Permanent Laser Hair Removal With Low Fluence High Repetition Rate Versus High Fluence Low Repetition Rate 810 nm Diode Laser—A Split Leg Comparison Study

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ABSTRACT

High fluence diode lasers with contact cooling have emerged as the gold standard to remove unwanted hair. However, laser hair removal is associated with pain and side effects, especially when treating dark or tanned skin. A novel diode laser with low level fluence (5–10 J/cm^2) with a high repetition rate at 10 Hz (Soprano XL in SHR mode, Alma Lasers, Chicago, IL) using multiple passes in constant motion technique was compared to traditional one pass high fluence (25–40 J/cm^2) diode laser (LightSheer ET, Lumenis, Santa Clara, CA) in a prospective, randomized split-leg study on 25 patients with Fitzpatrick skin types I–V. Hair counts were done six months following the fifth treatment and were found to be comparable with a 86-91% hair reduction. There was one superficial burn with the high energy diode treatment. The rapid, multiple pass in-motion technique was faster and associated with significantly less pain. Multiple passes of diode laser at low fluences but with high average power results in permanent hair removal with less discomfort and fewer adverse effects, especially on darker skin.

INTRODUCTION

Laser hair removal has enjoyed substantial popularity, and is presently the second most popular non-surgical cosmetic procedure in the U.S. following botulinum toxin injections.[1]

Laser and light-based techniques rely on the process of selective photothermolysis.[2] The selective absorption of red and near-infrared wavelengths by melanin in the hair shaft and follicular epithelium confines thermal damage to the hair follicles and, to a point, limits the untoward diffusion of excess thermal energy to the surrounding tissue. Laser hair removal was first described in 1987 in an experiment to remove rabbit eyelashes with an argon laser.[3] Subsequently, physicians used the Nd:YAG laser[4] and the ruby laser[5] to remove hair. The alexandrite laser[6] and diode followed;[7] all have been thoroughly described and reviewed.[8] All of these laser systems used the highest fluence possible without damaging the tissue surrounding the hair follicle with a single pass.

The approach of using low fluences with repetitive millisecond pulses to achieve heat stacking in the hair bulb and bulge represents a paradigm shift in laser hair removal methodology. This study compares efficacy, safety and treatment speed of a new low fluence rapid pulse with multiple passes 810 nm diode hair removal modality with a traditional high powered single pass 810 nm laser diode system.

This is the first study designed to evaluate the hypothesis that low level fluences done repetitively on a hair follicle will produce permanent hair removal with less discomfort and fewer side effects than a single high fluence pulse.

MATERIALS AND METHODS

This prospective single-center, bilaterally paired, blinded, randomized comparison study was conducted in accordance with recognized Good Clinical Practice (GCP/ICH) guidelines and applicable regulatory requirements. Thirty-three (33) female subjects (skin types I–V) with hair on the legs who in the opinion of the investigator were viable candidates for laser hair removal were enrolled in the study. These patients were offered five complimentary laser hair removal treatments on their legs as an inducement to enroll in the study. Alma lasers partially funded the cost of the study.

Subjects were to be between 25 and 65 years of age, in good general health with no known photosensitivity or use of medication with photosensitivity as a side effect, no obvious skin disease or history of chronic skin disease other than moderate facial acne vulgaris, no history of keloid or hypertrophic scar formation, and no tattooing in the treatment area. Subjects were excluded if they were pregnant, nursing or unwilling to use birth control during the study period if of childbearing age; had waxed the lower legs or undergone therapy with any radiofrequency or light source; used prescription or over-the-

counter therapy to the skin of the lower leg within 30 days prior to enrollment; had history of any confounding cancerous or pre-cancerous skin lesions; or had been treated with an investigational drug or device within 30 days prior to and during the study period. Tanning for at least 30 days prior to and during the study period was discouraged. Shaving the legs was permitted; waxing was prohibited.

Using manufacturer-recommended methods and settings, one leg of each patient (randomly determined) was treated with the Soprano XL in SHR mode (Alma Lasers, Chicago, IL) using a technique of maintaining the handpiece in constant motion, fluence up to 10 J/cm^2, 10 Hz, 20 ms pulse duration. With the constant motion technique, an area of about 100 cm^2 was treated with six to ten mulitple passes. The operator never remains stationary in one spot, and is always moving the laser handpiece on the entire 100 cm^2 area, similar to ironing. By using this technique, the skin is never subjected to a single diode laser pulse greater than 10 J/cm^2. Since this is below the threshold of burning, the incidence of adverse effects should be lower, as well as the sensation of discomfort which is directly related to fluence. The purpose of the study was to evaluate the degree of discomfort using this constant motion technique and the amount of hair reduction. With six-month post-treatment hair counts, the efficacy of the low fluence-multiple pass technique could be compared to standard high fluence laser hair removal: the other leg was treated with the LightSheer device (Lumenis, Santa Clara, CA) using a conventional single pass, fluence to tolerance (20–50 J/cm^2), 2 Hz, 30 ms pulse duration. LightSheer parameters were aggressive so that there could be no criticism that the leg treated with the high fluence had inadequate energy. Subjects were treated five times at intervals of six to eight weeks with each device to permit hair regrowth and mimic real-life laser hair removal.[9]

Hair counts were made within a pre-determined square-shaped area (surface area=2.5 cm^2, measured 12 cm above the superior border of the malleolus) on each treated leg before initial treatment and at final follow-up, which occurred six months following the fifth and final laser treatment. Visual baseline hair density and final results were documented by digital photography. Hair counts were done by a university student who was blinded as to which laser was used on the leg and had no interest in the outcome of the study. The digitial photographs were enlarged so that any hair shafts growing within the 2.5 cm^2 grid were easily visible and counted.

