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Original Article

Clinical study of high-power diode laser in dynamic mode for fine hair removal: effects of pulse duration on efficacy and safety

Mariano Vélez-González[1], Gregorio Viera-Mármol[2], Gabriela Vergara-Vallejo[2]

[1]Centro Médico Ronefor, Barcelona, Spain
[2]Clinical and Scientific Department, Cocoon Medical, Barcelona, Spain

Running title: **Dynamic diode laser hair removal on fine hair**

Abstract

Background: Diode laser hair removal is the most commonly used method to permanently remove unwanted hair. The biggest challenge today is the treatment of fine hair. Various studies have shown that using a static modality (single shot with high fluence), better results are obtained.
Objective: this study aims to verify that diode laser hair removal, using a dynamic mode with high power and a short pulse, provides better results than moderate power with a longer pulse, while still being comfortable and safe.
Materials and Methods: subjects (n=14) with skin types II and III and brown and black hair were subjected to diode laser hair removal using the Primelase device (from Cocoon Medical). Left side areas were treated with a high power of 4,800W and a pulse duration of 3 ms, while right-side areas were treated with a power of 1,000W and a pulse duration of 10/14 ms; wavelength of 810 nm and the same fluence dose was used for both sides. Efficacy, pain, side effects and post-treatment satisfaction were evaluated after three sessions.
Results: an overall reduction of hair was observed using high power and shorter pulses (64%, SD 18%) compared to the use of moderate power and longer pulses (55%, SD 18%), with a statistically significant improvement of 16% ($p<0.024$). Greater improvements were found in subjects with skin type II (27%, $p<0.026$) and brown hair (30%, $p<0.0006$, and also in areas with thinner hair (56%, $p<0.07$). An oedema appeared after the treatment was higher for the side treated with 4,800W (48%, $p<0.03$).
Conclusions: the Dynamic mode of the diode laser device using high power and short pulses is more effective than using moderate power and longer pulses. When high power is used in a dynamic mode an improvement in hair reduction and greater satisfaction are obtained, especially on light skin and thinner hair.

Keywords
Photoepilation, hair removal, dynamic mode, thin hair, high-power diode lasers, short pulse duration

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Corresponding Author

Gregorio Viera Mármol, MD

Address: C/ del Gall 22, 08950, Esplugues de Llobregat, Barcelona, Spain
Phone: +34934588566
E-mail: gregorioviera@cocoonmedical.com

Introduction

Unwanted hair growth is a common cosmetic problem for women and men, for which different types of treatments have been developed such as the use of light for hair removal. Photoepilation has established itself as an effective, safe and long-lasting hair removal option and is one of the most widely used hair removal techniques worldwide.

Photoepilation consists of the laser light being absorbed by a specific chromophore (melanin in the hair) that transforms the energy into heat[1-3]. According to the extended theory of photothermolysis, to achieve a reduction in the follicular structure, it is necessary to damage the germinal structures of the follicle (non-pigmented structures), generating heat from the structures that contain melanin (hair shaft, follicular epithelium and matrix) and diffusing the heat to the areas where the cells are located[4,5]. To achieve the destruction of the germ structures of the follicle it is essential that they are in the anagen phase[6,7].

Among the most common light-based hair removal systems are lasers (diode, Alexandrite, Nd:YAG and Ruby) and Intense Pulsed Light (IPL), which have proven to be sufficiently effective for hair removal[8]. However, thin or residual hair is the biggest challenge for these procedures, because the reduced diameter causes less heating since it cools more easily compared to thicker hair, making it difficult to remove. Therefore, since they are unable to remove thin hair effectively, photoepilation procedures have been found to be limited for the goal of completely removing unwanted hair. To get permanent results, it is necessary to find technologies that allow fine hair to be heated with a high efficiency.

A wavelength of 810 nm is mainly used in diode laser hair removal and its effectiveness depends on the different parameters involved (fluence and pulse duration)[9]. However, few studies tackle the impact of these parameters on its efficacy for thin hair[10-13]. Furthermore, these studies only include the use of diode lasers in the static mode for hair removal, where each zone is treated once by the applicator with a high fluence dose (15-40 J/cm^2) and low frequency (1 to 3Hz). Currently, it is possible to use the so-called dynamic mode, treating each zone multiple times with a low fluence per pass (3-10 J/cm^2) at a higher frequency (usually 10Hz), which reduces side effects and increases subject comfort and safety[5,6,14]. However, there has not been a study of hair removal in the dynamic mode that analyzes fine hair.

