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New 4,800W, 810 nm Diode Laser with a Spot Size of 20x15 mm for Permanent Hair Removal: Pilot Clinical Study

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Abstract— Background*: The diode laser is currently the most widely used method for permanently removing unwanted hair, and has consolidated itself as an effective, safe and permanent technique. The results obtained with this technique depend mainly on the parameters used, such as pulse duration and fluence, with better results being achieved using higher powers and shorter pulses. One of the limitations of the diode laser is that, to obtain better results, small spot sizes must be used to apply shorter pulses, which slows down the treatment. Larger spots can epilate faster but are not efficient enough at removing fine hair.* ***Objective****: This study presents a high-power (4,800 W), 810 nm diode laser with a spot size of 20x15 mm, which will allow treatment to be carried out on both large and small areas, improving the overlap between each shot and achieving permanent hair removal in less time.* ***Materials and methods****: To evaluate efficacy and safety, a pilot study was designed involving two subjects and eight treatments on different body areas, using both static and dynamic application modes in a single hair removal session.* ***Results****: The new 4,800 W, 810 nm diode laser with a spot size of 20x15 mm is suitable for effective, safe and fast treatments. The sessions were quick, with a mean time of 5.5 minutes (SD 4.4), and ranged from 2 to 13 minutes depending on the area treated. The applicator was able to epilate large and small areas, in both static and dynamic modes, with a mean hair reduction of 74.4% (SD 11.4%) in just one session. No side effects were reported, except for perifollicular edema just after treatment, which is considered a desirable end point.* ***Conclusions****: The new high-power diode laser applicator with a spot size of 20x15 mm is highly effective, allowing large and small areas to be treated with an optimized spot size. It is also expected that it will produce permanent results in fewer sessions. This new applicator enables comfortable and safe treatments thanks to its optimized sapphire-crystal cooling system.*

Keywords— *Hair removal, high-power diode laser, primelase, contact cooling, fast treatments, high efficacy.*

I. INTRODUCTION

Unwanted hair growth is a common aesthetic problem worldwide. Photoepilation is one of the treatments currently available for hair removal. This type of hair removal has consolidated itself as an effective, safe and permanent option for removing unwanted hair and is one of the most commonly used hair removal techniques by both men and women. During photoepilation, light is absorbed by the melanin of the hair, generating heat which damages the germ structures of the follicle that are in the anagen phase (1-3).

The most commonly used photoepilation systems are lasers (Diode, Alexandrite, Nd:YAG and Ruby) and intense pulsed light (IPL), which have been shown to be effective in removing unwanted hair (4). However, diode laser technology is the most widely used, primarily with a wavelength of 810 nm, and has replaced solid-state lasers (e.g., Alexandrite) due to its low cost, longer lifetime, ease of use and absence of consumables. Different studies have included the use of diode lasers in static mode, with the area being treated once by the applicator using a high fluence dose (15-40 J/cm^2) and a low-frequency (1-3 Hz) light pulse. It is also possible to use the dynamic mode, which treats each zone several times with a low fluence per pass (3-10 J/cm^2) and higher-frequency (10 Hz) light pulses (2, 5-6).

The use of this technology entails certain application limitations, such as the use of a lower power compared to solid-state lasers. This limitation forces the use of much smaller spot sizes to obtain good results, thereby slowing down the treatment. Devices with larger spots can epilate faster, but are limited when it comes to removing fine hair. Several studies have demonstrated the effectiveness of removing unwanted hair, including fine hair, using a high-power diode laser, which allows permanent hair removal results to be achieved in both static and dynamic mode (exclusive to diode lasers) (7-8).

II. OBJECTIVE

The main objective of this study is to present a new high-power diode laser with a larger spot size of 3 cm^2 (20x15 mm). This new spot size allows treatments to be performed on large and small areas, improving the overlap between each shot and achieving permanent hair reduction in a shorter treatment time.