Pain during treatment was measured subjectively by patients on a 0–10 visual analogue linear scale (0=no pain, 10=unbearable pain) and recorded by evaluators for each leg after each treatment session. Treatment time (in minutes) was recorded for each treatment session. Subjects were also asked which laser they preferred based on their results following the fifth and final laser session. Adverse events were noted by the investigator.

Data were to be analyzed using appropriate statistical tests based on normality of data distribution.

RESULTS

Twenty-five subjects completed the study. Seven patients were removed from the study for failing to return for scheduled appointments. One patient withdrew from the study due to minor superficial burns on the LightSheer-treated leg. Adverse effects were not observed in any other subject.

Data were analyzed and expressed non-parametrically as medians and interquartile ranges (IQR) because values for final hair count, treatment time, or pain score were not normally distributed. IQR is a measure of dispersion determined by the difference between the 75th and 25th percentiles. Statistical significance was measured by Wilcoxon Signed Rank test. In any case where n=123, this represents 125 total treatment sessions (five sessions x 25 patients) minus two missing data points due to evaluator error.

Based on final hair count values (n=25), overall median hair reduction was 86% with Soprano XL in SHR mode and 91% with LightSheer. According to Wilcoxon signed rank test comparing hair removal percentages between LightSheer and Soprano, differences were not statistically significant (P=0.1564). These results are demonstrated graphically in Figure 1.

Overall study results showed a statistically significant difference (P<0.0001, Wilcoxon Signed Rank test) in median treatment times between Soprano (20 min) and Lightsheer (26 minutes) over the course of five treatments (n=123). This is shown in Figure 2. IQR for each was 4.0 and 6.0, respectively.

FIGURE 1. Graph comparing the overall median hair removal percentages for Soprano XL in SHR mode (86%) and LightSheer (91%).

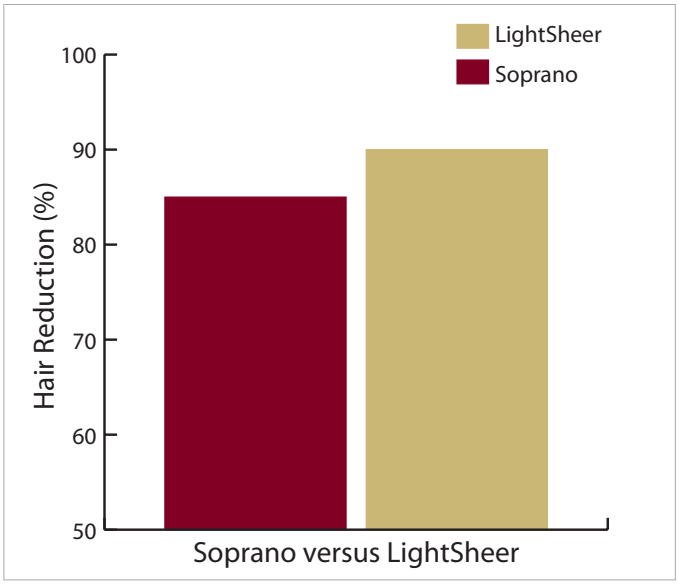


FIGURE 2. Graph comparing the overall median treatment times for Soprano XL in SHR mode (20 minutes) and LightSheer (26 minutes).

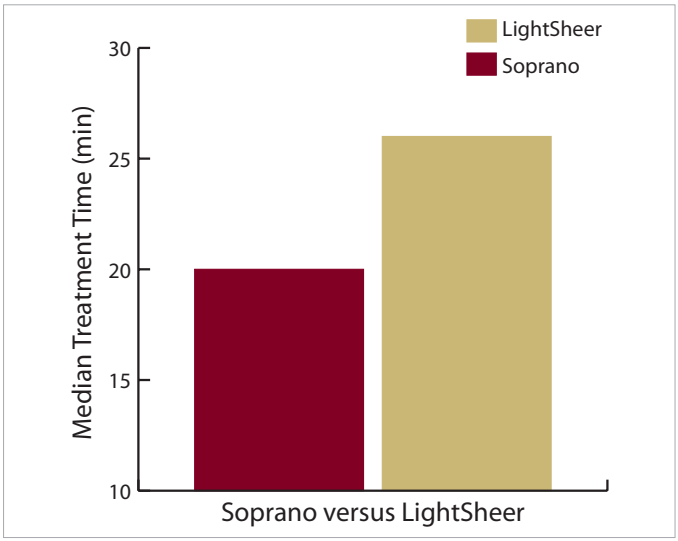
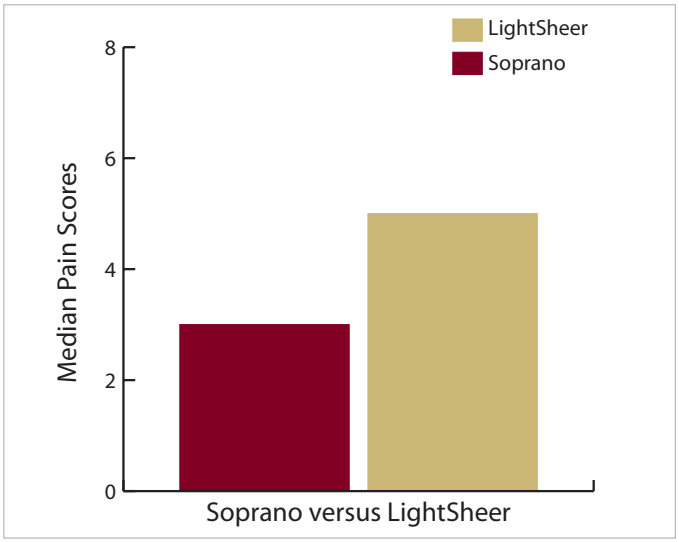


FIGURE 3. Graph comparing the overall median pain score data (0–10 scale) for Soprano XL in SHR mode (3) and LightSheer (5).