In static mode, the use of short pulse durations with high-power diode lasers has been shown to achieve better results in removing fine hair[12]. When the power is increased and the pulse duration decreased, the hair is heated to higher temperatures producing greater thermal damage. This was found to be particularly important for the thinnest hair because it is heated much more effectively with short pulses than with long pulses.

The aim of this clinical study was to analyze the dynamic mode of diode laser hair removal and compare the efficacy of applying high power (4,800W) and short pulses with moderate power (1,000W) and longer pulses. In previous studies, we predicted the efficacy of photoepilation as a function of hair thickness and laser pulse duration using a 3D mathematical simulation model developed in our laboratory[15]. In this study, we present clinical data evaluating the effect of the pulse duration on the efficacy of thin hair removal when using a dynamic mode, without affecting the comfort and safety of the treatment.

Materials and methods

In this small sample-size, single-center and side-by-side study, 14 female subjects were selected who were between 18 and 49 years of age (median 26.5, SD 8.3), with skin types II (4 subjects) and III (10 subjects) according to the Fitzpatrick classification, and black and brown hair colors. Of those subjects, 7 received treatment on the arms, 6 on the legs, and 1 on the buttocks. All subjects had thin hair and had undergone no previous hair removal treatments, no previous waxing treatments or other avulsion hair removal techniques during the last month, and no hormonal treatments. 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.

A diode laser device (Primelase Excellence, from Cocoon Medical, Barcelona, Spain) was used for the clinical study, operating in dynamic mode at 10Hz. All the subjects underwent a diode laser hair removal treatment with a wavelength of 810 nm and a beam size of 20x9 mm^2. On the left side, subjects received the treatment with the highest peak power of the device (up to 4,800W), while on the right side they received it with moderate peak power (1,000W). Each subject received identical fluence doses and accumulated energy on both sides. The parameters used for subjects with skin type II were: accumulated energy of 3.5 kJ, fluence of 8 J/cm^2, and pulse duration of 3 ms (4,800W) for the left side and 14 ms (1,000W) for the right side. The parameters used for subjects with skin type III were: accumulated energy of 3 kJ, fluence of 6 J/cm^2, and pulse duration of 3 ms (4,800W) for the left side and 10 ms (1,000W) for the right side.

Before carrying out the hair removal sessions, the areas that needed to be treated were shaved and a thin layer of transparent Aqualaser gel (Ultragel) was applied. The diode laser head was placed in contact with the skin while exerting slight pressure. The device emitted laser energy through a cold sapphire crystal window that was also used to cool the skin via continuous-contact cooling. The treatment was performed in a dynamic mode by moving the head of the device horizontally or vertically in a sweeping motion until the target total accumulated energy was reached. In this treatment mode, low fluence values are used, so it is necessary to pass the applicator over the same area multiple times in order to reach the accumulated energy and the temperature necessary to damage the hair follicle. A constant speed was maintained to ensure an even sweep of the entire grid (treated area).

The approximate average speed of movement across each grid was 10 cm/s. The exact parameters were chosen by a board-certified dermatologist using the treatment tables recommended by the manufacturer, in accordance with the skin and hair type of each treated subject. After each treatment session, aloe vera gel was used for a post-treatment massage. The device used has a CE mark. 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.

This study compared hair removal efficacy, the pain experienced by the subjects during the treatment and other post-treatment side effects, adverse effects and the satisfaction of both the subjects and the physician.

The efficacy was compared using hair counts from before and after photographs, and semi-quantitative scales. Images were taken before each session and three months after the third session. Hair counts were performed across an area of 16 cm^2 (4x4 cm template). A Lumix camera (Panasonic DMC-LX100) was used to take the pictures, which were processed with Microsoft© Image using the SAKE filter. For the semi-quantitative assessment, the physician visually assessed the hair reduction and ranked the results: 4 points for very good efficacy with 91-100% hair reduction, 3 points for good efficacy with 61-90% hair reduction, 2 points for moderate efficacy with 31-60% hair reduction, 1 point for low efficacy with 1-30% hair reduction, and 0 points for no effect with 0% hair reduction).

The pain experienced by the subjects during the treatment was evaluated using a scale from 0 (no pain) to 10 (unbearable pain), as were the other post-treatment side effects, such as edema, erythema, and stinging, where a range of 0 (no effect) to 10 (maximum effect) was used. Also, the satisfaction of the subjects and the physician was evaluated on a scale from 0 (not satisfied) to 10 (very satisfied). Adverse effects such as thermal injuries, blisters, crusting, ulcer infections and possible hypo- or hyperpigmentation were also evaluated.

