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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-thecounter 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%).

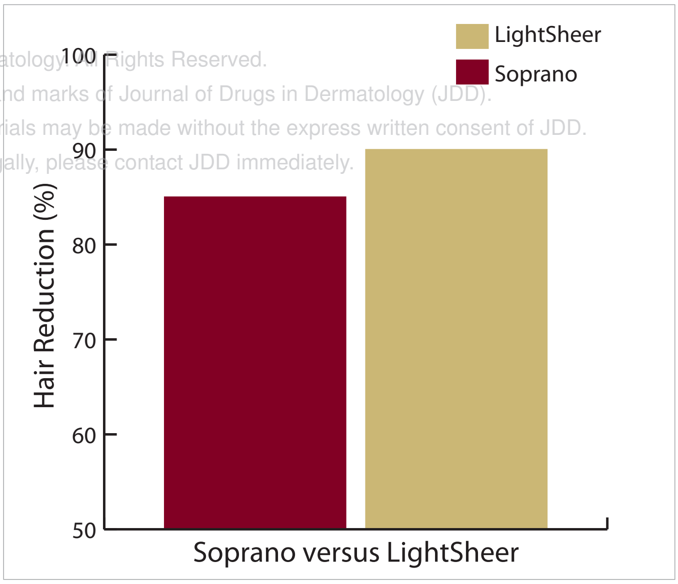


FIGURE 2. Graph comparing the overall median treatment times for Soprano XL in SHR mode (20 minutes) and LightSheer (26 minutes).

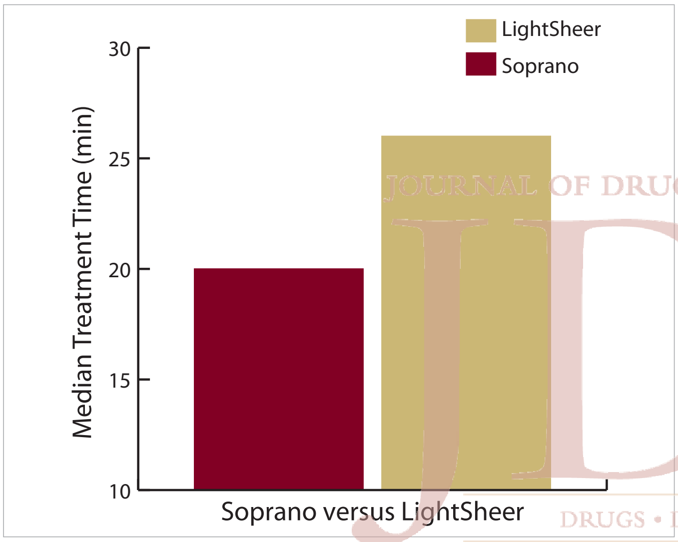
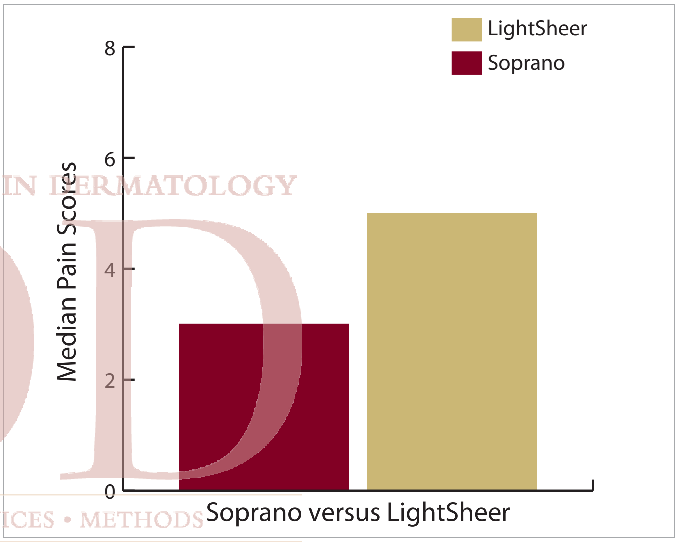


FIGURE 3. Graph comparing the overall median pain score data (0–10 scale) for Soprano XL in SHR mode (3) and LightSheer (5).



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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