Comparison of High-fluence, Single-pass Diode Laser to Low-fluence, Multiple-pass Diode Laser for Laser Hair Reduction With 18 Months of Follow Up

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ABSTRACT

Laser hair removal is the most popular laser procedure in the United States (U.S.), yet there has not been a prospective study demonstrating long-term efficacy of diode laser hair removal beyond six months. A prospective, single-center, bilaterally paired, blinded, randomized comparison split leg study was carried out with 22 patients comparing high-fluence, single-pass diode laser to low-fluence, multiple-pass diode laser. Hair counts were done six and 18 months following five treatment sessions and were found to be comparable 190–94 percent hair reduction. Hair counts at six months following the fifth treatment were comparable to hair counts at 18 months, indicating that sixth-month hair counts can be considered indicative of long-term results. The low-fluence, multiple-pass in-motion technique was associated with significantly less pain compared to the high-fluence, single-pass technique. Multiple passes of a diode laser at low fluences but with high average power results in permanent hair removal with less discomfort and fewer adverse effects, especially in darker skin.


INTRODUCTION

High-fluence diode lasers with contact cooling have emerged as the gold standard to remove unwanted hair.¹ There have been multiple studies demonstrating efficacy of laser hair removal at one to six months following the final treatment, including a meta-analysis² and a Cochrane review.³ However, there has been only one prospective study demonstrating hair removal efficacy beyond six months following the final treatment, which in that case compared the alexandrite to the Nd-Yag laser.⁴ In addition, 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/cm²) with a high repetition rate at 10 Hz (Soprano SHR by Alma Lasers, Chicago, IL) and using multiple passes in constant motion was compared to a traditional one-pass high fluence (25–40 J/cm²) diode laser (LightSheer ET, Lumenis, Santa Clara, CA).

The first study was designed to evaluate the hypothesis that low-level diode laser fluences done repetitively on a hair follicle will produce permanent hair removal with less discomfort and fewer side effects than will a single high-fluence pulse was published in this journal.⁵ Hair counts were done six months following the fifth treatment comparing the two lasers, and were found to be comparable. This paper reports further data from the original study with an 18-month follow-up following the final treatment. Hair counts done at six months following the final treatment correlate very well with hair counts done one year later.

PATIENTS, 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 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 doing the initial 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; they had waxed the lower legs or undergone therapy with any radiofrequency or light source; they used prescription or over-the-counter therapy to the skin of the lower leg within 30 days prior to enrollment; they had history of any confounding cancerous or pre-cancerous skin lesions; or they 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 low-fluence, multiple-pass device using a technique of maintaining the hand piece in constant motion, fluence up to 10 J/cm², 10 Hz, 20 ms pulse duration. With the constant motion technique, an area of about 200 sq. cm was treated with six to 10 multiple passes. The operator never remains stationary in one spot, and is always-moving the laser hand piece on the entire 200 cm² area, similar to ironing. By using this technique, the skin is never subjected to a single diode laser pulse greater than 10 J/cm². 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 and 18 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 high-fluence device using a conventional single pass, fluence to tolerance (20–50 J/cm²), 2 Hz, 30 ms pulse duration. The high fluence parameters were aggressive so that there was 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.

Hair counts were made within a pre-determined square-shaped area (surface area=2.5 cm², 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 and 18 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 digital photographs were enlarged so that any hair shafts growing within the 2.5 cm² grid were easily identified 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
Thirty-three subjects were enrolled in the study. Seven patients were removed from the study for failing to return for scheduled appointments. One patient with Type V skin withdrew from the study due to minor superficial burns on the high-fluence-treated leg. The burns resolved without any sequelae. Adverse effects were not observed in any other subject. The remaining 25 patients completed hair counts six months following the fifth treatment. Twenty-two of these patients were found one year later, and completed hair counts 18 months following the fifth treatment. The data of these 22 patients were compared at six and 18 months following the fifth laser treatment. Five patients had Type V skin.

Based on final hair count values (n=22), overall mean hair reduction was 82 percent with low fluence and 86 percent with high fluence at six months. Differences were not statistically significant. These results are demonstrated graphically in Figure 1.

