LIGHTSHEER™ 800 NM PULSED, HIGH-POWER DIODE LASER HAIR REMOVAL SYSTEM

Robert M. Adrian, M.D., F.A.C.P.
Assistant Clinical Professor
Georgetown University Medical School
Center for Laser Surgery
Washington, D.C.

Recent technological advances in laser hair removal have been accompanied by a tremendous degree of public enthusiasm for this procedure. Unfortunately, clinical studies regarding safety and efficacy of these procedures have lagged behind the actual widespread use of this modality throughout the world. Traditional methods of hair removal such as shaving, plucking, waxing, and electrolysis are associated with clinical limitations and side effects; thus the introduction of laser hair removal has been embraced by the public despite relatively little data regarding clinical safety and long-term efficacy.

At the present time, the primary chromophore for laser hair removal is melanin residing in the hair shaft. In addition, melanin residing in the inner and outer root sheath may also serve as a secondary chromophore. In theory and most likely in clinical treatment, the laser energy delivered to the hair shaft serves as a heat sink, which transfers energy to the surrounding hair follicle and perifollicular tissue. The conduction of heat from the shaft is what ultimately damages the follicle. Sufficient follicular damage is necessary to achieve permanent hair reduction. Although multiple factors play a role in the response of a given follicle to the procedure, it appears that wavelength, fluence, pulse duration, and spot size are the main determinants of clinical response.

Ruby (694 nm), alexandrite (755 nm) and diode (800 nm) are currently the major wavelengths present in most laser hair removal systems. Pulse durations of these systems vary from less than one millisecond (ms) to 60 ms. Although available fluences vary, clinically-effective lasers are capable of delivering in excess of 30-40 J/cm^2. Over the past four years, we have had the opportunity to use five different systems for laser hair removal. Results of our clinical studies indicate that longer pulse durations are associated with greater efficacy and with fewer postoperative clinical side effects such as blistering and pigment disturbances.[1]

The ideal pulse duration for hair removal is felt to be between 10 and 50 ms.[2] This pulse duration is longer than the thermal relaxation time of the epidermis but shorter than the thermal relaxation time of the hair shaft and follicle. Pulse durations in this range seem to provide some degree of epidermal preservation during treatment, allowing the delivery of higher fluences. Hair removal lasers with short pulse durations are associated with a higher incidence of epidermal damage in the form of blistering and crusting. In addition, these lasers may be associated with a higher incidence of prolonged hypopigmentation as a result of non-selective damage to epidermal and follicular melanin. Clinical studies have shown that longer pulse durations provide a greater margin of safety when treating darker skin type individuals by allowing higher fluence delivery and fewer postoperative side effects.

Fluence appears to be the primary consideration in the efficacy of any system. In essence, the correct wavelength for specific absorption by the target and ideal pulse duration for selective photothermolysis must be accompanied by significant delivered energy in order to achieve follicular destruction rather than temporary laser epilation. The goal of laser hair removal is to achieve follicular destruction rather than temporary epilation resulting from heating of the hair shaft alone. Destruction of the hair shaft without transfer of sufficient energy to the follicular and perifollicular tissue will most likely provide only temporary epilation. This is most often noted with low-power scanned lasers; and may explain the rapid regrowth seen with low energy hair removal systems.

Much debate surrounds the exact area of the follicle which must be destroyed in order to achieve clinical efficacy. Histologically, follicular and perifollicular coagulative changes appear to correlate with the degree of clinical efficacy (Figures 1 and 2). Lack of significant follicular damage histologically is accompanied by poor clinical efficacy.