The variables were studied according to descriptive analysis and t-student, using the mean, median, lowest and highest score, outlier, and standard deviation (SD) of the variables. Standard deviation was used to study the dispersion of the data and the variability of individual observations. Also, the improvement when using 4,800W was calculated by subtracting the percentage reduction of 4,800W from the percentage reduction of 1,000W; the result was then divided by the percentage reduction of 1,000W.

A t-student test was used for analysis: two tailed, paired samples. Statistical data for pain and side effects were represented using column and boxplot charts. In the boxplot charts, the median is represented by a straight line inside the box, the mean by an "X" inside the box, the lower and upper horizontal lines are the lowest and the highest scores within the lower and upper limit, and a circle outside the box represents an outlier. The box represents the middle 50% of the scores, without the lowest 25% and highest 25%. Statistical significance was considered to be at $p<0.05$. Microsoft Excel was used for the statistical analysis.

Results

The Analysis of the data from this clinical study revealed, first of all, a significant reduction in hair density for both cases, where an overall greater efficacy for hair reduction with 4,800W (64%, SD 18%) compared to 1,000W (55%, SD 18%) was observed, which corresponds with a statistically significant improvement of 16% ($p<0.024$) (*Figure 1*).

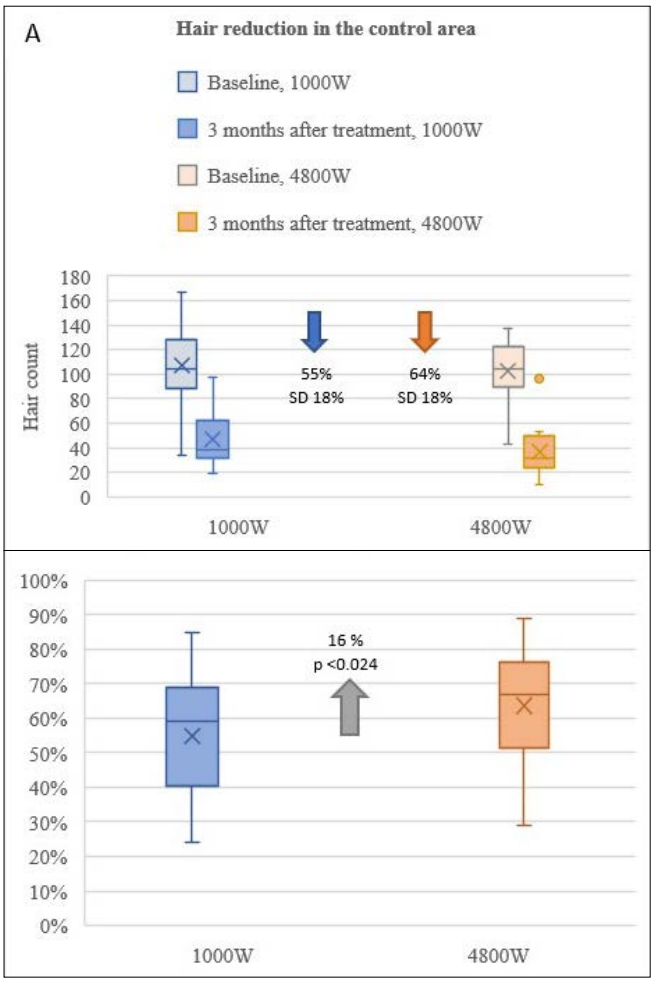


Figure 1 *- (A) Hair count in the control area (4x4 cm) before and after 3 months; (B) Comparison between average percetage of hair reduction and power used.*

In addition, analysis concerning the treated area revealed different improvements in hair reduction results. The area on the back of the upper leg showed the largest improvement (56%), achieving a hair reduction of 70% with 4,800W and 45% with 1,000W. The area on the buttock showed an improvement of 38%, the arms 13%, and the front of the upper leg 6%, but at $p<0.073$ there was no statistical significance.

Additionally, the efficacy of the treatment was compared based on the skin type and hair color of each subject. It was observed that subjects with skin type II presented greater hair reduction and a greater improvement when the highest power was applied. The subject with skin type II had an average hair reduction of 81% (SD 8%) with 4,800W and 64% (SD 8%) using 1,000W (27% improvement, $p<0.026$). The subject with skin type III

presented a reduction of 57% (SD 17%) with 4,800W and 51% (SD 20%) with 1,000W (a 12% improvement but not statistically significant at p<0.216).
An Evaluation according to hair color showed a 30% improvement when applying the highest power in subjects with brown hair, a reduction of 65% (SD 18%) with 4,800W and 50% (SD 17%) with 1,000W, with the difference being statistically significant at p<0.0006. Black hair was also compared but the difference was not statistically significant.
In addition, the visual assessments of the subjects after three months of treatment showed a more noticeable hair removal efficacy when applying 4,800W (64% of subjects with good efficacy) versus the application of 1,000W (36% of subjects with good efficacy) (*Figure 2*).
A mean score of 2.6 was obtained with 4,800W compared to 2.2 with 1,000W, which represented a statistically significant improvement of 18% with p<0.019.
The efficacy analysis was completed with a satisfaction survey of the subjects and physician (*Figure 3*).