In addition, the new optical and mechanical design of the applicator ensures a comfortable and safe hair removal treatment, not only with conventional contact cooling from the applicator tip being placed on the skin, but also when a distance is left between the tip and the patient's skin to allow the use of other non-contact cooling systems (e.g., cold-air cooling).

III. MATERIALS AND METHODS

A multi-center, proof-of-principle study has been performed on two different patients to evaluate the safety and

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efficacy of a newly developed diode laser applicator. One patient with skin type III and brown hair was treated in the Clinical Department at Cocoon Medical in Barcelona, and the other, who had black hair and was skin type IV according to the Fitzpatrick classification, was treated in the Hong Kong office. The study was conducted in compliance with the principles set forth in the current version of the Declaration of Helsinki, Good Clinical Practice, and the laws and regulatory requirements for the use of medical devices in Spain.

The Primelase Excellence diode laser device (from Cocoon Medical, Barcelona, Spain), fitted with a new applicator with a maximum power of 4,800 W, a wavelength of 810 nm and a spot size of 20x15 mm, was used to perform laser hair removal, with a pulse duration and fluence range of 3-7 ms and 1-10 J/cm^2 in dynamic mode, and 3-32 ms and 5-40 J/cm^2 in static mode. This new diode laser applicator features a redesigned integrated sapphire tip that ensures significant cooling power. The temperature of the tip was evaluated using a thermographic camera (Fluke® Ti200 thermal camera). Figure 1 shows the applicator with its sapphire tip.

Fig. 1. Applicator with sapphire tip.

TABLE I. Parameters of the Primelase Excellence 4,800 W platform and the skin types and hair characteristics of the patients (ST: static mode, DM: dynamic mode)

Center, Patient ID, Treatment ID	Sex	Skin type (Fitzpatrick scale), Hair color, hair thickness	Treatment area	Operation mode, fluence (J/cm^2), pulse duration (ms), frequency (Hz), accumulated energy in DM (kJ)
BCN, 1, 1	M	III, Brown, thick	Chest	ST, 9, 5, 3
BCN, 1, 2	M	III, Brown, thin	Arm, right, upper	DM, 5, 3, 10, 7
BCN, 1, 3	M	III, Brown, thin	Leg, left, upper, front	ST, 11, 6, 2.5
BCN, 1, 4	M	III, Brown, thin	Leg, right, upper, front	DM, 4, 3, 10, 6
HK, 2, 5	M	IV, Dark, thick	Leg, left, lower, front	DM, 4, 3, 10, 6
HK, 2, 6	M	IV, Dark, thick	Leg, right, lower, front	ST, 9, 5, 3
HK, 2, 7	M	IV, Dark, thick	Leg, right, lower, lateral	ST, 9, 5, 1
HK, 2, 8	M	IV, Dark, thick	Leg, right, lower, back	ST, 11, 6, 3

Two volunteer subjects were treated on the chest, arms and legs according to the parameters detailed in Table I, which provides a summary of the characteristics of the patients and the parameters used in the treatments. Both subjects were males with different hair and skin types. Each area underwent a hair removal treatment and the results were evaluated after 108 and 105 days (Patient ID 1 and Patient ID 2 respectively). Both the static and dynamic operation modes of the Primelase Excellence device were used. In static mode, frequencies of between 1 Hz and 3 Hz were used with pulses set to AUTO mode (minimum pulse duration based on the selected fluence), and in dynamic mode a frequency of 10 Hz was used, also with the minimum pulse duration.

Before carrying out the hair removal session, the areas being treated were shaved and an aloe vera gel was applied. The diode laser head was placed in contact with the skin while exerting slight pressure. The applicators emitted laser energy through the cold sapphire-crystal window, which was also used to cool the skin via continuous contact cooling. In static mode, the treatment was performed with a series of adjoining "stamps" in a single pass. In dynamic mode, the treatment was performed by moving the head of the device horizontally or vertically in a sweeping motion. A constant speed was maintained to ensure an even sweep of the entire grid (treated area). The approximate average speed of movement for each grid was 10 cm per second.

