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ORIGINAL ARTICLE

Six-month follow-up multicenter prospective study of 368 patients, phototypes III to V, on epilation efficacy using an 810-nm diode laser at low fluence

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Abstract Laser hair removal is currently a popular cosmetic procedure. Traditional high-fluence laser treatment for hair elimination is associated with discomfort and adverse events and it is restricted to low phototype skins. A multicenter study of hair epilation with low fluences and high repetition pulse rate using an 810-nm diode laser was carried out on 368 patients (phototypes III to V) to test its efficacy in a 6-month follow-up after five treatments on the face and various body areas. Objective and subjective assessment as well as histologies show a high index of patient satisfaction due to high efficacy of hair elimination, also proved histologically by the damage observed at hair structure level. Results obtained a high degree of patient satisfaction and a low index of adverse events. Laser epilation was well accepted regarding discomfort and was also complication-free for dark and tanned skins. Treatment is easy to conduct and requires adapting the movement of the hand-piece to a constant speed in order to achieve high-energy deposit on tissue avoiding risks of burning.

Keywords Laser epilation · Low fluence · Diode 810 · Dark phototypes

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Introduction

Laser epilation treatment has changed significantly and improved on traditional approaches, presenting increased efficacy, particularly with regard to the duration of hair clearance. Following the mechanism of *selective photothermolysis* [1], variations in results and efficacy can be explained (to a certain extent), by limitations related to risks arising due to the broad range of programs used and due to patients' skin color. The best candidates for laser epilation are subjects with light phototypes and dark hair. Also, laser epilation is limited during the summer season and on patients with tanned skin. Epilation with a 1,064-nm pulsed Nd:YAG laser shows positive effects in such candidates, but patients complain of pain during treatment. Most of them prefer to wait until the winter season or when they have lost their tan, seeking sessions of treatments that cause less discomfort (impressions collected at our clinics from patients; data not published).

A novel concept of epilation at low fluences using an 810-nm diode laser is proposed as a solution to the aforementioned setbacks. We present a 14-month follow-up of 368 patients that have received five treatment sessions on various body areas, at three different clinics.

Materials and methods

Patients

A study was carried out on 400 patients treated at three centers: 180 in Madrid (center #1), 140 in Malaga on the Spanish South Mediterranean coast (center #2), and 80 in Dubai, UAE (center #3). Patients' ages ranged from 19 to 58 years of age (mean age 32.4). Patient demographics are displayed in Table 1. Center #3 had a slight predominance of patients with phototype V, though not significant in comparison with centers #1 and #2. Details of the study and permission for the revision of clinical data was endorsed by the Ethics Committee of the Antoni de Gimbernat Foundation with which one co-author (MAT) is involved. All patients were informed of the nature of the various treatment sessions, and five patients from each center, representing a cross sample of their corresponding centers, gave authorization to have ellipsoidal biopsies of the axillae before and immediately after the first treatment session. Patients were scheduled to receive a maximum of five treatments in total at a fixed interval of 2 months between each epilation session. Then, 6 months after the fifth session, the patients were evaluated.

Patients were informed as to the goals of the study in order to ascertain the degree of efficacy and safety of the device used for epilation. Results were assessed at the fifth session and at the follow-up 6 months after the last (fifth) session (in total a follow-up of 14 months).

Patients were advised to stop treatment if they were satisfied with the results of the sessions already carried out, even if they had not completed the five treatments. In any case, patients were asked to attend the follow-up 6 months after the last epilation session.

Of the 400 patients recruited for the study, only 368 came to the last follow-up at 6 months. After the third session, four patients ceased treatment, but they were contacted via telephone and responded that they were satisfied with the results obtained and considered it unnecessary to attend further treatment sessions. Two patients failed to attend the fifth (last) session. When contacted by phone, they also stated that they were satisfied with the results obtained after four sessions and did not wish to continue treatment.

Photographs of the treated area were taken at all centers using the same type of digital camera, (Canon EOS 400D, Tokina ATX Pro 100 f 2.8 Macro, Sea&Sea Flash Macro DRF 14; Canon, Tokyo, Japan) equipped with a macro lens, keeping light conditions and position constant. Photographs were taken before the first session, before each following session, and 6 months after the last session (session number five).