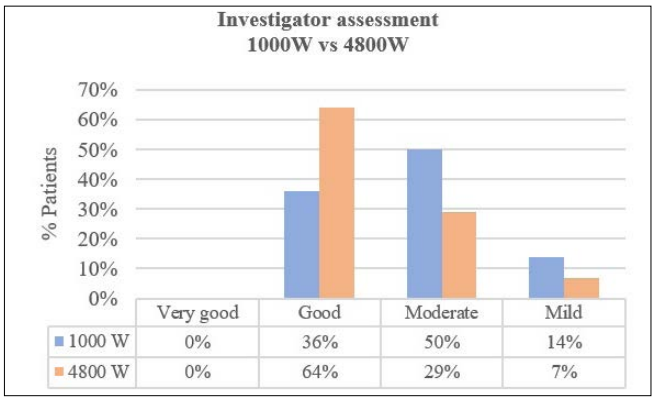


Figure 2 *- Comparative investigator assessment using semi-quantitative scales, with an overall improvement of 18%, statistically significant at p<0.019.*

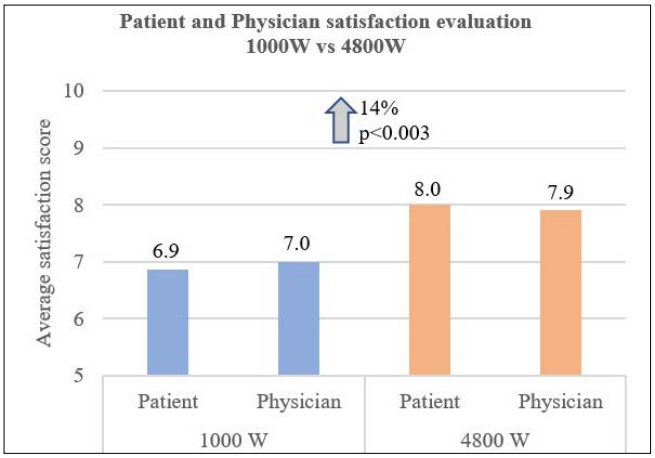


Figure 3 *- Graphical results of the satisfaction survey completed by the patients and physicians (10 is maximum satisfaction and 0 is not satisfied).*

The responses tended to be grouped around 7 points for 1,000W and 8 points for 4,800W (out of 10). There was greater satisfaction for the results obtained with 4,800W, with an improvement of 14% (p<0.003).
Figure 4 shows examples of before and after photographs of different subjects and different areas of application.

The side effect variables were also methodically evaluated during and after each treatment. On the whole, side effects were reported to be generally mild and disappeared in less than 48 hours.

FIGURE 4 - PATIENT 1

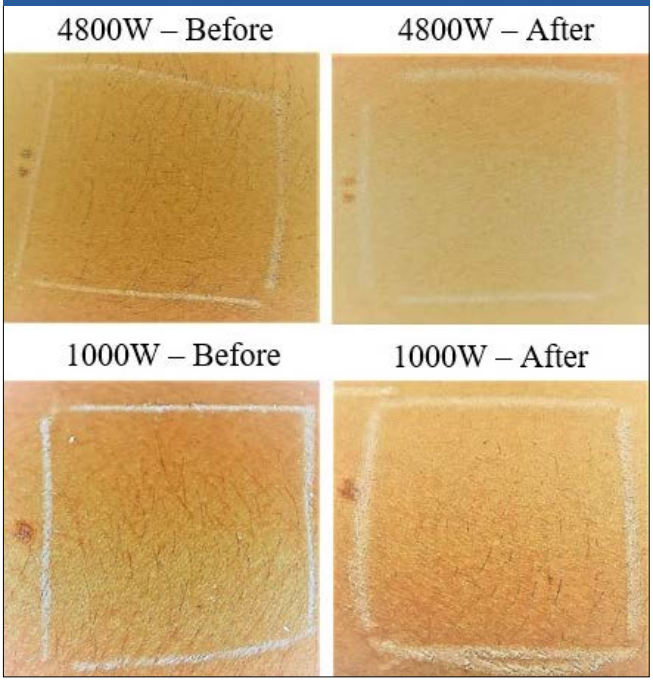


Figure 4 *- Examples of hair removal results: patient 1 (skin type III, brown hair, arms); patient 2 (skin type III, brown hair, arms); patient 5 (skin type III, black hair, arms); patient 6 (skin type III, black hair, front of upper legs); patient 8 (skin type III, brown hair, arms) and patient 9 (skin type II, brown hair, arms).*