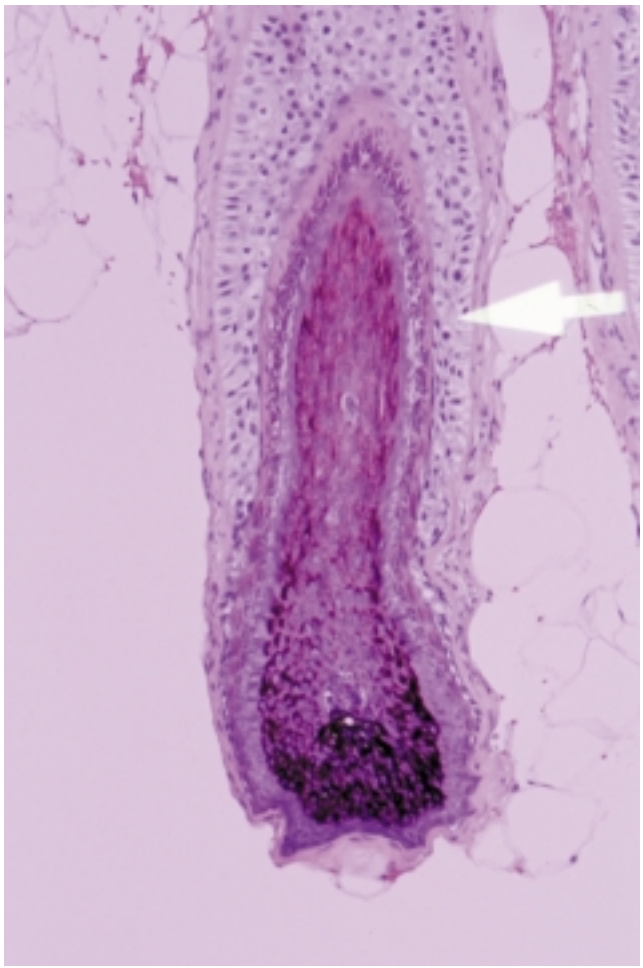


Figure 1. Normal Hair Follicle. The arrow indicates the outer root sheath.

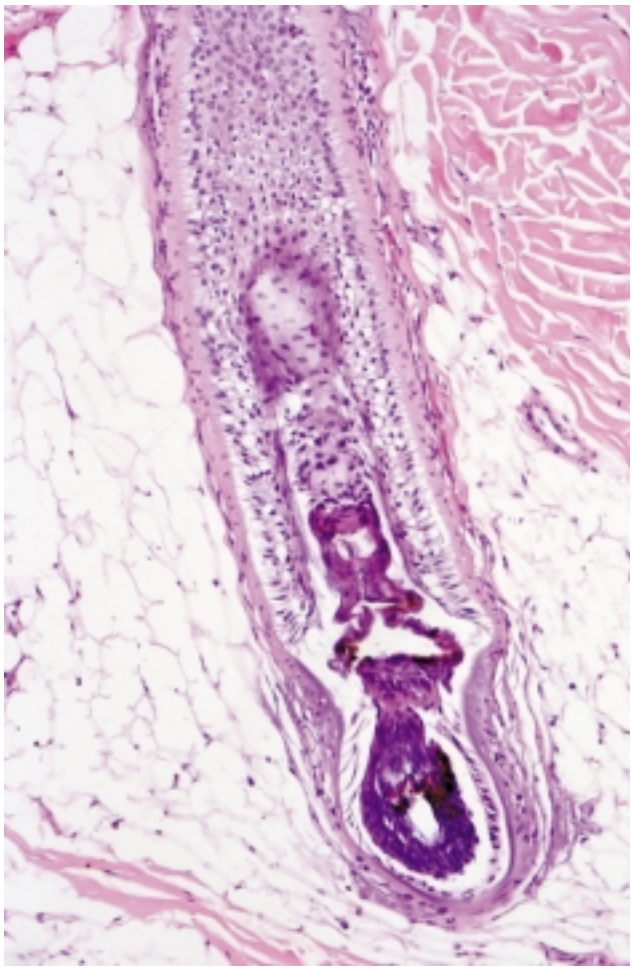


Figure 2. Anagen hair showing coagulative changes immediately after treatment with LightSheer Diode Laser at 35 J/cm^2.

In 1998, Coherent Medical introduced a new 800 nm high-power, pulsed diode laser system. Laser energy is delivered to the skin surface by means of a water-cooled, contact sapphire chill tip. The LightSheer Diode Laser (Coherent Medical, Santa Clara, California) consists of a Gallium Arsenide diode array coupled to a novel, water-cooled sapphire "chill" tip that is placed in contact with the skin during the delivery of laser energy. A 9 mm square imprint can deliver up to 60 J/cm^2 in one of the product's configurations, with selectable pulse widths of 5 to 30 ms. Two pulse width selections are available: a fixed 30 ms mode and the OptiPulse™ mode that fixes the pulse duration at one-half the delivered fluence (such as 40 J/cm^2 with a 20 ms pulse). Pulse repetition rate is one pulse per second (1 Hz) with a new 2 Hz system available. Clinical studies showed the ability of this system to deliver higher fluences with fewer clinical side effects and accompanied by significant clinical efficacy.

