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Efficacy of Permanent Laser Hair Removal with a High-Power Diode Laser and Air-Cooling of the Skin: A Small Sample Size Study

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Abstract – Background: *The objective of laser hair removal is to damage the hair follicle as much as possible without affecting the skin. This is achieved with skin cooling systems (direct or indirect). Non-contact cooling methods, especially air-cooling, have been widely used in dermatological laser therapy.* ***Objective:*** *This study aims to present a laser-diode hair removal device with an accessory that allows the skin to be cooled by a stream of cold air without sacrificing the comfort, safety and efficacy of conventional contact-cooling treatments.* ***Materials and methods:*** *To compare the new air-cooling with conventional contact-cooling, a side-by-side study was performed on 16 subjects and 93 treatment areas with skin types ranging from II to V according to the Fitzpatrick classification. This comparison assessed the subjects' pain or discomfort using the VAS scale (0-10). To evaluate efficacy and safety, a proof of principle study was performed on 4 subjects and 20 treatment areas. Efficacy was evaluated according to hair reduction 3 months after one treatment. Static and dynamic modes were used.* ***Results:*** *Statistically significant differences were not found in the comparison between air-cooling and contact-cooling. Both cooling systems produced a similar and moderate level of pain, with a pricking sensation being the prevailing type of pain due to selective heating of the hair. Regarding the efficacy and safety study, a 43.4% (SD 23%) reduction was seen and no side effects were found to last more than 48 hours, with the results being classified as good to excellent for the treated subjects.* ***Conclusions:*** *A diode laser applicator in combination with the air-cooling accessory has accomplished the best balance between rapidity, efficacy, comfort and safety for the subject in hair removal treatments, with good results for hair reduction.*

Keywords – *Laser hair removal, high-power diode laser, contact-cooling, air-cooling, fine hair, high efficacy, permanent.*

I. INTRODUCTION

Unwanted hair growth is a common aesthetic problem for people. Photoepilation systems and, specifically, laser systems (diode laser, Alexandrite, Nd:YAG and Ruby) have established themselves as efficient, safe and permanent solutions for hair removal. This technology is based on the absorption of light by the melanin of the hair, which generates heat and damages the germ structures of the hair follicle (1) (2) (3).

Diode lasers, especially with a wavelength of 810nm, have become the most widely used technology and have replaced, particularly in the beauty market, solid-state lasers (e.g. Alexandrite) due their low cost, longer lifetime, ease of use and absence of consumables. Studies have shown the effectiveness of using a high-power diode laser for permanent hair removal, including fine hair, which allows good results to be achieved in both static and dynamic mode (exclusive to diode lasers) (4) (5).

The goal of laser hair removal is to damage the hair follicle as much as possible without damaging the surrounding skin. To achieve this, cooling systems are commonly used on the skin during treatment. Cooling systems can be divided into two categories: contact and non-contact cooling. Contact-cooling can be achieved through ice, cold gels, or copper or sapphire tips on the applicators, while non-contact cooling is accomplished with cryogen sprays or cold-air streams (6).

Non-contact cooling methods, especially air-cooling, have been widely used in dermatological laser therapy (7) (8). In hair removal treatments, the use of non-contact-cooling systems has been studied, mainly, for Alexandrite and Nd:YAG laser systems (9) (10). In addition, when using an Alexandrite laser, it is not necessary to shave or use cosmetics on the skin, this being the most common and accepted method in markets where contact-cooling is not possible, such as the Middle East market.

However, the use of air-cooling systems with high-power diode lasers has not been the subject of much study. The purpose of this study is to demonstrate the safety and effectiveness for hair removal of a new high-power 810 nm diode laser in conjunction with air-cooling as a skin refrigeration system, and to compare subject satisfaction with that of conventional contact-cooling.

II. OBJECTIVE

The main objective of this study is to present and analyze a new high-power diode laser applicator with an optimized spot of 20x15 mm, in combination with a new accessory that enables the application of cold air during the treatment without coming into contact with the skin of the subject, as with Alexandrite laser treatments, thus retaining all the advantages of diode laser technology and the working comforts of a solid-state laser applicator.

Clinical studies were performed to compare the sensations of subjects when using contact and air-cooling systems, in order to evaluate the efficacy and safety of treatments with air-cooling.