Study results showed the median pain scores of Soprano and LightSheer to be three and five, respectively, as measured on a 0–10 scale (0=no pain, 10=unbearable pain) over the five-treatment course (n=123). This result is highlighted graphically in Figure 3. IQR for each was 3.0 and 2.0, respectively. The difference between median overall pain scores for Soprano and LightSheer for treatments overall was 2.0, which is statistically significant (P<0.0001, Wilcoxon Signed Rank test).

DISCUSSION

Laser hair removal is painful, and can result in hypopigmentation or post-inflammatory hyperpigmentation, especially in dark skin tones. Lowering the energy should result in less pain and potential side effects, but this could theoretically affect efficacy. This study shows that low energy, high repetition diode laser pulses (ie. high average power) with the Soprano XL in SHR mode results in comparable hair reduction to the traditional high fluence single pass technique using the LightSheer laser. The Soprano XL in SHR mode has several advantages over traditional high fluence treatments, including less pain and a lower chance of adverse effects, especially with dark skin.

There are multiple techniques to reduce pain associated with laser hair removal, including topical anesthetic creams[10], tumescent anesthesia[11], topical non-steroidal anti-inflammatory creams[12], and cooling with cryogen which can also lead to permanent hypo- and hyperpigmentation.[13] Topical creams are expensive, time-consuming, and their injudicious use has resulted in deaths due to lidocaine toxicity.[14] In motion technique using low fluences reduces the pain associated with laser hair removal and has eliminated our need for any of the aforementioned techniques to improve tolerability. The median pain score was 3/10 for the Soprano, verses 5/10 for the LightSheer. This difference was statistically significant. Furthermore, the only high pain scores of 9 or 10/10 occurred during the first session with the LightSheer. Again, the patient with apprehensive anxiety may report a higher pain score on their first treatment session, and may not return for further treatments.

An advantage of the Soprano diode laser is that it can also be used as a high fluence diode laser, up to 120 J/cm^2. The high fluence one pass mode is easier to perform for hair removal near small, awkward areas like ears or upper lips. Repetitive passes would be difficult, if not impossible, to perform on those types of anatomical areas. A previous study by Krauss demonstrated that the Soprano diode laser is efficacious for hair removal in its high fluence mode, similar to other diode lasers.[15]

Due to Drs. Rox Anderson's and Parish's theory of selective photothermolysis, it has generally been assumed that one has to treat the hair follicle with one pulse of high laser energy sufficient to disable the hair follicle but not damage the surrounding tissue.[2] Laser manufacturers have designed their lasers to produce high energy pulses, with one pass at maximum tolerated fluence over the hair bearing skin. Since the laser photons have to cross the epidermal melanin in order to reach the melanin of the hair bulge and bulb, there exists the potential for adverse effects to the epidermis including hypo- and/or hyperpigmentation. Adverse effects increase with darker skin tones and higher fluences as these individuals have more epidermal melanin.[16,17] A recent histological study demonstrated that repetitive low energy diode laser pulses do induce necrosis of the follicular structures. Using the Soprano SHR mode, investigators treated 30 patients with a single Soprano SHR 810 nm diode laser session using the identical parameters used in this study. They examined 5 mm punch biopsies following a single treatment

and demonstrated that the physical integrity of hair follicles was altered with inflammatory infiltrate, hair shaft detachment from its sheath, and perifollicular edema, related to incipient necrosis.[18] Although the present study did not include any histology, one can infer that multiple treatments will destroy more follicles than a single treatment.[16,17,18]

The reader may wonder how several smaller bursts of energy can induce necrosis of the hair follicle. The total energy delivered to the tissue with multiple passes exceeds the amount of Joules per cm^2 delivered with the conventional high fluence one pass technique. It is simple to calculate the mean amount of energy delivered to the tissue by multiplying the number of laser pulses by the joules per pulse, and dividing by the area (in cm^2). This figure was frequently in the range of 30-50 J/cm^2 which exceeded the 25–40 J/cm^2 used in the single high energy pass. The amount of energy is limited in the single pass high fluence diode laser technique due to tolerability of the tissue to a single laser pulse. One patient withdrew from the study: a Fitizpatrick type V skin female who sustained minor burns to her leg by the LightSheer. Despite assurances that we could reduce the fluence and treat her again safely with the LightSheer, she refused further treatments.

CONCLUSION

Treatment with the Soprano XL in SHR mode is significantly less painful than with the LightSheer. Both devices produced hair reduction counts in excess of 85% six months following the final treatment, and there were no significant differences in efficacy. Rapid pulse, low fluence constant motion laser hair removal with the 810 nm diode laser represents an advance in safety, efficiency, and tolerability of laser hair removal treatment. This type of laser hair removal represents a paradigm shift from conventional one pass, high fluence procedures. The Soprano XL in SHR mode provides a new level of safety for darker skin tones without compromising efficacy. Further study of this modality with larger populations and testing on different body areas would be beneficial to determine the optimal amount of average energy density required for the best results in various skin types.