Exclusion criteria included patients under 18 years of age, pregnancy, lactation, scars or infection in the treatment area, and/or a history of scarring and repeated herpes infections. Criteria for admission permitted the enrolment of patients with medium and thick hair, with phototypes III to V, and even those who were tanned.

Recruitment of patients began in November 2006, 3 months after summer and exposure to the sun. Eighty-two of the 368 patients were noted to present residual tanning at the start of treatment. Patients were distributed as follows: phototype III: 102, phototype IV: 211; phototype V: 55. Age: 18–30 years: 299, 31–40 years: 47; 41–60 years: 22. Of the total number of patients, 31 were male (8.42%) and 337 female (91.58%). Treated areas were 206 axillae, 93 bikini line, 11 lower abdomen, 55 pubis, and three thorax. Table 1 describes patients' characteristics at the three centers that participated in the study.

The laser system and the treatment

Late in 2006, we started to use a new diode laser emitting low-fluence pulses for hair removal, the Soprano™ XL laser (Alma™ Lasers, Israel). This device operates a conventional 810-nm diode laser system which, although designed for a traditional form of medical epilation, can also be tuned for emission in the so-called SHR or "super hair removal" mode. In this mode, the 810-nm diode laser uses low-fluence pulse emission. This technology proposes an increased profile of heat in tissue, or accumulative epilation. The thermal energy is deposited in the dermis by constant movement of the hand-piece over the target area of skin.

Laser pulses are emitted at a fixed rate of 10 Hz with fluences that can be selected from 5 to 10 J/cm^2. Pulse width adapts according to selected fluences, and ranges from 10 ms for 5 J/cm^2 to 20 ms for 10 J/cm^2.

Treatment technique was always and in all cases similar, involving the lateral movement of the hand-piece in a constant sweeping mode. The skin surface for treatment was divided into 10×10 cm squares and each received a total of 9.6 kJ. Thus, each 1 cm^2 of skin received on average 9.6 J/cm^2 (9600J/100cm^2=96 J/cm^2). The reason for dividing the treatment area into 100 cm^2 areas was to provide homogenous exposure to laser pulses and to carry out systematic epilation. Movement of the hand-piece over the skin was at a speed of approximately 10 cm per second.

The laser hand-piece has a 10×12 mm window which incorporates *Sapphire Dual Chill Window Technology* through which a coolant is in constant circulation at a temperature of 5°C. In addition, for treatment, the hand-piece, using an adapter provided by the manufacturer, was connected to a tube emitting cold air. The cooling tube is focused directly where the laser window is directed for

Table 1 Patient distribution

Phototypes			Ages			Sex		Treatment areas				
III	IV	V	18–30	31–40	41–60	Male	Female	Armpits	Bikini Line	Abdomen	Pubis	Thorax
102	211	55	299	47	22	31	337	206	93	11	55	3
27.72%	57.34%	14.95%	81.25%	12.77%	5.98%	8.42%	91.58%	55.98%	25.27%	2.99%	14.95%	0.82%
Hair type												
Thick		339	92.12%									
Medium		29	7.88%									
		368	100.00%									

continuous cooling of treatment area. The air cooling system (Cryo 5, Zimmer ElektroMedizin, Neu Ulm, D) was operated at intensity level #5 (high flow of cold air).

Immediately before starting each treatment session, target areas were shaved and thoroughly cleaned and then a fine layer of cold, transparent gel was used to make it easier for the hand-piece to slide over the skin. Epilation areas were marked using a fine-point white washable pen, with the aim of carrying out a similar treatment in the whole area and to follow a systematic technique. Then, a number of passes were applied with the hand-piece over area selected for epilation, producing the feeling of a progressive temperature increase. Due to heat accumulation in dermis, temperature gradually propagates and patients experience a burning sensation, therefore, all patients were instructed to inform of any discomfort during treatment, and the end point considered for all areas treated was in general bearable regarding pain, burning sensation, or intense skin redness. The goal was to build up to 9.6 kJ of heat in tissue for every 10×10 cm area. Once this was achieved (as indicated on the console screen), the hand-piece was moved to an adjacent area continuing the epilation procedure.

