Use of the LightSheer™ Diode Laser System for the Treatment of Benign Pigmented Lesions

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*Summary provided by
Lumenis Inc.*

BACKGROUND. Laser treatment of benign pigmented lesions is becoming an increasingly popular alternative to traditional methods such as dermabrasion, electrodessication, chemical peeling, chemical bleaching, or surgical excision. Numerous laser systems are currently available offering different methods for protecting the epidermis from thermal injury during treatment.

OBJECTIVE. To study the effectiveness of 800-nm Lumenis Inc.™ LightSheer diode laser system with contact cooling in treating benign pigmented lesions in subjects with a variety of skin types.

METHODS. An 800-nm, high-energy, long-pulsed diode laser with contact cooling has been used to provide treatment for benign pigmented lesions in subjects with a variety of skin types. The LightSheer diode laser was used with fluences of 30–40 J/cm^2 and pulse widths of 15–30 ms to treat a variety of pigmented skin lesions, including junctional and congenital melanocytic nevi. Subjects received up to 2 treatments at 4–6 week intervals.

CONCLUSION. One month after the second treatment 57% of subjects had at least 75% clearing of the lesion, including 20% who had greater than 95% clearing. The overall safety profile was excellent with only minor side effects observed.

Detailed descriptions of the use of the LightSheer laser for pigmented skin lesions are presented.

INTRODUCTION

BENIGN PIGMENTED SKIN LESIONS are an extremely common dermatological problem numbering in excess of 10 billion in the U.S. population alone [1]. Patients consider a number of these lesions cosmetically undesirable because of their location, color, size, or other clinical features.

For convenience, pigmented lesions may be divided into three types according to the location of the pigment within them. *Epidermal pigmented lesions* include benign melanocytic lesions such as lentigo solaris, speckled letiginous nevus (nevus spilus), café-au-lait macules, sebhorrheic keratoses, and ephelides (freckles), and benign junctional nevi. *Epidermal-dermal pigmented lesions* with both an epidermal and dermal component include compound nevi, Becker's nevi, disorders such as melasma, and postinflammatory hyperpigmentation. *Dermal pigmented lesions* include blue nevi, nevi of Ota or Ito, and nevomelanocytic nevi (acquired and congenital).

Prior to the introduction of lasers, treatment options for pigmented lesions were varied with the modality depending principally on the depth of the pigment. Dermal lesions were usually not amenable to treatment except by surgical excision. For other lesions, chemical depigmenting agents, such as topical hydroquinone or tretinoin, have been used [2]. Epidermal lesions, in particular, have been successfully treated using a destructive modality to remove the epidermis containing the lesion. Destructive modalities have included cryotherapy, dermabrasion, electrodessication, and chemical peeling [3,4]. Because such methods are essentially nonspecific in their destruction of the epidermis, however, side effects such as permanent hypopigmentation, atrophy, scarring, and skin surface textural changes may result. Therefore, treatment of pigmented lesions by selectively targeting the pigment-containing cells is preferable.

Recent advances in laser technology have provided a safe and effective alternative for the treatment of many types of benign pigmented skin lesions [5–7]. Selective destruction of pigmented lesions has been best achieved via selective photothermolysis [8] using pulsed, pigment-specific lasers. Through prudent selection of the laser parameters (i.e. wavelength, pulse duration, fluence, and spot size), a subcellular chromophore can be targeted directly enabling selective destruction of the offending pigment while preserving surrounding normal skin and minimizing cosmetically unacceptable side effects.

The target chromophore present in many of the pigmented lesions mentioned above is melanin. Although melanin absorption decreases as wavelength increases, it is still significant at wavelengths of 600 to 1200 nm, whereas absorption by the competing chromophore oxyhemoglobin is relatively low. In addition, the relatively long wavelength penetrates to a significant depth into the dermis. Thus, lasers operating in the 600 to 1200 nm range are ideal for specifically targeting melanosomes.

In order to attain maximum selectivity, the laser energy is applied with a pulse duration that approximately equals the thermal relaxation time of the target. In this manner, the heat is predominantly confined to the chosen target, thereby minimizing collateral thermal damage. For epidermal lesions consisting of sparsely distributed melanosomes of 0.5 to 1 μm in size, pulse durations on the order of 1 μs or less produce selective melanosomal fracture [9]. For dermal lesions, especially those with densely concentrated melanosomes, longer pulse durations enable higher, more effective fluences to be used by allowing some of the energy absorbed by the epidermal melanin to dissipate, thereby sparing the epidermis from injury.

