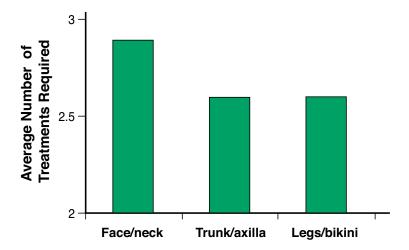


Figure 5: Number of Treatments for Good or Excellent Response



Type II 70 Type III 60 Type IV % of Treatments 50 Type V 40 30 20 10 -0 Mildly Satisfied Very Satisfied **Dissatisfied** Moderately Satisfied

Figure 6: Treatment Satisfaction by Skin Type



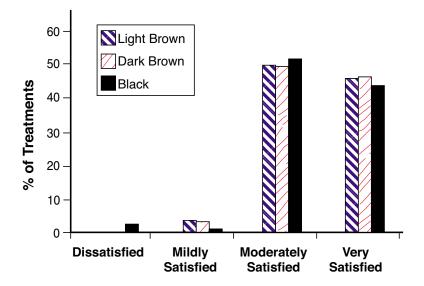
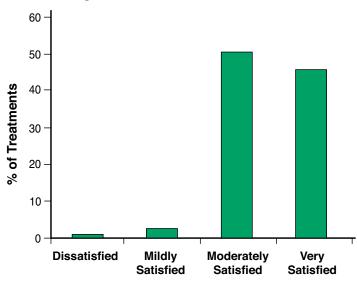


Figure 8: Overall Treatment Satisfaction



anesthesia was used for only 20% of treatments and 6% of patients. The most commonly used topical anesthetic was EMLA (12% of treatments).

CONCLUSIONS

- The LightSheer 800 nm high-power, long-pulsed diode laser provides effective reduction of pigmented hair in a heterogeneous population of 144 patients with 250 body sites, involving 800 treatments.
- Treatment was equally effective for Fitzpatrick skin types II-V and treatment response was similar for all hair colors treated (light brown, dark brown, and black).
- Treatment response was good or excellent in 84% of areas following the second and subsequent treatments. Patients were moderately or extremely satisfied with over 96% of their treatments.
- Laser hair reduction with the LightSheer Diode Laser System was very safe for all skin types treated. Side effects were noted for only two out of 800 treatments (0.25%). These were transient in nature.
- The use of the 100 ms pulse width, which was not available for this study, provides additional flexibility for treating skin types V-VI.
- The longer pulse widths and the unique cooling system available with the LightSheer Diode Laser System reduce skin damage and allow for safe and effective hair reduction even in darker skinned patients.

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