DISCLOSURES

Dr. Braun is a consultant for Alma Lasers, Inc., and received a stipend for performing this study.

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SHORT REPORT

Hair structures are effectively altered during 810 nm diode laser hair epilation at low fluences

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Abstract

Background: Diode lasers with high fluence and cooling technology are effective at removing unwanted hair but are also associated with discomfort and morbidity, especially when treating dark or tanned skins. *Methods*: Thirty patients with skin phototypes IV and V (range: 23–62 years of age; average: 39 years) underwent a single hair removal treatment using a new diode laser (810 nm) technology that incorporates low fluence but very high average power. The treatment technique employed multiple, in-motion, repetitive laser passes on a 100 cm^2 area of the skin. A 5 mm punch biopsy was carried out before and after a single treatment. Tissue samples were harvested and stained with haematoxylin-eosin. *Results*: The physical integrity of hair follicles was altered with inflammatory infiltrate, hair shaft detachment from its sheath, and perifollicular oedema, related to incipient necrosis. *Conclusion*: Low fluence but high average power diode laser technology yields significant changes in hair structure and architecture in patients with dark skin types. The procedure caused low levels of discomfort and was well tolerated.

Key words: *Fluences, hair removal, histology, laser, melanin*

Introduction

Photo-epilation was the most practised medical intervention in 2008 (1). Unwanted hair causes psychological distress due to 'imposed' social rules. Several techniques that use different light devices can be used to remove hair, but there are limitations when treating dark or tanned skins.

When laser epilation is carried out on light skin and dark hair, the rate of success is high (2). The selective absorption of laser light by the hair follicle in the 810–1200 nm spectrum band is expected to cause thermal damage to the hair follicle growth centres–bulge, bulb and papilla. Reports based on histology observations present extensive immediate damage of hair follicles after laser treatment (0–8). Reports on low fluence epilation with IPL devices (9), filterless flashlamp systems (10), and the alexandrite laser (11) produce partial degeneration of hair follicles and changes such as coagulation in the standard pattern of the neighbouring tissue. Thus, there is a need for an improved method for hair removal which heats the hair follicles to a sufficient temperature for hair removal while delivering a minimal amount of thermal energy to the epidermis (to achieve minimal discomfort).

A new 810 nm diode laser device for hair removal may have clinical advantages for epilation on dark and/or tanned skins due to its very high average power, high repetition rate, albeit at low a fluence, and may be a safer procedure that offers the possibility of achieving high clearance rates of hair removal with low morbidity. In order to evaluate the extent of treatment effects at the level of the hair follicle and to assess the extension of these effects in tissue, we have examined the histology of epilated areas in 30 patients immediately after a single treatment session.

Materials and methods

Patients with phototypes IV and V (15 males and 15 females in each group), ranging from 23 to 62 years

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of age (average 39 years), were enrolled. No patient had undergone any previous photo-epilation and all had dark, thick hair that they regularly epilated using either electric or blade razors.

The study was approved by the Ethics Committees of the Antoni de Gimbernat Foundation.

Patients underwent a single hair removal treatment with the 810 nm Soprano® XL diode laser device (Alma Lasers, Caesarea, Israel). The nozzle of the laser hand-piece incorporates Sapphire Dual Chill Window Technology through which a coolant is in constant circulation. Also, the hand-piece has an adapter to connect a cold air tube that focuses directly where the nozzle is pointed and continuously cools the area of treatment. The window from which the laser emits is 12 × 10 mm in size. The cooling system (Cryo 5; Zimmer ElektroMedizin, Neu-Ulm, Germany) was set to operate at intensity level #5 (high flow of cold air).

The diode laser pulses at a fixed rate of 10 Hz and at fluences varying from 5 to 10 J/cm^2. Lower fluences can be used in darker skin types; 8 J/cm^2 was used in this study. The pulse width adapts according to selected fluences, and ranges from 10 ms for 5 J/cm^2 to 20 ms for 10 J/cm^2. The treatment technique involves moving the hand-piece in a sweeping constant movement. The skin surface for treatment was divided into 10 × 10 cm squares and each received a total of 8 kJ. Thus, each 1 cm^2 of skin received on average 80 J/cm^2 (8000 J/100 cm^2 = 80 J/cm^2). The reason for dividing the treatment area into 100 cm^2 areas was to provide homogenous treatment exposure and to carry out systematic epilation. The hand-piece was moved over the skin at a speed of approximately 10 cm per second.

Areas of epilation were four side burns, 12 axillae, four bikini lines, six legs and four arms. Treatment areas were shaved and thoroughly cleansed with soap and water. Then, a thin coat of gel at an ambient temperature was applied to the skin surface for the purpose of facilitating the sliding of the laser nozzle over the skin at the time of treatment. During treatment, tissue temperature progressively increased. The end point for stopping laser passes was when intense erythema, pain or a burning sensation was present or when an accumulative energy of 8 kJ was attained. Patients were told to expect a heat sensation and were asked to advise the therapist when they felt unbearable pain or an intolerable heat sensation. The purpose of the treatment was not to burn the skin but only to reach levels of tolerable pain or intolerable heat sensation. In order to have a reference of the temperature achieved, skin temperature was measured during treatment with an infra-red (IR) surface thermometer (IR Surface Thermometer A28886; Zenit Measuring/Testing Instruments™, USA). At the time of treatment, the temperature never exceeded 42°C. Presumably, due to the high average power and depth of penetration of the 810 nm diode, the tissue temperature in the dermis was higher, as well as at the level of the hair follicle, due to its significant higher density in melanin content acting as a chromophore conductor for the 810 nm laser emission. Once patients felt minor pain and/or a heat sensation (12), the hand-piece was moved to the neighbouring area, continuing the epilation procedure.