Both short-pulsed (10–100 ns) lasers and long-pulsed (ms) lasers have been used for the treatment of pigmented lesions. Short-pulsed lasers, such as the flashlamp-pumped pulsed dye laser (504–510 nm, 300–500 ns), the frequency-doubled Q-switched Nd:YAG laser (532 nm, 4–20 ns)[10], the Q-switched ruby laser (694 nm, 20–40 ns)[11], and the Q-switched alexandrite laser (755 nm, 45–100 ns) are particularly useful for treating epidermal lesions and some dermal lesions where the melanin is evenly dispersed. The Q-switched Nd:YAG laser (1064 nm, 5–20 ns) is especially useful for dermal lesions.

Although less penetrating, the shorter wavelengths of the pulsed dye and frequency doubled Nd:YAG lasers are strongly absorbed by melanin and are appropriate for treating lesions where the abnormal pigmentation is confined to the epidermis and superficial dermis. Such wavelengths are also strongly absorbed by oxyhemoglobin; however, the relatively short nanosecond-to-microsecond pulse durations enable more selective targeting of the smaller melanosomes. The longer wavelengths of the ruby, alexandrite, and Nd:YAG lasers penetrate deeper into the dermis with much less absorption by oxyhemoglobin making them useful for treating both epidermal and dermal pigmented lesions. The deeper penetration is useful for treating dermal melanocytosis such as the nevus of Ota [12].

Long-pulsed lasers, such as the long-pulsed ruby laser (694 nm, 0.3–3 ms) and long-pulsed alexandrite laser (755 nm, 2–40 ms) are particularly suited for treating nevi in which the melanin is more densely concentrated in large masses, thereby creating a larger target. For this reason, these lasers were among the first used for hair removal.

The Lumenis Inc. LightSheer is a high-energy, long-pulsed diode laser system that delivers pulsed near-infrared laser light with a wavelength of 800 nm. It has selectable pulse durations of 5–100 ms and selectable fluences of 10–60 J/cm^2. The LightSheer laser has been shown to be very effective for removing hair [13]. Like other long-pulsed lasers, the LightSheer operates on the basis of selective photothermolysis, which effectively damages the target tissue while limiting damage to the surrounding tissue. Epidermal damage is particularly limited with the LightSheer by the use of a chilled sapphire window (ChillTip™). The pressure of the ChillTip against the skin not only provides excellent thermal contact for conductively cooling the surface of the skin during treatment, but also squeezes out the blood from superficial vessels and forces the target structures closer to the surface. Thus, use of the ChillTip enables higher fluences to be used, minimizes oxyhemoglobin interference, and provides partial anesthesia by minimizing the temperature rise in the epidermis [14]. The 800-nm wavelength, longer pulse widths, and effective epidermal cooling also enables the treatment of darker skinned patients with minimal side effects to the epidermis [15].

CLINICAL STUDY

Summary

This study investigated the safety and effectiveness of the Lumenis Inc. LightSheer Diode Laser System for the treatment of benign pigmented lesions.

Study Design

The study was conducted in 24 patients (2 males and 22 females) with Fitzpatrick skin types I-IV. Patients with a personal or family history of melanoma were excluded. No dysplastic nevi were treated. A total of 69 nevi, located on various regions of the body and with diameters less than 6 mm, were treated. These nevi included junctional melanocytic nevi and congenital melanocytic nevi.

Patients were treated with the 800-nm LightSheer diode laser system equipped with a 9x9 mm sapphire ChillTip (Lumenis Inc. Medical, Santa Clara, California). Pre-study investigations indicated that treating with the ChillTip cooling turned "on" protected the epidermis surrounding the nevus, preventing pigmentary changes. Use of the ChillTip did not appear to reduce the efficacy of individual treatments.

Initial treatments were conducted with 30–40 J/cm^2 fluences, 15–30 ms pulse durations, and a double pulse. The exact starting parameters depended on the patient's skin type. Pulse durations of 30 ms were used for patients with darker skin. Fluences up to a maximum of 60 J/cm^2 were used later in the study when higher fluences became available.

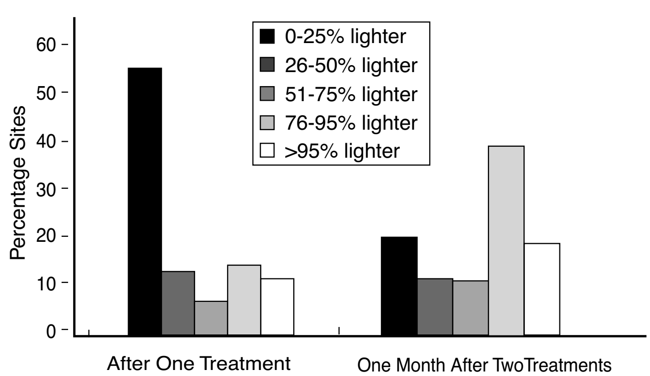

Figure 1. Percentage of nevi with clearing after treatment with the 800-nm Lumenis Inc. LightSheer diode laser.

