A Comparison of Two 810 Diode Lasers for Hair Removal: Low Fluence, Multiple Pass Versus a High Fluence, Single Pass Technique

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Background & Objective: Laser hair removal has become an increasingly popular method to remove unwanted or excessive hair. We have assessed the relative efficacy and discomfort associated with competing hair removal techniques, namely a high average power 810 nm diode laser using an "in-motion" technique with a market-leading 810 nm device with a single-pass vacuum-assisted technique. This study has determined the long-term (6–12 months) hair reduction efficacy and the relative pain induction intensities of these devices.
Study Design/Materials and Methods: Prospective, randomized, side-by-side comparison of either the legs or axillae was performed comparing the Soprano XL 810 nm diode in super hair removal (SHR) mode (Alma Lasers, Buffalo Grove, IL) hereafter known as the "in-motion" device vs. the LightSheer Duet 810 nm diode laser (Lumenis) hereafter known as the "single pass" device. Five laser treatments were performed 6 to 8 weeks apart with 1, 6, and 12 months follow-ups for hair counts. Pain was assessed in a subjective manner by the patients on a 10-point grading scale. Hair count analysis was performed in a blinded fashion.
Results: There was a 33.5% (SD 46.8%) and 40.7% (SD 41.8%) reduction in hair counts at 6 months for the single pass and in-motion devices respectively ($P = 0.2879$). The average pain rating for the single pass treatment (mean 3.6, 95% CI: 2.8 to 4.5) was significantly ($P = 0.0007$) greater than the in-motion treatment (mean 2.7, 95% CI 1.8 to 3.5).
Conclusions: This data supports the hypothesis that using diode lasers at low fluences and high average power with a multiple pass in-motion technique is an effective method for hair removal, with less pain and discomfort, while maintaining good efficacy. The 6 month results were maintained at 12 month for both devices. Lasers Surg. Med. © 2014 Wiley Periodicals, Inc.

Key words: laser; hair removal; diode; in-motion

INTRODUCTION

Excess or unwanted hair growth remains a treatment challenge and considerable resources are spent achieving a hair-free appearance. Traditional treatments such as shaving, plucking, waxing, chemical depilatories, and electrolysis are not considered ideal for many individuals. These methods can be tedious and painful and most only produce short-term results. Hair removal with laser devices and intense pulsed light has become commonplace and is currently the 3rd most popular non-surgical cosmetic procedure in the United States [1].

Laser hair removal was first described in an experiment to remove rabbit eyelashes with an argon laser in 1987 [2]. Current laser treatments rely on the technique of selective photothermolysis [3] the goal of which is to target a defined structure using a particular wavelength of light delivered in or about the time that the target structure loses 50% of its heat, also known as the *thermal relaxation time*. The energy absorbed selectively heats the target while allowing the surrounding area to remain relatively untouched. In laser hair removal, melanin in the hair shaft is the target chromophore, whence heat is transferred to the associated stem cells and follicular bulb. While many wavelengths can target melanin, this study compares two 810 nm diode lasers.

Eight hundred ten nanometers of diode lasers were FDA cleared for hair removal in 1997. They are currently considered amongst the most effective lasers for hair removal [4]. We compared two methods of delivery; low fluence, high average power, in-motion technology and high fluence, vacuum assisted single pass technology. A previous study histologically demonstrated that repetitive low fluence laser devices do indeed induce necrosis of the hair follicle [5]. This study compared two widely available diode lasers to evaluate both the efficacy and relative discomfort during treatment. The manufacturers of both laser companies were invited to fund this investigator initiated study. As indicated above, only one company elected to assist in this manner.

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MATERIALS AND METHODS

Study Design

This was an investigator initiated, prospective, single-center, randomized, side-by-side comparison study. Twenty subjects with Fitzpatrick skin types II-V were enrolled. Each patient was randomized to receive treatment on their axillae or legs. There were 10 subjects in each group. One side (randomly determined) was treated with the in-motion device (low fluence, high repetition rage, 810 nm). Fluences ranged from 6 to 12 J/cm^2 with a 20 milliseconds pulse duration. Areas of 100 cm^2 were treated with multiple passes until reaching *a cumulative energy dose* between 6 and 10 kJ. The other side was treated with the single pass (high fluence, vacuum assist) device. Fluences ranged from 6 to 12 J/cm^2 with pulse durations between 30 and 70 milliseconds. Each treatment was conducted with low or medium vacuum assist. Each subject received five treatments 6 to 8 weeks apart. All treatments were performed without any pre-treatment anesthesia or cooling. Each treatment was conducted with *equal fluences for both devices*, starting with lower fluences and titrating higher depending on the clinical response. There were three follow-up visits at 1, 6, and 12 months post-last laser treatment. Pre-treatment and follow-up photographs were taken as well as a brief satisfaction questionnaire at each follow-up visit. This study was approved by the UC Irvine Institutional Review Board (HS# 2010–7704).