Efficacy was evaluated using two indicators: the immediate reaction of the skin (end point) after the treatment and the reduction of the hair in the area after a determined period of time. The procedure consisted of the application of the 810 nm diode laser for one session using different parameters depending on the type of skin, the characteristics of the hair and treatment area, and the patient's tolerance. No topical or local anesthesia was administrated alongside the laser treatment.

The time spent on each treatment area was also measured and immediate (erythema, edema and post-treatment pain) and posterior (bruising, pigmentation and burns) side effects after the treatment were evaluated. Hair counting was carried out by marking a zone in the treatment area with a 3x4 cm template. Figure 2 shows the applicator performing a treatment.

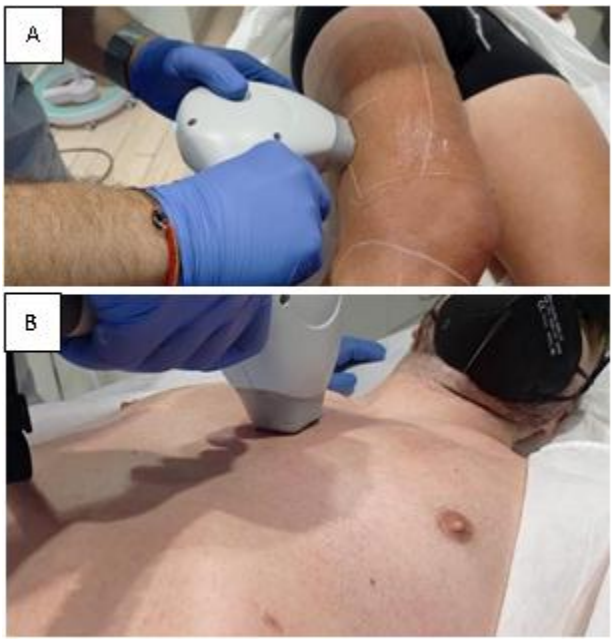

Fig. 2. Applicator performing a treatment. (A) Front upper leg treatment; (B) Chest treatment.

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IV. RESULTS

Figure 3 shows the image of the tip of the applicator taken with the thermographic camera. As can be seen, the entire surface of the sapphire tip is at a temperature of 7^0 C, allowing the skin to be cooled through contact. A skin temperature of 19ºC can be seen when the tip of the applicator touches the skin, assuring a safer and more comfortable treatment for the patient.

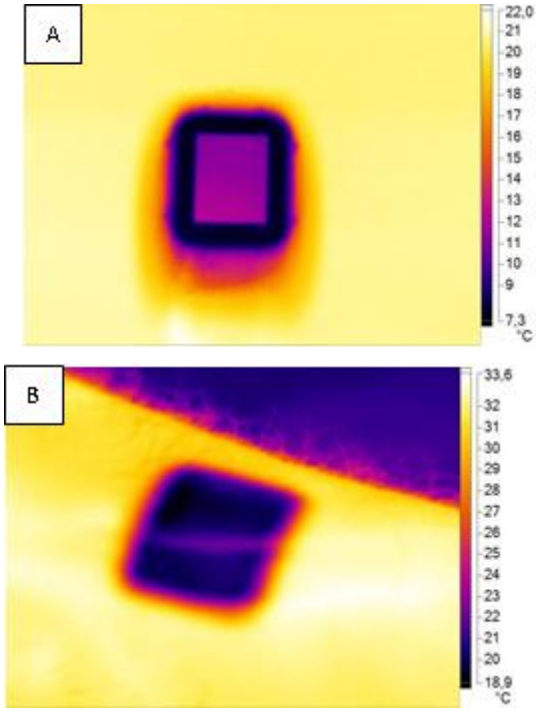

Fig. 3. (A) Sapphire applicator tip cooled to 7ºC; (B) Skin cooled with the sapphire applicator tip.