III. MATERIALS AND METHODS

A multi-center small sample size study has been performed to evaluate the comfort, safety and efficacy of hair removal treatments, comparing the results achieved with the new air-

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cooling system versus the conventional contact-cooling system. Subjects were treated in the Clinical Departments at Cocoon Medical in Barcelona and the Hong Kong offices. Prior to treatment, all subjects received a detailed and clear explanation of the planned procedure and signed an informed consent form. None of the subjects had undergone any previous waxing treatments, other avulsion hair removal techniques, or hormonal treatments during the month prior to the study.

Furthermore, subjects with hypersensitivity to visible and infrared light or those undergoing treatments with visible and infrared photosensitive drugs, subjects with white or very blond hair, and subjects with any infection sensitivity issues or with an oncologic process in the treatment area were excluded. 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.

A Primelase Excellence diode laser platform (from Cocoon Medical, Barcelona, Spain), fitted with a new CE-approved applicator with a maximum power of 4,800 W, a wavelength of 810 nm and a spot size of 20x15 mm (Figure 1), was used for the study with both cooling systems.

Figure 1. 4,800 W, 810 nm, 20x15 mm diode laser applicator (left). Air-cooling accessory mounted on the 20x15 applicator (right).

Before carrying out the hair removal session, the newly developed air-cooling accessory (CoolPrime, Cocoon Medical, Barcelona, Spain) was mounted on the applicator. The air-cooling accessory consists of an adaptor that connects the hose of the cold-air device (Zimmer ZCryo, Zimmer MedizinSysteme GmbH, Neu-Ulm, Germany) to the diode laser applicator, and a set of disposable elements that allow the treatment to be performed without touching the skin of the subject while permitting the cold air to cool the area during the treatment (Figure 1).

The device allows either “static” or “dynamic” mode to be used. Treatments performed in static mode were carried out with a series of single overlapped high-energy shots across the entire treatment area. In dynamic mode, treatments were carried out using a series of repetitive low-energy pulses while moving the head of the applicator horizontally or vertically in a sweeping motion, with a constant average speed being maintained to ensure an even sweep of the entire grid (treated area).

The procedure consisted of the application of the 810 nm diode laser in either static or dynamic mode for just one session using different parameters depending on the type of skin, the characteristics of the hair and treatment area, and in accordance with the treatment tables recommended by the manufacturer. No topical or local anesthesia was administrated alongside the laser treatment. Before carrying out the hair removal session, the areas treated were shaved. Parameters were set with a pulse duration of 3 ms and a fluence range of 3-8 J/cm^2 at a frequency of 10 Hz in dynamic mode, and 6-100 ms and 9-21 J/cm^2 at 1 Hz and 3 Hz in static mode.

Two studies were conducted. Study 1 compared the hair removal process when using the conventional contact-cooling system with using the new air-cooling system. Study 2 assessed efficacy and safety when using the air-cooling system.

1. Study 1. Comparison Of Air-Cooling Vs Contact-Cooling

To compare contact-cooling and air-cooling, a side-by-side study was carried out in 16 subjects (6 men and 10 women) aged between 23 and 52 years (mean 36.7, SD 11.5) with skin types II to V according to the Fitzpatrick classification. A total of 93 different areas on 16 subjects were treated with the same parameters for contact-cooling and air-cooling.

Table 1 shows a summary of the characteristics of the subjects and the parameters used in the treatments in the comparison trials.

TABLE 1. Summary of the characteristics of the subjects and the parameters used in the treatments for the side-by-side comparison of contact-cooling and air-cooling (study 1). ST: static operation mode, DM: dynamic operation mode.

Characteristics of the subjects		**Parameters of the treatments**	
Variable	*N (%)*	*Variable*	*N (%)*
Subjects	**16**	**Frequencies (Hz) [operation mode]**	**93**
Men	*6 (37.5)*	*1 Hz [ST]*	*31 (33.3)*
Women	*10 (62.5)*	*3 Hz [ST]*	*32 (34.4)*
Skin type (Fitzpatrick scale)	**16**	*10 Hz [DM]*	*30 (32.3)*
II	*1 (6.3)*	**Fluence (J/cm^2) [operation mode]**	**93**
III	*4 (25.0)*	***Skin type II***	***4 (6.5)***
IV	*7 (43.7)*	*21 [ST]*	*3 (75.0)*
V	*4 (25.0)*	*5 [DM]*	*1 (25.0)*
Treatment areas	**93**	***Skin type III***	***25 (26.9)***
Lower arms	*3 (3.2)*	*10 [ST]*	*2 (8.0)*
Lower legs	*44 (47.3)*	*16 [ST]*	*12 (48.0)*
Upper legs	*46 (49.5)*	*18 [ST]*	*2 (8.0)*
Hair characteristics	***93***	*5 [DM]*	*9 (36.0)*
Brown, thick	*25 (26.9)*	***Skin type IV***	***35 (37.6)***
Brown, thin	*16 (17.2)*	*12 [ST]*	*8 (44.4)*
Black, thin	*29 (31.2)*	*13 [ST]*	*4 (22.2)*
Black, thick	*23 (24.7)*	*14 [ST]*	*10 (28.6)*
		3 [DM]	*4 (11.4)*
		4 [DM]	*6 (33.3)*
		Skin type V	***29 (31,2)***
		12 [ST]	*8 (27,6)*
		14 [ST]	*12 (41,4)*
		3 [DM]	*9 (31,0)*