Side by side comparison with the long-pulsed PhotoGenica LPIR™ Alexandrite system (Cynosure, Chelmsford, MA) and EpiLaser™ Ruby system (Palomar, Lexington, MA) (3 ms pulse-width) confirmed the ability of active, contact cooling with the sapphire tip to allow delivery of higher fluences in dark skin (type IV and V) individuals (Figures 3A and 3B). Since March of 1998 we have treated over 125 patients using this system. Our experience regarding clinical safety and efficacy is presented.

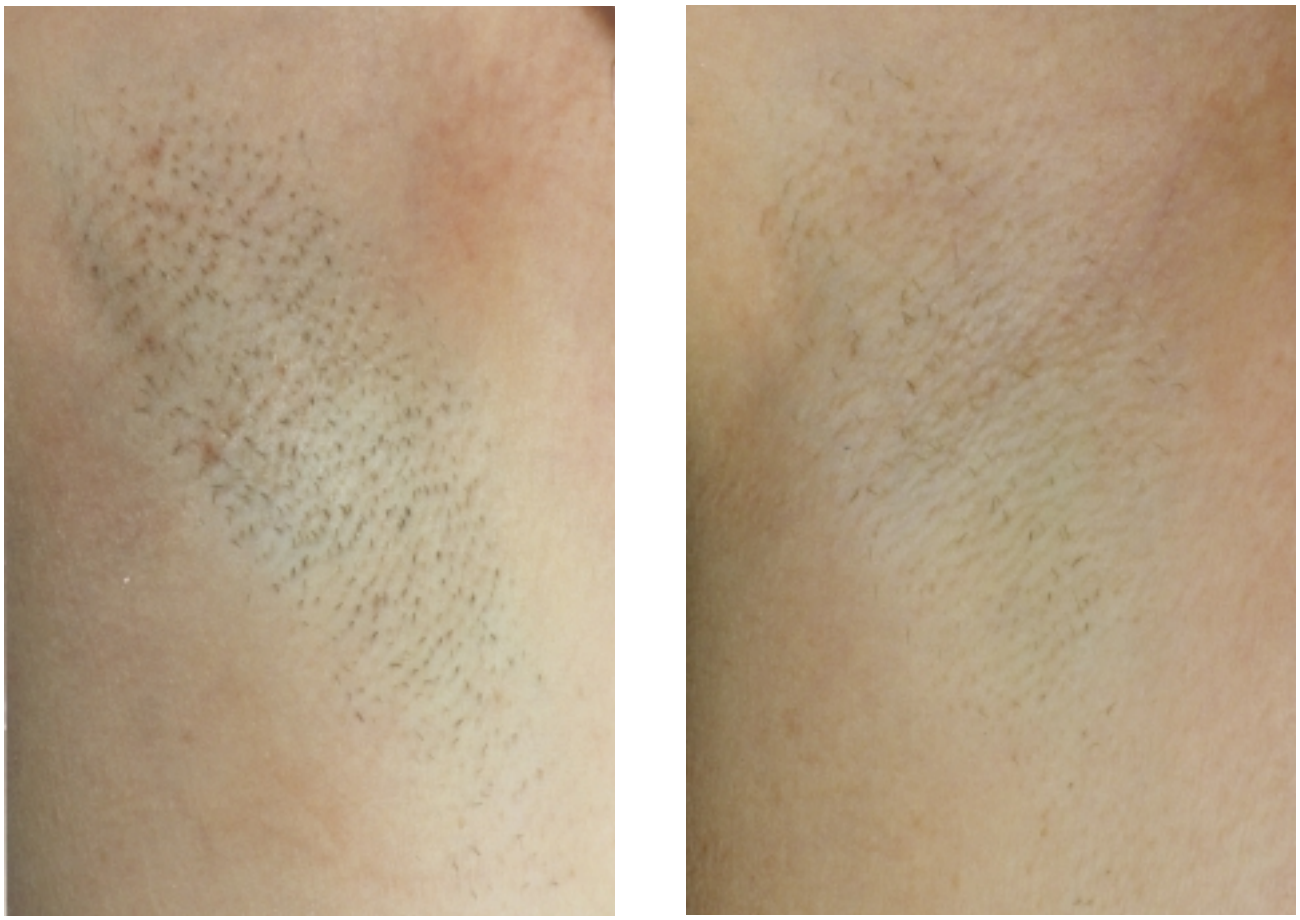


Figures 3A and 3B. Patient with skin type V before and two months after a single LightSheer treatment. The neck treatment fluence was 25 J/cm^2 and the pulse duration was 30 ms.