An appropriate clinical endpoint was a darkening of the nevus. Adequate treatment was also indicated by mild to moderate erythema and edema immediately surrounding the nevus appearing several minutes following the treatment.

Each patient underwent 2 treatments at 4–6 week intervals. If the patient's response to the initial treatment was satisfactory, the fluence was increased up to a maximum of 60 J/cm^2, and the number of pulses increased to 3, at subsequent treatments. The percent of clearing was graded and side effects were recorded following each treatment and at 1 month after the second treatment. The treatment parameters were the same regardless of the size or thickness of the nevus. However, thicker nevi usually required more treatments than thinner ones.

Topical anesthetic was available, but was not required by any subjects in the study, for any treatment session.

Results

After one treatment, 46 (67%) of lesions were less than 50% clear, but 18 (26%) were more than 75% clear, including 8 (12%) that were more than 95% clear. One month after the second treatment, only 22 (32%) of nevi were less than 50% clear, but 39 (57%) were more than 75% clear, including 12 (17%) that were more than 95% clear (Fig. 1). Preliminary results indicate clearance of most nevi continues to improve after an additional treatment, or 3 months after two treatments.

Representative photographs of a skin lesion before and after treatment are presented in Fig. 2. No repigmentation was noted at the 3-month follow-up if the lesion was considered 100% clear.

The overall safety profile was excellent. Immediately after treatment, whitening to graying or darkening of the lesions occurred. Edema and sometimes erythema developed over the first 3 minutes. Side effects included temporary hypopigmentation surrounding 5 treated nevi, which cleared within 2 months (Fig. 3). Patients experiencing hypopigmentation were tanned. An interesting anecdotal observation was that the nevi in these patients cleared with fewer treatments than in untanned patients. Mild hyperpigmentation was noted for 3 patients, which cleared with hydroquinone and sunscreen treatment.

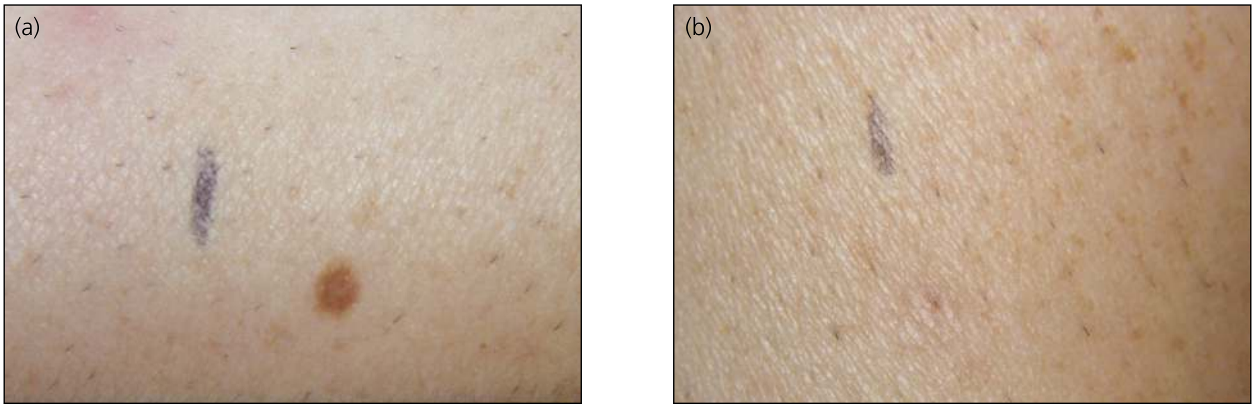

Figure 2. A nevus on the forearm of a 19-year–old female patient with Fitzpatrick Type III skin (a) before treatment, and (b) 10 weeks after one treatment with the LightSheer diode laser using 40 J/cm^2 and a pulsewidth of 30 ms. Clearance was rated as 95%.

Discussion

The 800-nm LightSheer high-energy, long-pulsed diode laser with contact cooling provides for safe and effective treatment of melanocytic nevi. The greatest efficacy was observed when high fluences and short pulse-widths were used. Darker and thinner nevi appeared to respond with high levels of clearance, as did nevi on skin that had received recent sun exposure.

Minimal side effects were observed, and these were of short duration and easily treated.