To evaluate the results, subjects were told to assess the pain or discomfort of the treatments according to a Visual Analogue Scale (VAS) from 0 to 10 (0 = none, 1-3 = mild, 4-7 = moderate,

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8-10 = intense) and the type of pain (pricking, extended heat or both). To evaluate the end point, a scale of 0 to 3 was used, where 0 is no end point, 1 is a mild end point, 2 is a moderate end point and 3 is a severe end point.

2. Study 2. Air-Cooling: Efficacy, Satisfaction and Safety Case Study

This proof of principle study included 4 subjects (3 men and 1 woman) aged between 21 and 49 years (mean 36.0, SD 13.6) with skin types II, III and IV according to the Fitzpatrick scale. A total of 20 different areas were treated.

Efficacy was evaluated using the reduction of hair approximately 3 months after the first session. Hair counting was carried out by marking a zone in the treatment area with a 3x4 cm template and counting the hair before the session and 3 months after using "before" and "after" high-resolution images.

Patient satisfaction was also evaluated 3 months after the first session. A scale from 1 to 3 (1 = poor, 2 = good, 3 = excellent) was used.

Figure 2. Treatment images with the 4,800 W, 810 nm high-power diode laser with a 20x15 mm spot and the air-cooling accessory.

Safety was evaluated by assessing immediate (erythema, edema or pain) and delayed (pigmentation, bruising and burns) side effects after the treatment on a 0-3 scale (0 = no reaction, 1 = mild reaction, 2 = moderate reaction, 3 = severe reaction). Moreover, the time spent on each treatment was measured. Figure 2 shows the applicator together with the air-cooling accessory during some of the treatments.

Table 2 shows a summary of the characteristics of the subjects and the parameters used in the treatments.

TABLE 2. Summary of the characteristics of the subjects and the parameters used in the treatments for the efficacy and safety study with air-cooling (study 2). ST: static operation mode, DM: dynamic operation mode.

Characteristics of the subjects		**Parameters of the treatments**	
Variable	*N (%)*	*Variable*	*N (%)*
Subjects	**4**	**Frequencies (Hz) [operation mode]**	**20**
Men	*3 (75.0)*	*1 Hz [ST]*	*1 (5.0)*
Women	*1 (25.0)*	*2 Hz [ST]*	*2 (10.0)*
Skin type (Fitzpatrick scale)	**4**	*2.5 Hz [ST]*	*1 (5.0)*
II	*2 (50.0)*	*3 Hz [ST]*	*10 (50.0)*
III	*1 (25.0)*	*10 Hz [DM]*	*6 (30.0)*
IV	*1 (25.0)*	**Fluence (J/cm^2) [operation mode]**	**20**
Treatment areas	**20**	***Skin type II***	***14 (70.0)***
Chest	*1 (5.0)*	*16 [ST]*	*7 (50.0)*
Arms	*2 (10.0)*	*18 [ST]*	*3 (21.4)*
Lower legs	*9 (45.0)*	*5 [DM]*	*3 (21.4)*
Upper legs	*8 (40.0)*	*8 [DM]*	*1 (7.1)*
Hair characteristics	***20***	***Skin type III***	***4 (20.0)***
Black, thick	*3 (15.0)*	*9 [ST]*	*1 (25.0)*
Brown, thick	*14(70.0)*	*11 [ST]*	*1 (25.0)*
Brown, thin	*3 (15.0)*	*4 [DM]*	*1 (25.0)*
		5 [DM]	*1 (25.0)*
		Skin type IV	***2 (10.0)***
		9 [ST]	*1 (50.0)*
		11 [ST]	*1 (50.0)*

3. Statistical Analysis

Study 1 focused on the comparison of the 810 nm treatment with contact-cooling against the same treatment with air-cooling. The hypothesis was that subjects would experience similar results with the two different methods of skin cooling.