CLINICAL OBSERVATIONS

A major consideration in any clinical laser procedure is patient comfort. Most patients treated using this high-power, pulsed diode laser reported mild to moderate discomfort from diode laser impacts. Topical EMLA (Astra, Herfordshire, England) was used in approximately 60% of cases. No patient discontinued the treatment program due to this factor.

Clinically efficacy was judged on an individual basis by the patient, a laser nurse, and by the treating physician. Most patients treated experienced substantial (greater than 60%) long-term (greater than 6 months) efficacy after two or three treatments (Figures 4-7). Postoperative side effects were limited to epidermal crusting and temporary hypopigmentation in darker skin type patients. Over the past ten months, greater than 125 patients have received a total of one or more treatments using the LightSheer Diode Laser system. A variety of anatomic sites were treated including lip, face, neck, axillary, bikini areas, and backs. Our protocol involved treatment with follow-up at one week and one month after each treatment. Patients were re-treated when significant regrowth had occurred, which ranged from one to three months' time. Over 90% of patients had two treatments and over 70% had three treatments.



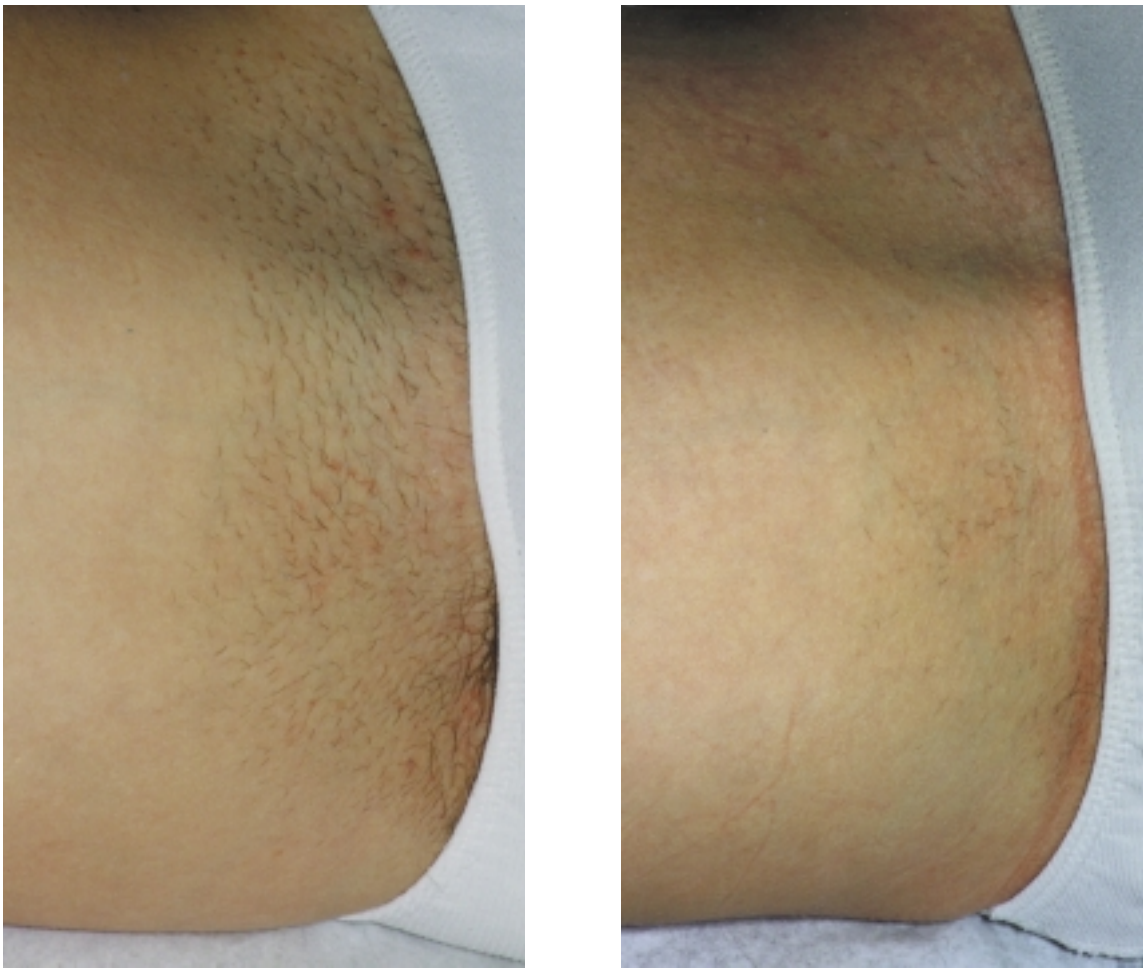
Figures 4A and 4B. Patient with skin type II before and eight months after three LightSheer treatments. The axilla treatment fluence was 40 J/cm^2 and the pulse duration was 20 ms.