All subjects were female and aged between 23 and 57 at the time of screening (Table 1–Demographics). Subjects were all in good general health with no known photosensitivity, no history of keloid or hypertrophic scarring, and had no skin conditions in the treated area that could affect assessments. In addition, pregnant women were excluded. Only shaving in the treatment area was allowed; waxing or other forms of hair removal were prohibited. Tanning was also prohibited during the study treatment period.

Hair counts were made in a pre-determined 2 cm × 1.5 cm area. A single observer who was blinded to treatment modality conducted all hair counts.

Pain during each treatment was measured subjectively by patients on a 0–10 visual analogue scale (0 = no pain, 10 = unbearable pain). At each of the three post-treatment follow-up study visits, patients were asked about their level of satisfaction with their treatment (excellent, very good, good, fair, poor). Adverse events were also noted at each visit.

Statistical Analysis

This was a two-arm randomized trial to compare the efficacy of the in-motion versus the single pass lasers for removal of hair on the legs or axillae. The primary efficacy endpoint was the percentage of hair reduction at 6 months relative to baseline. Secondary analyses of the primary endpoint include hair reduction at 1 month and 12 months and assessment of change between 6 month and 12 months. The analysis of primary efficacy, difference between treatments, is based on the t-test at level 0.05 and similarly for the secondary analyses comparing treatments at 1 and 12 months. Point estimates along with 95% confidence intervals (CIs) of percent reduction are presented. The comparison between 6 and 12 months is based on a linear mixed model (LMM) where a feasible compound symmetry covariance structure (or correlation) among repeated measurements were used. As summarized in the Results Section, to obtain a more precise estimate of the amount of hair reduction at 6 and 12 months we averaged over the treatments using a linear mixed effects model without interaction between treatment and time. The secondary is outcome is pain rating (scale 0 to 10) at five treatment sessions, about 1 month between sessions. Analysis of the repeated measurements of pain rating was similarly based on a LMM. Analyses were performed in SAS version 9.3.

RESULTS

All 20 subjects completed five treatments. All subjects completed their 1-month follow-up visit. Eighteen subjects completed both their 6 month and 12 month follow-up visits.

TABLE 1. Demographics: A comparison of low fluence, multiple pass 810 nm diode laser hair removal vs. standard single pulse technique

Characteristics	Value
Age	23–57 years
Fitzpatrick skin type	
II	4
III	6
IV	8
V	2
Race, n (%)	
Caucasian	10 (50)
Asian or Pacific Islander	3 (15)
Hispanic	7 (35)

Fig. 1. Photo of burn following treatment with the single pass device.

There were no unexpected adverse events. There was one burn with blistering associated with the single pass device which resolved completely after 3–4 weeks with no permanent sequelae (Fig. 1). This subject was treated with fluocinonide 0.05% cream twice daily for 1 week. Of note there were 10 instances where a superficial "stamping pattern" in the shape of the output guide was visible after treatment with the single pass device. In all instances this completely resolved without any residual pigmentary changes in three to 4 weeks.

Representative photographs of a study subject at baseline, 1 month, 6 month, and 1 year follow-up visits are show in Figure 2.

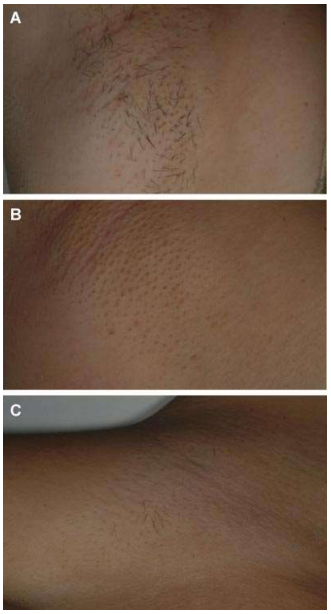

Fig. 2. Representative photographs of a study subject's axilla at (**A**) baseline, (**B**) 1-month, and (**C**) 12-month follow-up visits.

Primary Endpoint: Hair Reduction

Determination of the difference in efficacy between the single pass and in-motion device treatments was based on percentage hair reduction at 6 months relative to baseline. Figure 3 shows the percentage of hair reduction by treatment type at 1, 6 and 12 months post-last laser treatment. The average percentage of hair reduction at 6 months relative to baseline for the single pass and in-motion treatment were 33.5% (SD 46.8%) and 40.7% (SD 41.8%), respectively. The difference of 7.2% between treatment types (95% CI: −6.7% to 21.1%) was not statistically significant ($P = 0.2879$). Results based on a LMM are the same and are not reported.