Study 2 hypothesized that the new 4,800 W, 810 nm, 20x15 mm diode laser applicator, using air-cooling, would provide high efficacy with only 1 session. Several studies have reported hair reduction results of between 22% and 59% (11), with the American Association of Dermatology estimating that the number of hairs will reduce by 10% to 25% after the initial session (12). For this study, hair reduction of 25% was set as the efficacy end point.

A descriptive statistical evaluation (mean and standard deviation) was performed using the Excel statistical package and the student's t-test for paired data with two tails. The Grubbs test (95% confidence) was used to detect outliers in the individual results obtained per area. The differences between the compared data were expressed in percentages and considered significant if the p-value was less than 0.05.

IV. RESULTS

1. *Study 1. Air-Cooling vs Contact-Cooling*

Figure 3 shows the results for pain during the treatment and Figure 4 shows the type of pain in the areas (N=93). In static mode, pain stayed mild-moderate on average with both air-cooling and contact-cooling (3.6, SD 2.46; and 4.24, SD 3.02, respectively), but in dynamic mode, pain was mild with air-cooling (2.23, SD 1.93) and mild with contact-cooling (3.43, SD 2.74). However, the difference was found to be statistically non-significant with both cooling systems ($p > 0.05$).

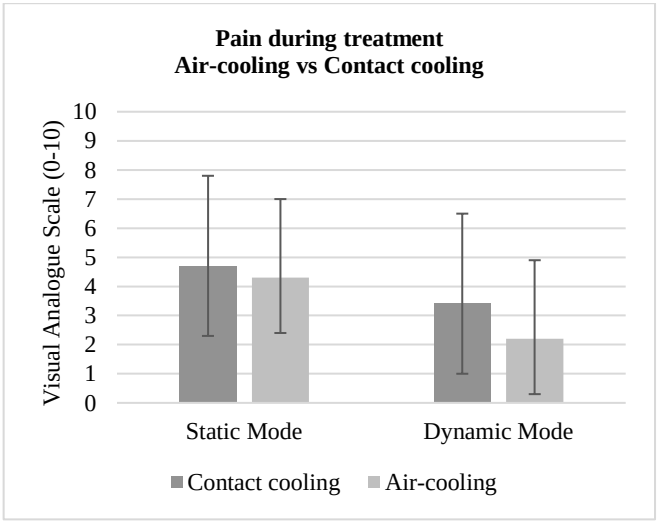

Figure 3. Results for pain during the treatments (N=93).

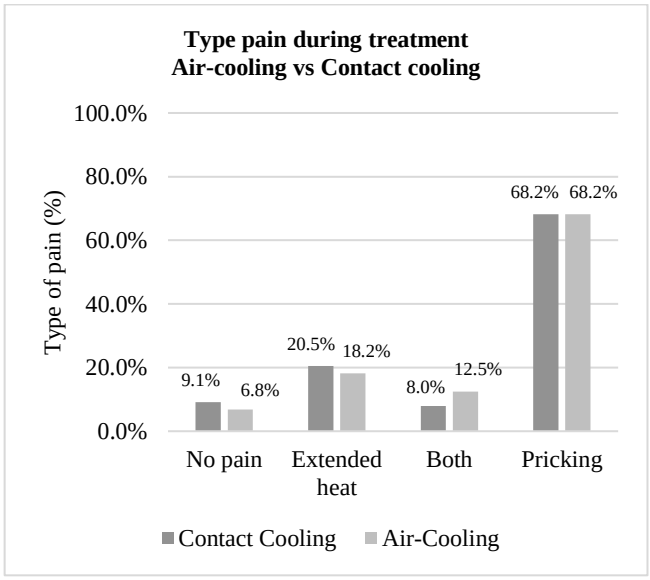

Figure 4. Results for type of pain during the treatments (N=93).

Regarding the type of pain (Figure 4), subjects reported pricking in almost all treatments (68.2% for air-cooling and contact-cooling) and there were no statistically significant differences between air-cooling and contact-cooling, as expected ($p > 0.05$).

It was observed that pricking was the most common sensation in the subjects treated, indicating selective heating of the hair being treated.

In relation to the end point, the results also showed that the mean end point with contact-cooling was not significantly different to that reached with air-cooling ($p > 0.05$) (Figure 4).