Hair removal sessions performed with the applicator have been fast on large areas, with an average time of 5.5 minutes and a standard deviation (SD) of 4.04 minutes. The dispersion of the application time depends on the area being treated and can vary between 2 minutes (upper arm) and 13 minutes (upper leg, front). The applicator was able to epilate all types of areas, both large and small. Table II shows the treatment time in each area and the percentage hair reduction.

The device is capable of being used in static and dynamic mode, both have been tested within this study. The hair removal results with the 810 nm diode laser using the 20x15 mm applicator show an average hair reduction of 74.4% with a standard deviation (SD) of 11.4%. Results are satisfactory in both static and dynamic modes. A greater reduction percentage was observed on skin type IV and dark, thick hair in both static and dynamic operation modes, with a mean reduction of 79.2% in static mode. Moreover, good results in dynamic mode on skin type III with brown, thin hair were recorded, with an average hair reduction of 68.2%.

Figure 4 shows the images used for the hair count before and after Treatment IDs 1, 2 and 7 respectively.

TABLE II. Results of first hair removal session after 108 days (Patient ID 1) and 105 days (Patient ID 2). Treatment time and hair reduction is shown.

Treatment ID	Skin type, hair color, hair thickness	Operation mode, fluence (J/cm^2), pulse duration (ms), frequency (Hz), accumulated energy in DM (kJ)	Treatment time (min)	Time until hair recount (days)	Hair reduction
1	III, brown, thick	ST, 9, 5, 3	9	108	67.4%
2	III, brown, thin	DM, 5, 3, 10, 7	2	108	67.3%
3	III, brown, thin	ST, 11, 6, 2.5	8	108	62.9%
4	III, brown, thin	DM, 4, 3, 10, 6	13	108	69.1%
5	IV, dark, thick	DM, 4, 3, 10, 6	4	105	90.9%
6	IV, dark, thick	ST, 9, 5, 3	3	105	71.4%
7	IV, dark, thick	ST, 9, 5, 1	2	105	73.3%
8	IV, dark, thick	ST, 11, 6, 3	3	105	92.9%

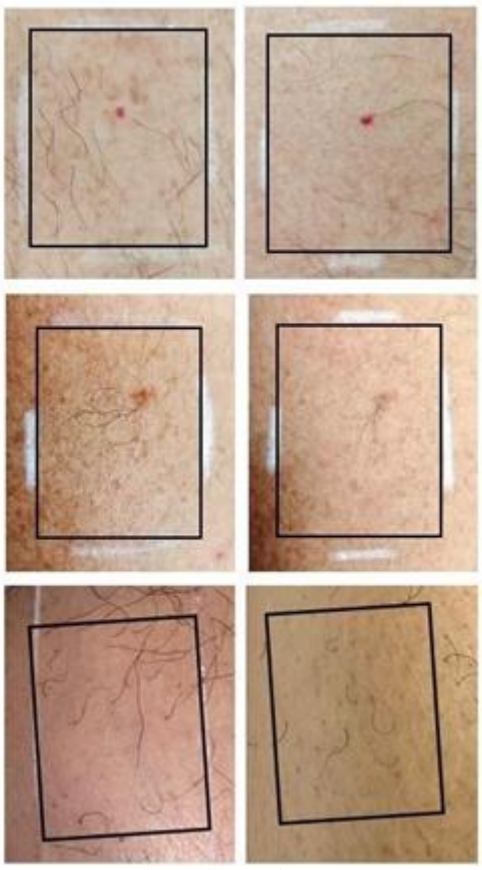

Fig. 4. Hair count images before (left) and after (right) the period between hair count for Treatment IDs 1(top), 2(middle) and 7 (bottom).