Figures 5A and 5B. Patient with skin type III before and three months after one LightSheer treatment. The neck treatment fluence was 35 J/cm^2 and the pulse duration was 30 ms.



Figures 6A and 6B. Patient with skin type III before and five months after three LightSheer treatments. The facial treatment fluence was 35 J/cm^2 and the pulse duration was 30 ms.



Figures 7A and 7B. Patient with skin type II before and four months after three LightSheer treatments. The bikini treatment fluence was 40 J/cm^2 and the pulse duration was 30 ms.

Our results show an average clearance of over 60% after two treatments at monthly intervals. Fair skin type dark-haired subjects experienced excellent results; however, even skin type V patients could be treated safely.

Long term follow-up in 25 patients showed greater than 60% clearance at six months after treatment. Adverse effects were limited to erythema and edema postoperatively which lasted from 12-24 hours. Crusting and blistering were occasionally seen, however, no evidence of persistent pigmentation disturbances was noted. No textural changes or scarring was noted at any treatment sites.

Based on our clinical and histologic data and experience using ruby and alexandrite laser systems, it appears that the LightSheer Diode Laser system at 800 nm is quite effective when compared to other lasers in current clinical use. In addition, the availability of contact cooling allows the delivery of higher fluences in darker skin type individuals expanding the numbers of

individuals who may be treated (Table I). Although other laser systems can be used to treat darker skin type individuals, it is the unique ability of this laser to deliver significant fluences in darker skin type individuals that underlies its clinical advantages in laser hair removal procedures. Although limited in scope, our initial clinical evaluation and tissue studies would appear to indicate that the LightSheer Diode Laser provides a safe, comfortable method for significant long-term reduction in unwanted body hair.

Skin Type	**Fluence (J/cm^2)**	**Pulse Duration (ms)**
I	40	20 (OptiPulse)
II	30 - 40	15 - 30 (OptiPulse or fixed)
III	25 - 35	30
IV	20 - 30	30
V	15 - 25	30

Table I. Fluence related to skin type in diode laser procedures.

The settings provided above are based on substantial experience with laser hair removal systems. These LightSheer treatment parameters are provided as a guide and are not a substitute for clinical observation of laser-tissue interaction and clinical endpoints. Understanding the skin type and presence of tan are a critical step in the choice of settings. Training is available for the LightSheer. Contact your Coherent sales representative.

REFERENCES

1. Adrian, RM and Tanghetti, E. Clinical Evaluation of a High Energy Long-Pulse Ruby Laser for the Treatment of Unwanted Body Hair. Lasers in Surgery and Medicine Supp 9:36, 1997.

2. Grossman, MC, Dierickx, C, Farinelli, W, et al. Damage to Hair Follicles by Normal Mode Ruby Laser Pulses. Journal American Academy of Dermatology 35:6, 889-894, 1996.

COHERENT MEDICAL GROUP

2400 Condensa Street, Santa Clara, California 95051 Tel: 800-635-1313 Fax: 800-505-1133
408-764-3000 408-764-3999

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