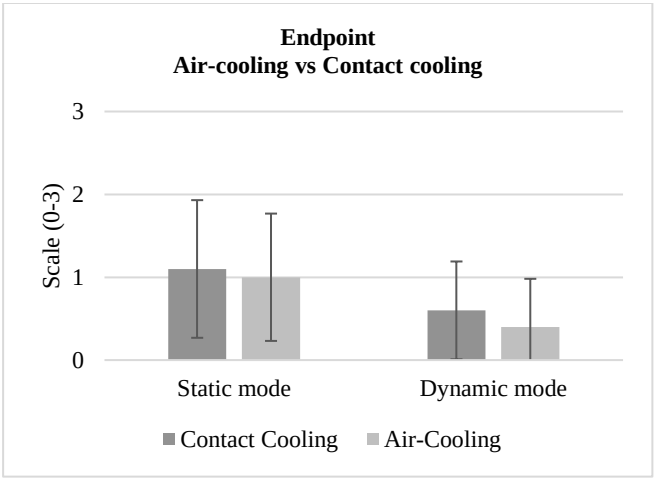

Figure 5. End-point results after the treatments (N=93).

2. *Study 2. Air-Cooling: Efficacy, Satisfaction and Safety*

Treatment Time

The sessions performed were fast for all treated areas (small and large). A total time of 43.3 minutes has been estimated for a full-body treatment, including legs, chest, abdomen and arms.

Patient Satisfaction

Patient satisfaction was assessed using a scale of 1 to 3, obtaining an overall rating of 2.5 (SD 0.6) for the 4 patients, which was evaluated as good-excellent.

Reaction of the Skin and Side Effects

Instantly after the hair removal treatment, the treated areas presented a positive reaction of the skin (perifollicular edema), which showed the thermal damage that the applicator caused in the hair follicle. No side effects, such as bruising, burns or pigmentation, were reported after the treatments. Figure 6 shows examples of the immediate skin reaction for some of the treatments in both dynamic and static mode with air-cooling.

Figure 6. Immediate reaction of the skin after a hair removal treatment. Top left (chest, skin type III, dynamic mode, 5 J/cm^2, 10 Hz), bottom left (armpit, skin type II, static mode, 16 J/cm^2, 2 Hz), right (leg, skin type II, static mode, 18 J/cm^2, 3 Hz).

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Hair Reduction

In the hair-count study, 4 subjects and 20 areas were analyzed, generating an average reduction of 43.4% (SD 23%), with a maximum of 93% and a minimum of 15%. According to the Grubbs test used, none of the individual efficiency results obtained were outliers. The results obtained were within acceptable parameters to be considered as good results (> 25% statistically significant, $p < 0.05$). Figure 7 shows some "before" and "after" images of 3 subjects from the study.

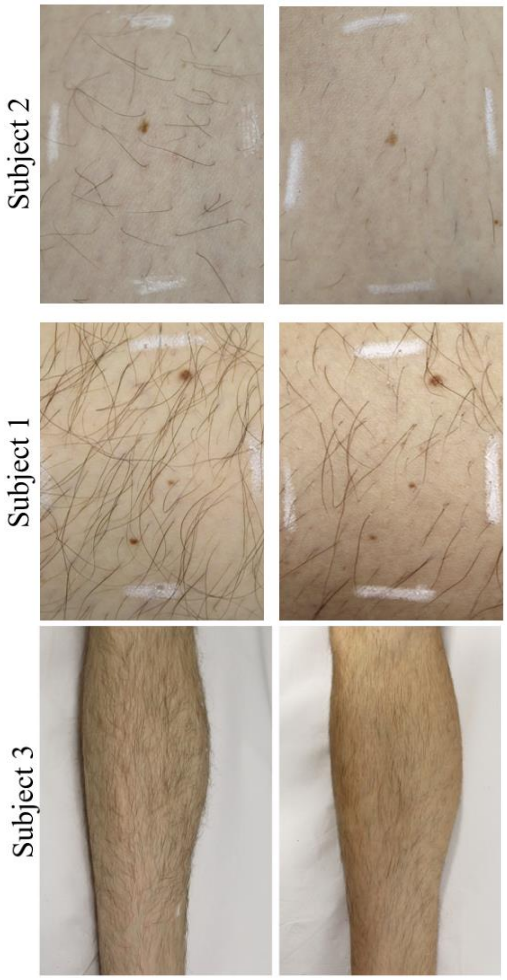

Figure 7. Hair reduction in subjects 1, 2 and 3. Before (left) and after (right).