FIGURE 4 - PATIENT 2

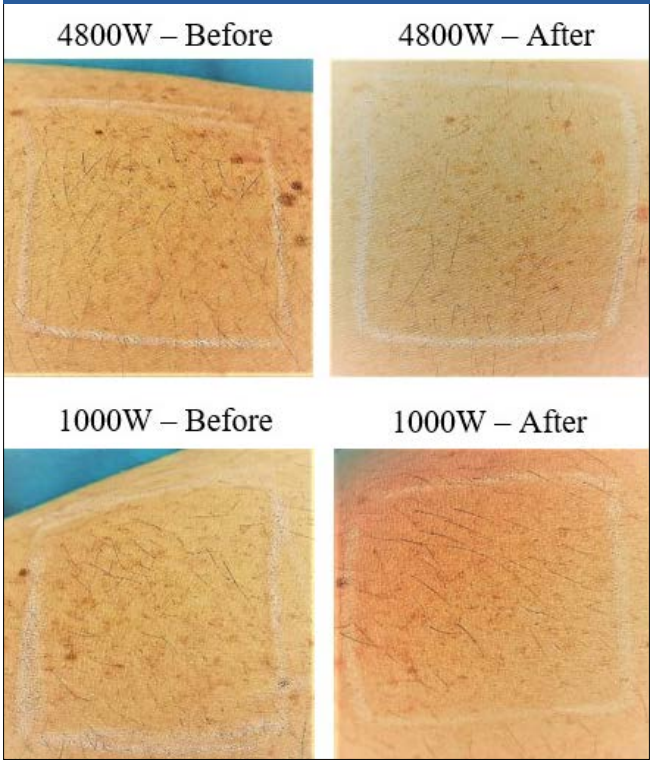


FIGURE 4 - PATIENT 5

FIGURE 4 - PATIENT 8

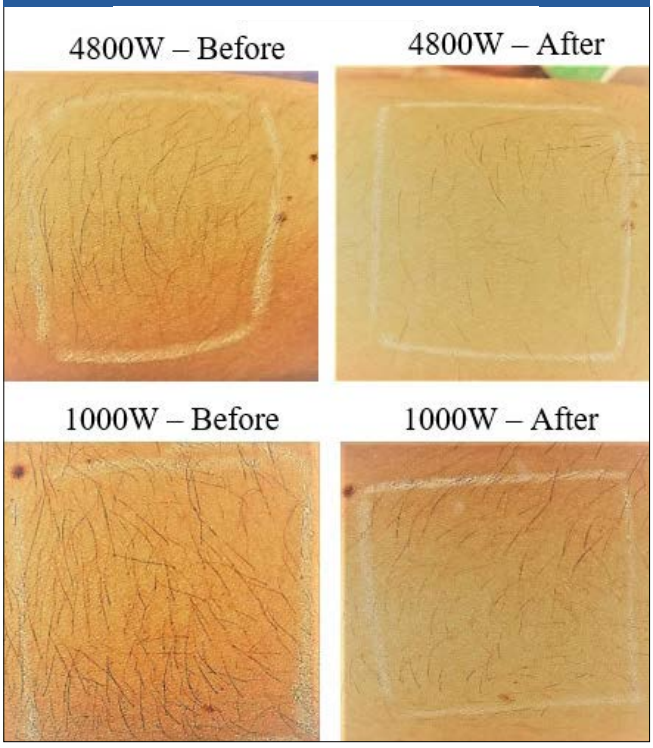


FIGURE 4 - PATIENT 6

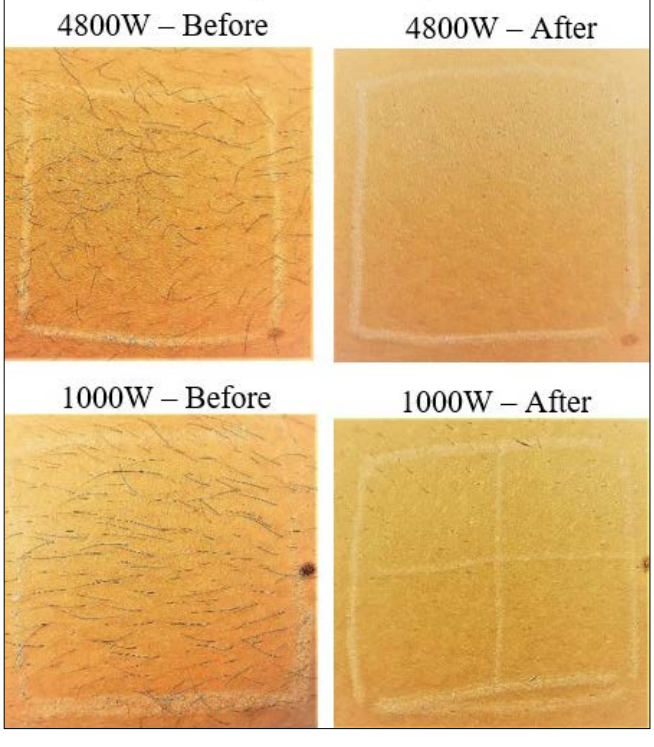
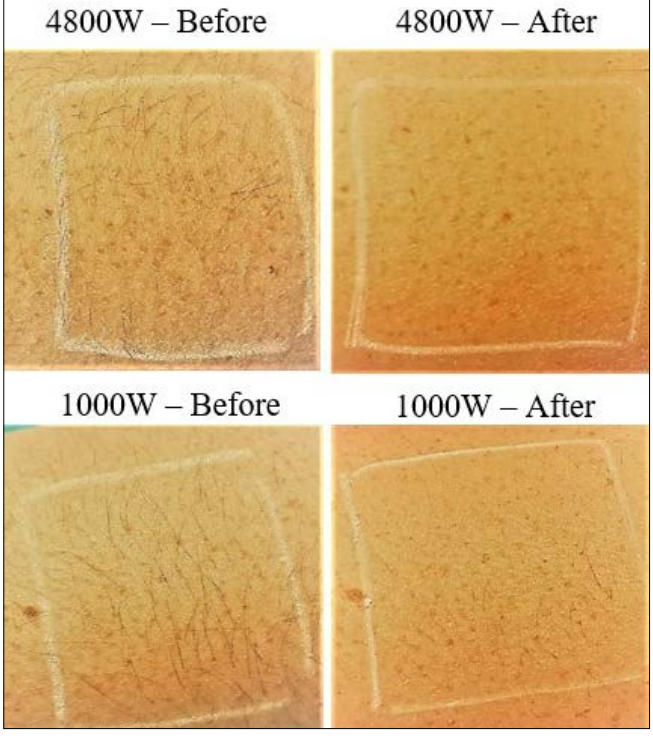


FIGURE 4 - PATIENT 9



Regarding the subjects' comfort during the treatment, the sensation of pain was similar for 4,800W and 1,000W (*Figure 5*). It was observed that subjects tended to feel mild pain with a mean score of 3.1 (SD 2.44) for 4,800W and a mean score of 2.9 (SD 1.86) for 1,000W (on a scale from 0 to 10), with the difference not being statistically significant (p<0.487). For skin type II the pain was greater, with an average of 6.25 (SD 2.21) with 4,800W and 5.25 (SD 0.95) with 1,000W (not a statistically significant difference, p<0.252), compared to skin type III with an average of 1.9 (SD 0.99) with 4,800W and 2 (SD 0.15) with 1,000W (not a statistically significant difference, p<0.726).

Regarding the side effects after treatment (*Figure 6*), for 4,800W and 1,000W the subjects reported a mean score for stinging immediately after treatment of 2.50 (SD 1.74) and 2.64 (SD 1.70) respectively (not a statistically significant difference, p<0.547), with an average duration of 2 minutes with 1,000W and 3 minutes with 4,800W. For erythema, a higher mean score was observed with 4,800W (2.43, SD 1.6) than with 1,000W (1.93, SD 1.38), which was also not statistically significant (p<0.089). However, an oedema did show a statistically significant higher mean score with 4,800W (2.43, SD 1.6) versus 1,000W (1.64, SD 0.93), an increase of 48% (p<0.035). Although a perifollicular edema is the result of thermal damage, it is a temporary reaction with instantaneous action and, in all cases, there was no persistent dermal damage, disappearing in less than 48 hours.

Regarding complications or adverse effects (burns, blisters, crusting, ulcer infection, and possible hypo- or hyperpigmentation), they were not observed in any of the subjects.