Once total fluence was achieved in the whole area of treatment, a 5 mm punch biopsy was carried out in the same manner as it was performed prior to the start of treatment. A local injection of 0.5 ml of lidocaine, without vasoconstrictor, was administered. Samples were processed and stained with haematoxylin-eosin and were examined by an independent pathologist, who was requested to comparatively evaluate the changes occurring before and after treatment.

Results

The post-treatment epidermis was of normal configuration, and the keratin layer was intact with no identifiable changes. The samples of seven patients had some epidermal–dermal junction contraction, represented by more noticeable papillary crests in the dermis together with cytopathic and vacuole changes at the keratinocyte level (Figure 1). Moderate oedema, particularly in the dermis, was visible in its superficial layer. The dermis appeared normal and viable. Hair shafts detached from hair sheaths with perifollicular oedema, related to incipient necrosis, clearly visible due to the darker colour of the staining. There were variations in the standard physical integrity of hair follicles with inflammatory infiltration. None of these changes were present in the pre-treatment samples (Figures 2 and 3). Perifollicular oedema was clearly visible in all samples, together with signs of haemorrhage between the collagen fibres located at stroma level, representing a trauma which could be responsible for the epilation effect. Low-fluence laser epilation caused anatomical changes in the follicle that compromised its integrity.

Discussion

Safety and efficacy standards are not well established for laser hair removal in patients with a dark skin type. Methods to destroy hair follicles while keeping the epidermis alive are needed. We found that an 810 nm diode laser delivering a very high average power at a low fluence altered hair structure. While the changes were not dramatic, clinically there were fewer and finer hairs in the treated areas. Patients reported delayed regrowth at follow-up 1 month after treatment. A

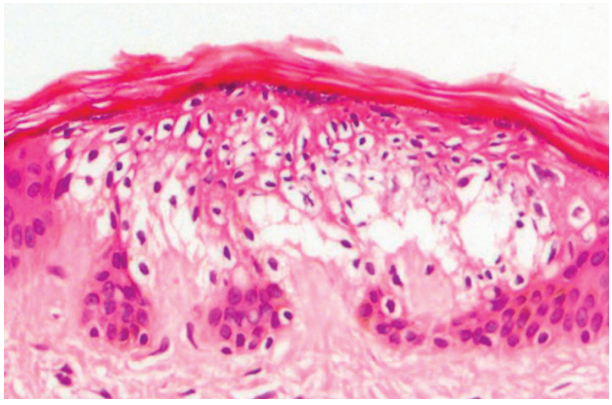

Figure 1. Skin × 125 H&E. Cytopathic and vacuole changes at the keratinocyte level are clearly seen.

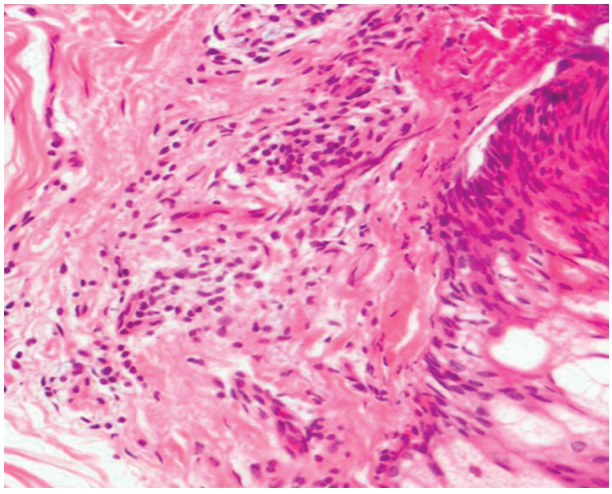

Figure 2. Skin × 400 H&E. Perifollicular oedema and peribulb thermal damage, represented by darker staining, and polymorphic nuclear cell inflammatory infiltration are noticed respecting the integrity of the neighbouring tissue.

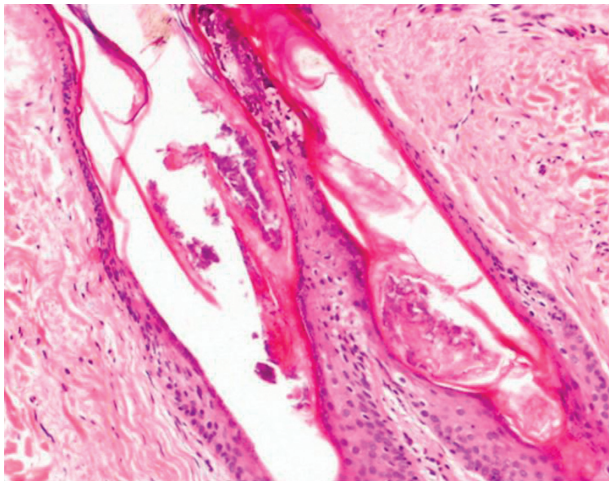

Figure 3. Skin × 250 H&E. Images of haemorrhaging are seen in between the collagen fibres at the stroma hair level.