Side effects were non-existent or disappeared during the first 48 hours after the treatment.

V. DISCUSSION

The laser hair removal sector has evolved very little in recent years. The two most widely used technologies, the Alexandrite solid-state laser and the 810 nm diode laser, have very large differences between them. While the Alexandrite laser has a greater optical power, is conducted through an optical fiber and can be applied without contact, the power of the laser diode is lower, the laser beam is transmitted through a cold sapphire window and application is performed by making contact with the skin.

There is not an intermediate solution between the two technologies that can achieve a perfect balance between the rapidness of the treatments with diode lasers and the efficacy of Alexandrite lasers. Moreover, while Alexandrite lasers are limited by the use of consumables that increase their cost, diode lasers are limited by their power and the use of conventional contact-cooling. Therefore, there is an important opportunity in this market for high-power laser diodes that are capable of non-contact operation with air-cooling of the skin.

High power is important to obtain good results, but the speed at which the treatments are performed is just as important when treating large areas with a lot of hair. Diode lasers allow higher frequencies to be worked with than Alexandrite lasers due to their superior energy efficiency. The use of larger spots decreases treatment times. However, when increasing the size of the spot, there is an associated decrease of the thermal damage to the hair as well as a limitation on treating small areas. It is therefore essential to choose the optimal spot size that allows short laser pulses to be used and for all areas to be treated with precision and efficacy.

The 810 nm diode laser with a spot size of 20x15 mm (3 cm^2), combined with 4,800 W of power, has shown great results for hair removal thanks to its short laser pulses; achieving a balance between performing fast treatments on both small and large areas, great results for hair reduction, and safe treatments with permanent results (13).

Air-cooling and cryogen-cooling are the systems most widely used by doctors for non-contact laser hair removal. This study has presented a new high-power diode laser that allows for the incorporation of air-cooling of the skin without diminishing any of the advantages of a diode laser. Moreover, it has been shown that the applicator with the air-cooling accessory achieves effective and fast treatments on both small and large areas. This is accomplished thanks to the use of high frequencies in combination with the efficacy of the 4,800 W diode laser platform.

With both cooling systems, the pain results have been evaluated as mild. As expected, pricking was the greatest pain sensation felt by the subjects with both cooling systems. Pricking is characteristic of the selective heating of the hair follicle, as a result of the high power of the 4,800 W applicators. In relation to the end point, in both cases it was evaluated as moderate. These results show the possibility of increasing the fluence of the treatments, thus achieving better results for hair removal.

In the evaluation of efficacy with the new air-cooling method, a hair reduction of 43.4% (SD 23.0%) was observed in just one session, while pain was kept at mild to moderate levels and no other side effects were produced. This is considered a good result in terms of reduction, taking into account the average improvement (25%) accepted by dermatologists (11) (12). The high value for standard deviation is due to the small sample size of the study and the different characteristics of the subjects (different hair characteristics, skin types, and areas). Subjects were satisfied or very satisfied with the hair removal results.

The results demonstrate the high level of efficacy of the new 4,800 W, 810 nm, 20x15 mm diode laser applicator, which not

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only assures good results for hair removal with conventional contact-cooling, but also with air-cooling. Future clinical studies will aim to increase the sample size in order to include more subjects with more varied characteristics in terms of skin, hair and treatment areas, as well as using more treatment sessions to obtain results that reaffirm and corroborate the results of the present study.

VI. CONCLUSIONS

The combination of the high-power 4,800 W, 810 nm, 20x15 mm diode laser applicator with the air-cooling accessory has accomplished the best balance between rapidity, efficacy, and subject comfort and safety in hair removal treatments. It has been possible to perform treatments on skin types II to V (Fitzpatrick scale) with good results for hair reduction in both static and dynamic operation modes. Treatment with the air-cooling system has been evaluated as good and excellent for the treated subjects in terms of efficacy, treatment comfort and patient safety.

Both cooling systems have been found to be similar in terms of the level and type of pain, the reaction of the skin, and the results.

Finally, this study has shown that diode laser technology can be used with both contact-cooling and air-cooling systems to achieve the same efficient, safe and permanent results for hair removal treatments.

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CONFLICTS OF INTEREST

Some of the authors of this publication conduct research at Cocoon Medical S.L.U., a company that is developing products related to the research being reported. However, this publication strictly adheres to the objectivity and ethics of independent research.

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