Assessment

Objective

At all centers, results were photographically recorded. Areas of epilation were photographed before treatment at a fixed distance of 18 cm with the help of a spacer. Photographs included a 10×10 cm square marked with a white washable pen, randomly selected from the treated area. A hair count was taken in the selected squares by two different therapists unfamiliar with the study.

Also, biopsies were taken before and immediately after treatment in 15 patients, as a representative cross sample. Staining was carried out with Hematoxylin and Eosin (H&E) stain.

Subjective

Previously, the patient was shown how treatment would be carried out in order to instruct them as to how to appreciate the symptoms arising as the hand-piece passed over the skin and how they should judge the intensity of the symptoms. In general, a sensation of local heat build-up began to appear when irradiating at half of total energy. Patients were to notify as to the start of pain and heat. In these circumstances, the hand-piece was shifted to an adjacent (10×10 cm) area, and then the area being treated was returned to when the same occurred in the new treatment area, the speed of movement of the hand-piece remaining constant. When intense erythema and/or perifollicular edema occurred, this was recorded. Patients were required to inform on a digital scale as to the degree of pain experienced during treatment at each of the sessions. The degree of pain was classified from 0–10 in accordance with the Numeric Pain Intensity Scale: Very High (10–8); High (7–5); Average (4–2) and Low (1–0) [2]. This same scale was implemented for heat sensation and skin reddening.

Satisfaction index

All patients were instructed to assess the results in accordance with the Global Aesthetic Improvement Scale (GAIS) [3] to which they scored percentages of clearance for the two assessments of the study, i.e., prior to the fifth session and 6 months after the last session. Patients also had to evaluate the degree of discomfort experienced according to the international scale, and their subjective degree of improvement. The physician who carried out treatments objectivized the degree of epilation efficacy, also using the GAIS scale (Table 2).

Table 2 Patient satisfaction and pain evaluation. Doctor's objective evaluation

		Patient assesment (Pain) NPIS					Patient satisfaction (GAIS)					Physician's opinion				
AREA	No. of sessions	VERY HIGH	HIGH	AVERAGE	LOW		75–100% VERY GOOD	50–74% GOOD	25–49% AVERAGE	0–24% POOR	WORSE	VERY GOOD	GOOD	AVERAGE	POOR	
Armpits																
206	1,030	6	4	48	148		9	145	31	21		18	140	39	9	
Bikini																
93	465	3	2	1	87		16	62	11	4		19	66	6	2	
Pubis																
55	275	12	4	9	30		6	44	5	0		19	33	2	1	
Pectorals																
3	15	0	0	1	2		0	3	0	0		0	0	3	0	
Lower abdomen																
11	55	0	0	1	10		0	4	6	1		0	1	7	3	
		21	10	60	277		31	258	53	26		56	240	57	15	
	1,840															
		5.71	2.72	16.3	75.27		8.42	70.11	14.4	7.07		15.22	65.22	15.49	4.08	
		100					100					100				

Results

Efficacy

Two different therapists unfamiliar with the study gave their opinion regarding the percentage of clearance of hair density at the follow-up 6 months after the fifth session. The results of the 368 epilated areas treated were as follows: 0–24%: 29 patients; 25–49%: 102 patients; 50–74%: 219 patients; 75–100%: 18 patients (Table 3). No paradoxical effects were observed.

Histologies

Prior to and immediately post-treatment, the configuration of the epidermis was normal and the stratum corneum present as well as the keratin were intact with no identifiable changes. In nine of the 15 patients biopsied, cytopathic and vacuole changes at the basal layer were present. There was also focal epidermolysis at this level (Fig. 1). Edema was mild and more prevalent in the superficial dermis and hair shafts presented architectural changes with some inflammatory infiltration (Fig. 2).