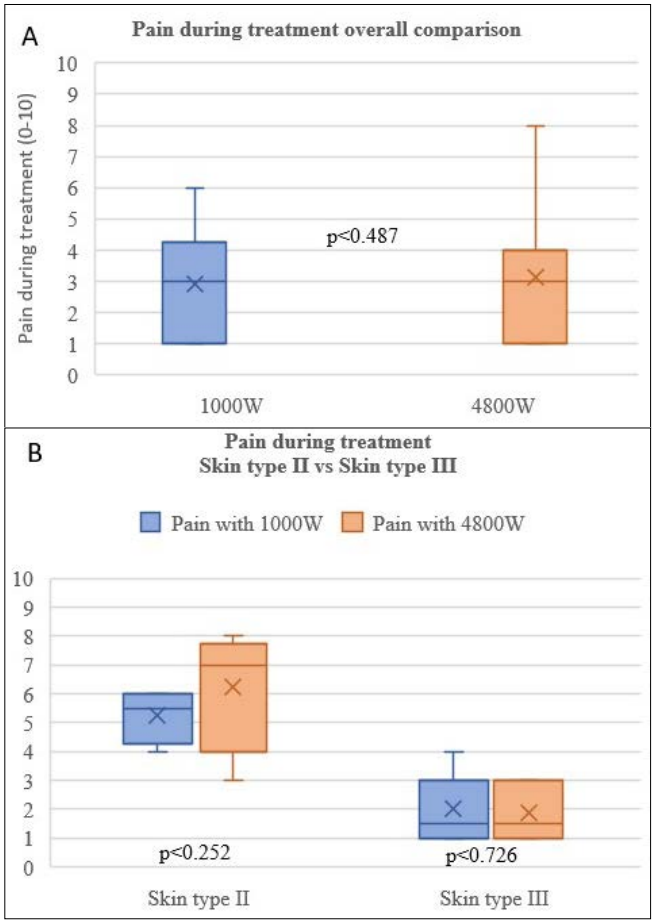


Figure 5 *- Comparison between power and mean pain during treatment. (A) Comparison between 1,000W and 4,800W; (B) Comparison between skin type II and skin type III.*

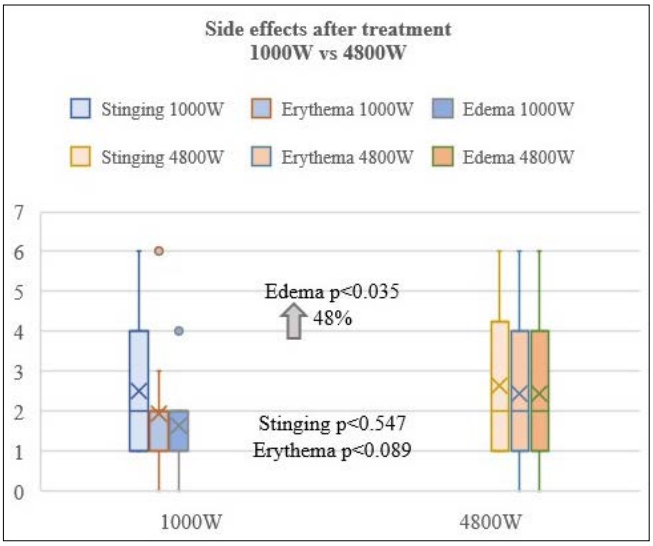


Figure 6 *- Comparison between power and side effects after treatment.*

Discussion

Diode laser hair removal technology is already considered to be one of the most relevant options available on the market. However, the approach of using a dynamic mode with a short pulse duration still represents a paradigm shift for the treatment of fine hair. Consequently, the focus of this study has been to evaluate the application of diode laser hair removal techniques in dynamic mode with different laser powers and, therefore, with different laser pulse durations, with special attention being paid to the removal of fine hair. This study compared therapeutic efficacy, subject and physician satisfaction, and safety. Two cases were studied on each subject to reduce the bias of the sample.

Both laser conditions produced significant hair reduction after treatment, with greater hair reduction being seen with the use of high power and short pulses (4,800W and 3 ms) over moderate power and longer pulses (1,000W and 10/14 ms) using the same fluence dose, meaning that better results are obtained with higher laser irradiance. This is explained by the fact that with shorter pulses, a higher temperature is reached in the hair follicle and therefore greater thermal damage is induced[5,10-12]. A previous in silico model generated by the coauthors of this article[15] had predicted an improvement in efficacy when using shorter pulse durations. This result has been corroborated by the present study.

Regarding subject and physician satisfaction, congruence has been observed between their subjective impressions and the hair counting analysis, since both the subjects and the physician reported a higher degree of satisfaction with the treatment performed using the shortest pulse duration.