Figure 4. Skin × 400 H&E. Perifollicular oedema is clearly noticed as a consequence of thermal effects.

Figure 5. Skin × 400 H&E. Presence of hair disruption with detachment from its shaft. Peri-isthmic fibrosis is observed together with inflammatory infiltration.

single session with the low-fluence, high pulse rate, 810 nm treatment can produce effective epilation.

Although the fluence of each individual pulse delivered is relatively low, the rapidly delivered pulses collectively effectively heat the patient's dermis. Since the hair follicle is in thermal equilibrium with the surrounding tissue and it is more sensitive to heat, it is more prone to thermal damage with repetitive, prolonged laser exposure. Thus, once the sub-dermal layer is significantly heated and the temperature at the hair follicle is sufficiently high, only a few additional high-rate pulses of low fluence are needed to raise the temperature

of the hair follicle to an effective temperature to impair the function of its biological elements. More-over, melanin in the hair follicle acts as a chromophore, providing a degree of selective heating. Because an excessive heat gradient may cause pain, once the sub-dermal layer is sufficiently heated, individual pulses should only provide enough energy to the hair follicle to achieve a critical temperature to impair the function of biological elements and hair growth.

Some follicles were damaged in their outer root sheath, others appeared with lesions of the inner root sheath, and others were of normal aspect. This may be attributed to a different volume and degree of heat in contact with the target, which is translated into oedema (Figure 4). Also, heat propagation from dermis to epidermis may be responsible for cytoplasm changes and vacuole formation at the level of keratinocytes, as observed in practically all 'immediately after' samples (Figure 5).

The 810 nm diode laser causes significant thermal damage and histological alterations to the hair follicle but not to the epidermis, even in patients with dark skin types. This may have important clinical implications for the dark-skinned population seeking a safe and effective hair removal procedure.

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ORIGINAL ARTICLE

Safety and efficacy of low-fluence, high-repetition rate versus high-fluence, low-repetition rate 810-nm diode laser for permanent hair removal – A split-face comparison study

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Abstract

Background: This study was designed to evaluate the hypothesis that low-level fluences done repetitively on a hair follicle will produce permanent hair removal with less discomfort and fewer side effects than a single high-fluence pulse. *Objective*: To compare the safety and efficacy of a low-fluence, high-repetition rate versus a high-fluence, low-repetition rate 810-nm diode laser for permanent hair reduction in patients with facial hirsutism. *Methods*: Forty-two female patients with confirmed polycystic ovaries by ultrasonography with facial hirsutism were subjected to the low-fluence, high-repetition Soprano® XL laser in SHR mode and the LightSheer™ laser on each side of the face using preset parameters once a month for six sessions. Hair counts were done at the end of the sixth session using a 'Hi Quality Hair Analysis Program System' and the pain score was recorded by a visual analog scale. *Results*: The overall median reduction of hair was 90.5% with the Soprano XL and 85% with the LightSheer, with a standard deviation of 7 and 8.5 respectively. *Discussion*: This new technology, with low fluence and high repetition, showed a statistically insignificant increase in hair reduction compared to the LightSheer, but did show a significant reduction in hair thickness and a low pain score.

Key Words: *fluence, laser, LightSheer, Soprano XL*

Introduction

Laser hair removal has become an accepted form of long-term hair reduction and is now one of the most common dermatologic procedures (1). The absorption of the laser light by a specific chromophore, regardless of the active medium, transforms the energy into heat, with the rate and extent of heating determined by the power density (power output/effective spot size) and the duration of exposure. The resulting thermal damage can lead to denaturization or irreversible coagulation of proteins or, if the temperature is more than 100°C, vaporization of tissue (2).

In recent years, a variety of lasers and pulsed light sources have been introduced for hair removal (3). The first involved a Q-switched Nd:YAG laser (1064 nm) used in conjunction with a topical carbon-mineral oil suspension, the carbon acting as a chromophore. However, this system showed minimal effectiveness for long-term hair removal (4,5). More positive results have been achieved with the long-pulsed ruby laser (694 nm) (6,7), the long-pulsed alexandrite laser (755 nm) (8), the diode laser (800 nm) (9,10), and a variety of filtered, flashlamp pulsed-dye lasers (11,12), all of which use melanin as the chromophore for selective photothermolysis. Selective thermal damage of pigmented target structures occurs when sufficient fluence at a given wavelength, preferentially absorbed by the target, is delivered during a time approximately equal to or less than the thermal relaxation time of the target (13).

The present study compares the efficacy, safety and treatment speed of a new low-fluence, rapid-pulse, with multiple passes, 810-nm diode laser with a traditional high-powered, single-pass, 810-nm diode laser system. The approach of using low fluencies with repetitive millisecond pulses to achieve heat stacking in the hair bulb and bulge represents a paradigm shift in laser hair removal.

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Materials and methods

This was an open-label, single-centre, prospective clinical study. A total of 42 female patients above the age of 18 years with facial hirsutism with Fitzpatrick skin types IV and V with polycystic ovaries confirmed by ultrasonography were enrolled in the study. The following patients were excluded from the study: patients with obvious skin disease or a history of chronic skin disease other than moderate facial acne vulgaris; keloidal or hypertrophic scar tendency; skin types I, II, III, and VI; severe photosensitivity; and pregnant patients. Prior to treatment an informed written consent was signed by each patient.

Using the manufacturer-recommended methods and settings, one side of the face of each patient (randomly determined) was treated with the Soprano® XL (Alma Lasers Ltd, Caesarea, Israel) in SHR mode using a technique of maintaining the handpiece in constant motion, with a fluence up to 10 J/cm^2, 10 Hz, and a 20-ms pulse duration as recommended by the manufacturers.