The results from this study compare favorably with results obtained with other laser treatment studies. For example, use of a Q-switched ruby laser to treat congenital nevi in 18 children found an average of 57% clinical clearance of pigmentation after 4 treatments and an average maximal clearance of 76% after eight treatments [16]. Greater than 90% clearance was observed in five patients. However, partial repigmentation was seen in 11 of 12 patients after 2 to 9 months.

Q-switched lasers have also been shown to be effective for the treatment of small macular and slightly raised junctional nevi. However, lasers such as the long-pulsed ruby laser and the LightSheer diode laser, which have longer pulse durations, can achieve active destruction of melanocytes and may be better at targeting larger cellular nests.

Continued experience with the LightSheer diode laser beyond the above-described study has found that higher fluences (up to 60 J/cm^2) increased the efficacy and decreased the number of treatments required. Darker skin types, including Asians, Hispanics, and light-skinned African Americans have all been successfully treated with minimal hyperpigmentation. The use of the LightSheer diode laser is being explored for the treatment of additional epidermal and dermal pigmented lesions. Initial anecdotal results have also been promising for the treatment of Becker's nevi, lentigos, and café-au-lait macules.

Figure 3. Transient hypopigmentation was observed in this patient with Type III skin, using 40 J/cm^2 and a pulsewidth of 20 ms. The hypopigmentation cleared within two months after treatment.

CLINICAL GUIDELINES

Types of Lesions

Although it has only recently been introduced for the treatment of pigmented lesions, the LightSheer diode laser is similar to other lasers that have been used to treat a variety of epidermal and dermal lesions.

Reports of the success rates of laser treatments for these lesions vary widely and depend on the type of lesion being treated, the type of laser used, the treatment parameters, and the number and duration of treatments.

Laser treatment of congenital melanocytic nevi has been a topic of discussion because of the possible increased risk of melanoma. However, laser treatment has been performed for congenital nevi that are clinically benign and/or that are located in an area where surgical excision is unsuitable. Patients should be cautioned that congenital nevi can recur.

Very lightly pigmented nevi can be treated, but it may be difficult to achieve significant lightening. The low density of pigment in these nevi makes treatment by longer pulses less effective.

Very dark and dense nevi can be treated, but should be treated cautiously.

Dysplastic nevi should not be treated.

Patient Selection

The LightSheer diode laser is suitable for the treatment of benign pigmented lesions in adults and children with all skin types except very dark skin. Patients with a personal or family history of melanoma should not undergo laser treatment for skin lesions.

Description of the LightSheer Diode Laser

The LightSheer diode laser system consists of a console, footswitch, and a handpiece connected to the console with an umbilical. In standard use, the handpiece is pressed against the patient's skin and a laser pulse is delivered when the handpiece trigger is depressed. The handpiece tip is water-cooled to provide active skin cooling. Laser parameters and other system features are controlled from the touch-screen.

Preoperative Instructions

Patients should remove all make-up and sunblock from the area to be treated. The area around the nevus should also be shaved prior to treatment. Patients should be informed that they might experience long-lasting or permanent hair reduction in the area exposed to the treatment beam.

A thin layer of ultrasound gel can be applied to skin before treatment. If a marker is used to annotate the patient's skin near the nevus, black ink should not be used because it will absorb the laser light and heat the epidermis. Red ink can be used.

Operative Techniques and Parameters

Suggested parameters for initial and follow-up treatments of benign pigmented skin lesions using the LightSheer diode laser are shown in Table 1. These parameters are based on clinical experience, but as with all laser techniques, the exact parameters may need to be adjusted depending on: (1) the type of lesion (for example, a very dark, dense lesion should be treated with lower fluences), (2) the patient's skin type (for example, when treating darker skin, longer pulsewidths and lower fluences should be used), (3) the presence of a tan (when treating tanned skin, longer pulsewidths and lower fluences should be used), and (4) observations of clinical endpoints during and immediately after the application of the treatment pulses.

Table 1: Suggested parameters for use of LightSheer laser for pigmented skin lesions[a]

Fitzpatrick Skin Type	Fluence (J/cm^2)	Pulse Duration (ms)	No. of Pulses
Initial Treatment			
I-III	40	20 -30	2
IV-V	30-40	30	2
Follow-up Treatments[b]			
I-III	Up to 60	30	3
IV-V	Up to 60[c]	30	3

a. These parameters are for the 800-nm laser with a 9x9 mm chilled sapphire tip.

b. Exact parameters for follow-up treatments will depend on how the patient responds to the initial treatment.

c. With darker skin types, higher fluence levels should be approached with caution (e.g. in increments of 2-3 J/cm^2).