FIGURE 1. Graph comparing the overall mean hair removal percentages for Soprano SHR (82%) and LightSheer (86%). P=ns.

FIGURE 2. Graph comparing the overall mean hair removal percentages for Soprano SHR (90%) and LightSheer (94%) at 18 months. P=ns.
DISCUSSION

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. Laser hair removal is painful, and can result in hypopigmentation or post-inflammatory hyperpigmentation, especially in dark skin tones. This study shows that low-energy, high-repetition diode laser pulses (i.e., high average power) with low fluence results in hair reduction comparable to the traditional high-fluence single-pass technique at six and 18 months post-treatment. The low-fluence device used has several advantages over traditional high-fluence treatments, including less pain (Figure 3) and a lower chance of adverse effects, especially with dark skin. It was not surprising that the one burn in the study occurred in a patient with Type V skin color.

This study demonstrates that hair counts done at six months following the last treatment correlate very well with hair counts done at 18 months following the last treatment (Figures 1 and 2). There was a trend towards improved efficacy at 18 months compared to six months, although the differences are not statistically significant. In fact, a review of the individual hair counts demonstrates that the hair reduction achieved at six months following the final treatment correlated very well with the hair count at 18 months following the final treatment. In other words, a six-month result can be deemed "permanent."

Other than studies with patient self-reported outcomes and retrospective chart reviews, there is only one other prospective study in the laser hair removal literature that followed patients with hair counts out to 18 months. This Iranian study compared alexandrite and Nd-Yag lasers, and reported inferior reductions in hair compared to the diode lasers used in this study. The hair reduction counts with the alexandrite laser were 85 percent versus 74 percent for the Nd-Yag laser at 18 months on Persian patients. In fact, the 1064 nm wavelength of the Nd-Yag laser has been found to produce the least efficacious results in laser hair removal despite this wavelength’s popularity for darker skin tones. This study demonstrates that the diode laser wavelength at 810 nm results in superior outcomes.

It is interesting to note that the hair reductions were not normally distributed: half the patients in the study had 0–1 hairs visible in the grid to count at six and 18 months post-treatment. This would imply that a female patient has a 50 percent chance of having virtually no hair on her legs following five treatments with diode laser hair removal done at six to eight week intervals. Naturally, these patients are very pleased with their results, and have virtually perfect, hair-free legs that require no shaving. Included in these patients, are women with Type V skin.

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. Laser manufacturers have designed their lasers to produce high energy pulses, with one pass at maximum tolerated fluence over the hair bearing skin. These high energies are obviously painful. There are multiple techniques to reduce pain associated with laser hair removal, including topical anesthetic creams, tumescent anaesthesia, topical non-steroidal anti-inflammatory creams, and cooling with cryogen which can also lead to permanent hyperpigmentation. Topical creams are expensive, time-consuming, and their injudicious use has resulted in deaths due to lidocaine toxicity. 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, reducing cost, time in the clinic, and risk. The median pain score was 3/10 for the Soprano, versus 5/10 for the Lightsheet. This difference was the only statistically significant finding in the study. Furthermore, the only high pain scores of 9 or 10 occurred during the first session with the high-fluence device. Again, the patient with apprehensive anxiety may report a higher pain score on their first treatment session, and may not return for further treatments.

Since the laser photons have to cross the epidermal melanin in order to reach the melanin of the hair bulb 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. 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 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 oedema, related to incipient necrosis. Although the present study did not include any histology, one can infer that multiple treatments will destroy more follicles than a single treatment.12,13

CONCLUSION

Treatment with the Soprano SHR is significantly less painful than with the LightSheer. Both diode lasers produced long term hair reduction counts in excess of 90 percent 18 months following the final treatment, and there were no significant differences in efficacy. Hair counts at six and 18 months following the final treatment are comparable: the patients that had permanent hair removal at six months still had permanent hair removal at 18 months. Thus, hair reduction at six months following the final treatment can be considered “permanent.” Rapid pulse, constant motion laser hair removal with the low-fluence 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 providing 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.

Dr. Braun has received honoraria for speaking for Alma Lasers. This 18-month follow up study was not funded by any manufacturer.

REFERENCES