Secondary analyses of the primary endpoint examine hair reduction at 1 month and 12 months relative to baseline. At 1 month, hair reduction relative to baseline for the single pass and in-motion treatment were 52.7% (SD 32.2%) and 57.6% (SD 34.03%), respectively, and the difference of 5.9% was not statistically significant (95% CI: −6.9% to18.7%; $P = 0.3433$). At 12 months, 44.7% (SD 43.2%) and 47.5% (SD 38.41%) hair reduction was observed for the single pass and in-motion treatment, respectively. The difference of 2.7% was not statistically significant (95% CI: −9.2% to 14.6%; $P = 0.6339$).

Difference in Hair Reduction at 6 and 12 Months

We examined whether hair reduction at the longer follow-up time of 12 months differed significantly from 6 months. As stated above, to obtain a more precise estimate of the amount of hair reduction between these assessment times, we averaged over the treatments of both devices using a linear mixed effects model. Reduction in hair growth at 6 and 12 months were 36.7% and 46.1%, respectively. The difference of 9.4% was not statistically significant at level 0.05 ($P = 0.0818$, 95% CI: −20.0% to 1.2%).

Secondary Endpoint: Pain Rating

A summary of pain ratings for the five treatment sessions is presented in Figure 4. Overall, the average

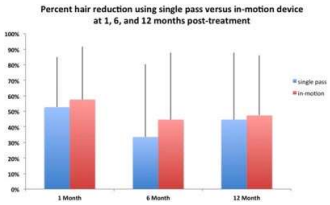

Fig. 3. Percent reduction in hair from baseline to follow-up.

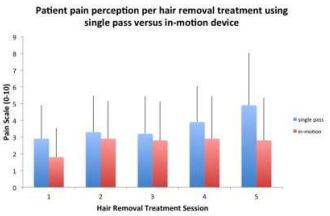

Fig. 4. Pain rating (scale 0 to 10) for each treatment session.

pain rating for the single pass treatment (mean 3.6, 95% CI: 2.8 to 4.5) was significantly ($P = 0.0007$) greater than the in-motion treatment (mean 2.7, 95% CI 1.8 to 3.5). Furthermore, the perception of pain became more obvious with increasing fluences during successive treatment sessions, particularly in the single pass technique when compared with the in-motion technique ($P < 0.0001$).

Satisfaction Questionnaire

At the one-month follow-up visit, all subjects reported excellent (11) or very good (9) satisfaction with their outcome. At the 6-month follow-up visit, subjects reported excellent (7), very good (5), and good (6). At the 12-month follow-up visit, subjects reported excellent (6), very good (8), good (3), and one fair. Figure 5 summarizes these findings.

Fig. 5. Summary of patient satisfaction at each follow-up visit.

DISCUSSION

Laser hair removal has proven to be an effective treatment modality but is not without pain and discomfort. This study sought to determine if a new treatment technique could result in effective hair removal while reducing patient pain and discomfort. This study shows that the multiple pass, low fluence in-motion device is both effective, and somewhat less painful than the traditional high fluence, single pass device.

In darker skinned patients, post-inflammatory pigmentation is also a concern. Earlier studies have shown that use of the in-motion device can be used safely on darker skinned patients without the adverse events such as increased pain, burning, and hypopigmentation [6].

Current methods to reduce patient pain and discomfort generally involve topical anesthetics, which increase total treatment time, might incur an additional cost to the patient, and have been associated with significant morbidity and mortality over the years. This study indicates that the low fluence in-motion technique reduces treatment discomfort and may reduce the need for topical anesthetics. The device can also be used in the traditional high fluence mode for locations where multiple passes can be impractical, such as the upper cutaneous lip. In terms of usability, the in-motion device was judged less elegant, somewhat heavier and less easy to use, and took on average 50% longer than the single pass device. These aspects need to be evaluated by prospective users to determine which type of device would be more appropriate for an individual practice.

Current literature states that diode lasers afford a hair count reduction in the range of 25 to 91% [6,7–14]. Our results were well within this reported range. The 6-month reduction was well maintained or even augmented, though not statistically, at 12 months. The latter was an interesting finding, but one previously reported in a similar study [15].

In summary, the in-motion and single pass 810 nm diode laser techniques studied were found to be equally effective at hair removal. The in-motion technology was found to be statistically less painful than the single pass technology when using equivalent fluences.

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