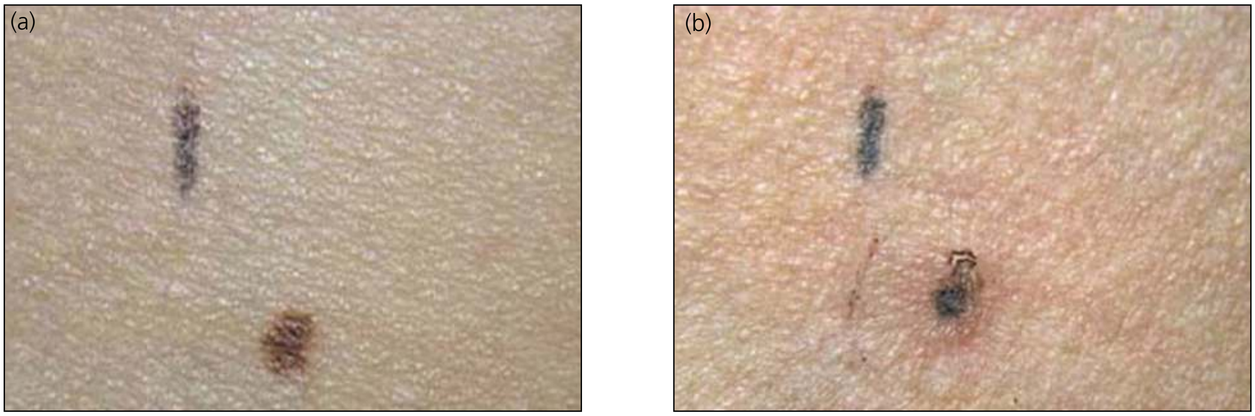

Figure 4. (a) Nevus on the hip of a 35-year-old female patient with Fitzpatrick Type IV skin prior to treatment. (b) The same nevus several minutes after treatment using 40 J/cm^2 and a pulsewidth of 20 ms. The nevus has darkened illustrating an appropriate clinical endpoint. Some erythema is visible immediately adjacent to the nevus. Surrounding the nevus, skin that was in contact with the ChillTip and exposed to the treatment beam appears normal.

The most effective treatment technique is to: (1) place the laser tip on the area to be treated, (2) apply the pulse or pulses (as suggested in Table 1), and (3) pick up the ChillTip and wipe it off. The same technique can be used for all sizes of nevi, but larger nevi usually require multiple tip placements and treatments. Using a sliding technique is not as effective since debris may accumulate on the tip.

Endpoints

For an individual treatment session, an appropriate clinical endpoint is the darkening of the nevus (Fig. 4). The appearance of mild-to-moderate erythema and edema around the nevus within several minutes following the treatment usually indicates satisfactory treatment. If the nevus is removed when the treated area is wiped, treatment outcome is often satisfactory.

If required, additional treatment sessions are administered until the lesion is completely cleared, or until no more clearing occurs. Typically, 2 to 5 treatments are required at approximately one-month intervals. Thicker and lighter nevi usually require more treatments than thinner and darker ones.

Postoperative Care

Postoperative stinging can be alleviated by the application of ice packs, gauze soaked in cold water, or an occlusive dressing. The treated area should be gently washed at least twice daily with soap and water. In the event the epidermis has been removed, an ointment, such as Aquaphor or aloe vera gel, and an occlusive dressing can be applied.

Patients should be instructed to avoid excessive sun exposure and use a zinc-oxide-based sunscreen with an SPF 20 or higher for several months after treatment to avoid the chance of hyperpigmentation.

Conclusions

- The 800-nm LightSheer diode laser provides safe and effective treatment for benign pigmented skin lesions.
- The greatest efficacy is observed with higher fluences, shorter pulse widths, darker nevi, and thinner nevi.
- Minimal side effects are observed, which are of short duration and easily treated.
- The 800-nm wavelength is effectively absorbed by melanin and allows deeper penetration into the skin for treating dermal melanocytes.
- The LightSheer diode laser is very effective for targeting clumped melanocytes of varying sizes because of its relatively long and variable pulse duration.
- The sapphire-tipped cooling device helps to spare the epidermis and decreases the risk of pigmentary and textural skin changes.
- The 800-nm wavelength, longer pulse widths, and cooling device all contribute towards making the LightSheer safe and effective for treating patients with darker skin.
- Treatment of benign pigmented skin lesions adds to the capabilities of the LightSheer diode laser, which is also used for the permanent reduction of hair and treatment of leg veins.

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