We achieved our desired results with fluences which ranged from 5 to 8 J/cm^2. The area to be treated was first shaved and a cool ultrasound gel applied.

The other side of the face was treated with the LightSheer™ (Lumenis, Inc., Santa Clara, CA, USA) using a conventional single-pass fluence to tolerance (25–35 J/cm^2), 2 Hz, and a 30-ms pulse duration (which was the pulse width found safest in our patient population based on past experiences on skin types IV and V).

The subjects were treated six times at intervals of 4–6 weeks with each device to permit hair regrowth and mimic real-life laser hair removal.

Baseline hair density and final hair counts after the sixth session were made within a predetermined square-shaped area (2×2 cm^2 area from the tip of the ear lobule to the jaw line) by using the hair analysis system SIF-1 for accuracy.

Pain during the treatment was measured subjectively by patients on a 0–10 visual analog scale (0 = no pain, 10 = unbearable pain) and recorded by evaluation for each side of the face after each treatment session.

Results

A total of 42 female patients above the age of 18 years with facial hirsutism completed the study. Nine additional patients were enrolled but did not finish the protocol and were excluded from the results. All the data were analyzed using appropriate statistical tests at the end of six sessions of treatment, which included the paired *t*-test. Statistical significance was considered to be $p < 0.05$.

Based on hair density recorded at the beginning and the end of the treatment session, we found that the overall median reduction of hair was 90.5% with the Soprano XL in SHR mode and 85% with the LightSheer, with a standard deviation of 7 and 8.5 respectively (Figure 1). Comparing the hair removal percentages between these two lasers using the paired *t*-test, we found that these differences were not statistically significant ($p < 0.063$).

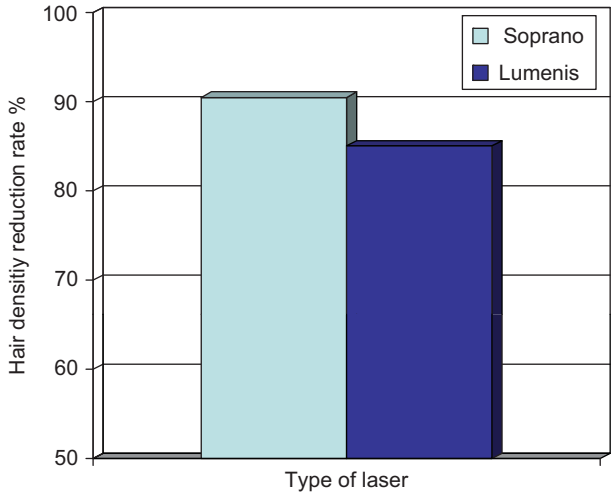

Figure 1. Graph comparing the overall median hair removal percentages for Soprano XL (90.5%) and LightSheer (85%).

However, on analyzing the hair width (mm) (measured using a hair analysis system), a much more striking observation was noted as the median hair width was reduced to 0.02 mm with the Soprano XL and 0.05 mm with the LightSheer (Figure 2). This was statistically different with a *p*-value of < 0.0005.

We observed that the median pain scores of the Soprano XL and the LightSheer were 2 and 6, respectively (Figure 3), as measured on a 0–10 visual analog scale (0 = no pain, 10 = unbearable pain) over the six treatment sessions. The difference between median overall pain scores was 4, which is statistically very significant ($p < 0.0005$).

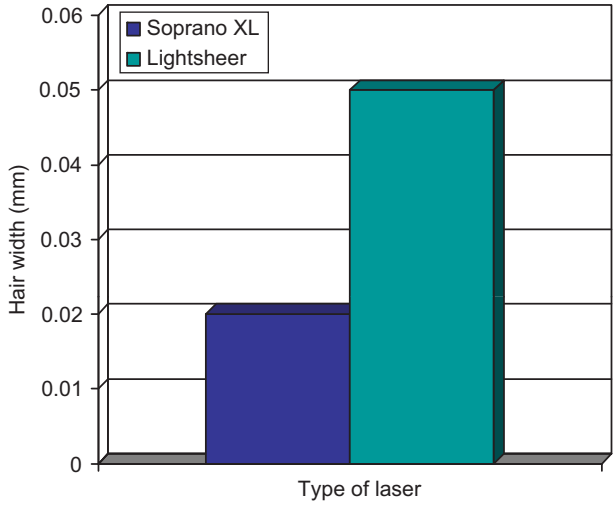

Figure 2. Graph comparing the overall median hair width reduction for Soprano XL (0.02 mm) and LightSheer (0.05 mm).

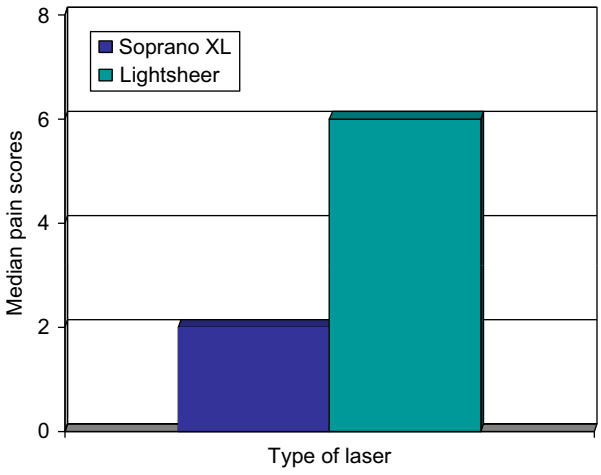

Figure 3. Graph comparing the overall median pain scores for Soprano XL (2) and LightSheer (6).