A statistically significant overall improvement in efficacy of 16% has been obtained after just 3 sessions of dynamic-mode hair removal when comparing 4,800W with 1,000W. The thermal relaxation time (TRT) and thermal damage time (TDT) of hair are key to understanding the results of this study[15]. In the case of original or untreated hair, the TRT is between 20 ms and 50 ms. Therefore, moderate-power lasers of 1,000W that operate with pulses of 10/14 ms, as used in the present study, can effectively heat this type of hair. However, residual fine hair exhibits a TRT of less than 10 ms. In these cases, high-power lasers in dynamic mode producing pulses of less than 10 ms (such as the 4,800W diode laser operating at 3 ms) allow fine hair to be heated with a high efficacy level and enable the high values of thermal damage required for permanent hair removal to be achieved.

The improvement in efficacy has been found to increase to 27% in subjects with lighter skin and hair (skin type II and brown hair). This is because the difference in pulse duration was greater for the subjects with skin type II (3 ms versus 14 ms) than for those with skin type III (3 ms versus 10 ms), thus producing a greater difference in hair heating and damage. Additionally, we have seen that the group with brown hair (with both skin type II and III) had even better results with the optimum pulse duration of 3 ms, achieving an increased improvement of 30%. This can be explained by the fact that brown hair is thinner and, as explained above, the thinner the hair, the better results there will be with the shortest pulse duration.

Interestingly, the highest improvement of 56% was found on the back of the legs compared to the front of the legs, buttocks, and arms. Again, this is probably due to the presence of thinner hair on this part of the leg, and the fact that the 4,800W device was capable of heating thinner hair with greater efficacy thanks to its pulse duration being shorter than the hair TRT[15].

Importantly, no complications or adverse effects have been observed, and side effects were either transient and mild or, in some cases, moderate. This shows that the application of the dynamic mode with a low fluence dose allows comfortable and safe dynamic-mode hair removal treatments to be performed, without them being significantly affected by the use of higher power and short laser pulses. The sensation of pain in both cases was similar, however, in subjects with skin type II there was a greater difference in the sensation of pain, possibly due to the greater fluence used for this skin type. Pain is closely related to the thermal damage of the hair follicle and was expected to be greater with 4,800W. However, it was found that the sensation of pain was similar in both cases because in the dynamic treatment mode used in study the pain was mild, so the subject could not differentiate between 1,000W and 4,800W. Other side effects such as stinging, perifollicular oedemas, and erythema increased slightly with 4,800W, but only the differences in edema were found to be statistically significant. The Perifollicular oedema is caused by the injury to the hair follicle, due to the thermal damage produced by exposure to the laser. As power increases and pulse duration decreases, thermal damage increases and so does the subsequent skin reaction, hence the increased occurrence of the oedema. The Perifollicular oedema is an immediate and temporary end point of laser hair removal, which usually disappears in less than 48 hours after the treatment.

This study has presented an evaluation of only 3 sessions with an overall hair reduction of 64%, although 5 to 7 sessions are reportedly recommended to obtain a reduction of 70 to 90% for moderate and thick hair in bodily areas[5,7]. The greater efficacy of the diode laser device on residual fine hair when operating at 4,800W suggests that the number of sessions needed to achieve permanent hair removal could be lower. The fact that 4,800W is more efficient on residual hair implies a great advantage, since, with the majority of commercialized diode lasers, residual hair is hard to remove, and the treatment is often painful.

In this study, some of the results obtained were not statistically significant ($p>0.05$). To obtain statistically significant results it would be necessary to evaluate a larger number of cases, carry out more treatment sessions, and have a longer post-treatment assessment period (greater than 6 months) in order to gather more objective data regarding long-term efficacy.

Conclusion

It has been observed that diode laser hair removal in a dynamic mode with a low fluence dose and high frequency is effective in removing unwanted hair, while the use of a high power of 4,800W and short pulses has been shown to produce a statistically significant improvement in its results.
The present clinical study has shown a mean hair reduction of 64% in just 3 sessions and a significant overall improvement of 16% with 4,800W, when compared with a moderate power of 1,000W ($p<0.024$). The satisfaction of the subjects and the researcher were consistent with the efficacy of the results. Additionally, subjects and areas with thinner hair and lighter skin showed greater improvement with 4,800W, as a consequence of greater thermal damage to the hair using the parameters of the high-irradiance laser. Accordingly, fewer sessions were found to be needed to achieve permanent hair removal with a high-power diode laser of 4,800W. Additionally, pain and other side effects remained mild and did not increase significantly with the short pulses, with the exception of the oedema which was greater with the use of 4,800W.
Increased patient comfort and the shorter treatments required to achieve the desired result, position this 4,800W laser equipment operating in dynamic mode as a very promising advance in aesthetic medicine.

Acknowledgments

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Conflict of interest disclosure

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

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