Immediately after the hair removal treatment, the treated area showed a high level of skin reaction which demonstrated the significant thermal damage that this applicator generates in the hair follicle without producing any side effects. Figure 5 shows the erythema or perifollicular inflammation (end point)

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results for Treatment IDs 1, 2 and 6 in static and dynamic modes.

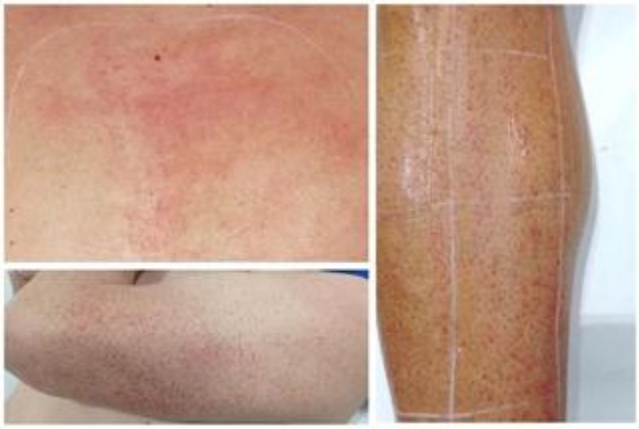

Fig. 5. Skin reactions immediately after finishing the treatment (end point); Treatment ID 1, chest (top left); Treatment ID 2, frontal upper left arm (bottom left); and treatment ID 6, frontal lower right leg (right)

No side effects (bruising, pigmentation or burns) were reported other than the perifollicular edema that occurred just after treatment.

V. Discussion

The application of high-power and hence short pulses with the new 810 nm diode laser applicator ensures a pulse duration lower than the thermal relaxation time (TRT) of the hair, allowing permanent hair removal to be achieved in fewer sessions. High-powered pulses allow satisfactory results to be obtained using moderate fluences that cause a high level of damage to the hair follicle without heating the skin, thereby decreasing the risk of side effects (7).

The new design of the applicator tip, with a spot size of 3 cm^2 (20x15 mm), provides a safe and comfortable treatment for the patient due to its new refrigeration system which makes use of the sapphire crystal inside the tip. Moreover, the optimized size of the tip achieves more efficient and rapid treatments on both large and small areas without the need to change the applicator.

The device is therefore capable of being used in both the traditional static mode and the newer dynamic mode; both have been evaluated in this study. Hair recount results confirm the great efficacy of high-powered short pulses in both modes with the new applicator. The best results are obtained with shorter pulse durations and, therefore, higher laser power, especially on skin type IV. The results recorded in dynamic mode are very satisfactory and agree with those found in previous studies performed with the Primelase Excellence 4,800 W, 810 nm diode lasers (8).

A high level of hair reduction has been achieved (74.4%), especially considering that this study has been carried out with only one session and an assessment 3 months later. It is worth noting that, on average, 6 to 8 sessions are recommended to achieve a 70 to 90% reduction of moderate and thick hair in bodily areas. The greater efficacy of the Primelase device on residual hair suggests that the number of sessions needed to achieve permanent hair removal will be lower.

Importantly, no side effects other than transient edema, which is the typical end point of a highly effective treatment, were observed.

Further investigations are expected, with the aim of including a large number of patients with different hair characteristics and areas to be treated. Those results will allow a better evaluation of the overall results produced by the new diode laser applicator with a spot size of 20x15 mm. Moreover, the hair removal results produced by the applicator when using an air-cooling refrigeration method are also expected to be studied.

VI. Conclusions

The new 810 nm Primelase Excellence applicator with a spot size of 20x15 mm is highly effective thanks to its high power of 4,800 W and optimized spot size, allowing quick and effective treatments on all areas of the body with permanent hair removal results in fewer sessions. In addition, the new applicator allows for safer and more comfortable treatments due to its improved cooling using the sapphire crystal.

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