There were no adverse events noted during the course of the study.

Discussion

High-fluence diode lasers with contact cooling have emerged as the gold standard to remove unwanted hair. However, laser hair removal can be painful, and can result in hypopigmentation or post-inflammatory hyperpigmentation, especially in dark skin tones (14,15). Lowering the energy should result in less pain and fewer potential adverse events, but this could theoretically affect the efficacy of the therapy. This study showed that results using low-energy, high-repetition diode laser pulses with the Soprano XL in SHR mode are comparable in hair reduction to the traditional high-fluence, single-pass technique using the LightSheer laser. The approach of using low fluences with repetitive millisecond pulses to achieve heat stacking in the hair bulb and bulge represents a paradigm shift in laser hair removal methodology. With the Soprano XL system, the epidermal protection is achieved by the handpiece's sapphire contact cooling system. The system does not target melanin as the principle target chromophore. Instead, the Soprano XL focuses on raising the temperature of the sub-dermal layer of the skin progressively to at least to 45°C, and to less than the thermal destruction temperature of the hair follicle without heating the epidermis of the skin region. Although the fluence of each pulse delivered to the skin is relatively low, the rapidly delivered pulses effectively heat the dermis.

The Soprano XL in SHR mode has several advantages over traditional high-fluence treatments, including less pain and theoretically a lower incidence of adverse effects, especially in dark-skinned individuals.

With this technique, the laser handpiece never remains stationary in one spot, but is always moving in the treatment area – similar to what we would do while ironing. Hence, the skin is never subjected to a single diode laser pulse greater than 10 J/cm^2. Since this is below the threshold of burning, the incidence of adverse effects is lower, as well as the sensation of discomfort, which is directly related to fluence. We had a median pain score of 2/10 for the Soprano XL, verses 6/10 for the LightSheer. This was statistically significant. Further, this new technology with low fluence and high repetition showed a statistically insignificant increase in hair reduction compared to the LightSheer, yet it did show a significant reduction of hair thickness when the remaining hairs were measured. This was subjectively felt by the patients in the study and confirmed by measurement of the hair shaft. The reduced level of pain with the low-frequency modality laser increased patient compliance with the procedure. This can be better explained by the fact that all patients who underwent laser hair removal with the Soprano XL were calm and relaxed during the procedure; however, with the LightSheer diode patients moved, by reflex, away from the handpiece owing to pain and physical discomfort. Patients who subjectively wished to treat other parts of the body opted for this less painful laser. Further, all 42 patients who were enrolled completed the study.

In a similar study by Braun (14), similar observations for pain score and hair reduction were seen. A significant difference was that our study was conducted on androgen-dependent facial hair in contrast to leg hairs in the Braun study. We were also able to quantify hair loss and the thickness of the remaining hairs with the help of a hair scanner device.

A histopathology study was not done as it was not considered relevant to the scope of this study.

Conclusion

We concluded that low-level fluencies performed repetitively on a hair follicle will produce permanent hair reduction with less discomfort and fewer side effects than a single, high-fluence pass. Both devices produced hair reduction counts in excess of 80% 6 months following the first treatment; however, treatment with the Soprano XL produced a more significant reduction in hair thickness in subsequent sessions as compared with the LightSheer. Overall, the concept of this new technology has translated into greater acceptance by patients in terms of finer recalcitrant hairs and less pain during the procedure.

Conflicts of interest

Dr Gold speaks on behalf of Alma Lasers and Lumenis.

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Low fluence - high repetition rate diode laser hair removal 12-month evaluation: Reducing pain and risks while keeping clinical efficacy

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Keywords:

- diode laser;
- F1 diode laser;
- hair count;
- laser hair removal;
- low fluence;
- miniaturisation

Abstract

Background and Objective

High fluence diode lasers with contact cooling have emerged as the mainstay modality for hair removal. However, the use of these devices is associated with pain and side effects, especially in patients with dark or tanned skin. A novel concept of depilation at low fluence using 810 nm diode laser has been introduced as a solution to these shortcomings. The purpose of this study was to evaluate the lasting efficacy and safety of low-level fluence 810 nm (15 J/cm^2) and high repetition rate (5 Hz) F1 Diode Laser™ therapy on hair reduction in patients with various skin types.

Study Design/Materials and Methods

This randomised, controlled, bilaterally paired within-patient, double-blind study compared low level fluence 810 nm (15 Joules/cm^2) laser diode therapy to nontreated shaved control areas on long-term hair reduction. Seventeen patients with skin type II–V were treated four times at 1 month intervals. Hair count was assessed monthly over 10 months using an objective computerised method. Safety and tolerability were assessed by adverse reactions monitoring.

Results

Statistically significant differences in hair count between treated and control sites were observed at each follow-up visit. The majority of patients reported a slight but bearable sensation of heat during the laser treatment, and transient erythema post-treatment.

Conclusions

This study showed that laser hair removal with the F1 Diode Laser™ system was generally well tolerated, safe, and efficacious in this small sample study of patients with various skin types. After just four treatments, permanent hair reduction following one complete hair cycle has been shown. Controlled studies on larger groups of patients within each skin phototype are needed to confirm these promising results. Lasers Surg. Med. 44:277–281, 2012.