Safety

Intense erythema and perifollicular edema were noticed in most patients at each of the sessions but these signs were transient. Pseudofolliculitis was observed mostly in the perineum. First-degree burns occurred in three axillae, two bikini-line, two perineum, and two lower abdomen. Second-degree burns occurred in three sessions (one axilla, one bikini line, and one perineum). Hyperpigmentation was observed in one axilla and one bikini line, and hypopigmentation in three axillae, two bikini line, three perineum, and three lower abdomen. However, no long-term adverse effects (6 months after the fifth session) were noticed (Table 4).

The appearance of short-term adverse effects was minimal (appearing in 13 out of 1,840 sessions: 0.7%). This observation differed from other papers regarding statistics of adverse effects appearing in the short-term, which reflect a higher percentage of transitory and post-inflammatory hyperpigmentation (10%) and post-inflammatory hypopigmentation (2%) [4, 5].

Satisfaction index

Subjective evaluation by patients as to improvement was: Very Good in 31 patients, Good in 258, Average in 53, and Poor in 26.

Objective assessment by physicians carrying out the treatment scored: Very Good in 56 patients, Good in 240,

Table 3 Percentage clearance: results

AREA	No. of sessions	0–24%	25–49%	50–74%	75–100%
ARMPIT (206) Tanned	1,030	21	59	116	10
BIKINI (93) Tanned	465	4	31	52	6
PUBIS (55) Tanned	275	1	5	47	2
PECTORALS (3) Tanned	15	1	1	1	0
LOWER ABDOM. (11) Tanned	55	2	6	3	0
		29	102	219	18
	1,840	7.88	27.72	59.51	4.89

Average in 57, and Poor in 15. (Figs. 3, 4). No patient was observed to have a worse outcome than at baseline (Table 2).

Discussion

The degree of clearance of hair density was similar in our experience to that obtained with conventional epilation [4]. The areas that reacted most favorably were the bikini-line, the perineum, and the axillae, which coincide with the observations of epilation using other laser systems. Hair loss per session was gradual and proportional to the number of sessions carried out. Clearance at 6 months after the fifth session was greater than that observed in the prior assessment at the fifth session. Residual hair was similar at the follow-up prior to the fifth session and 6 months after the last session, even in those dark-haired patients of phototypes IV and V.

Patients reported that hair was gradually falling off after the laser session, which differs from conventional laser epilation which immediately eliminates hair after the laser pulse. In fact, according to patients, 2 or 3 weeks following treatment with the 810-nm SHR depilation mode, hair will be seen to reappear but will fall when rubbed.

Patients were satisfied, presenting fewer and some finer residual hairs in all treated areas. After the first two epilation sessions, patients reported delayed re-growth and less dense hair in the areas treated.

In general terms, the degree of patient satisfaction was high. In the opinion of the treating physicians, the degree of efficacy scored slightly higher. However, there were only slight differences between the two points of assessment.

The appearance of short-term adverse events was minimal compared with reports of traditional epilation (low pulse repetition frequency of high fluences) [5]. It is interesting to highlight that of the 1840 sessions carried out in total, 82 patients with residual tanning showed no

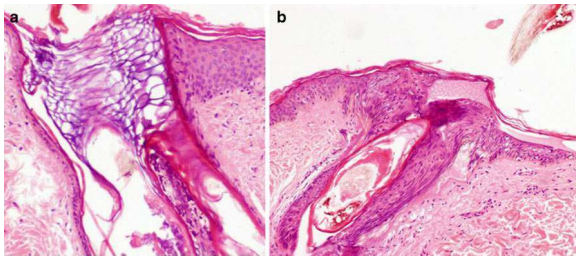

Fig. 1 Cytopathic and vacuole changes are noticed at the basal layer (**a**). There is a focal epidermolysis at this level (**b**)

Fig. 2 Cytopathic and vacuole formation are clearly seen with architectural changes in the hair shaft

differences compared with untanned patients, either with regard to efficacy or adverse events.

The appearance of adverse effects in the axillae or bikini line in this study compared to the greater frequency of appearance on the arms or legs is due to the fact that neither the legs nor the arms were included in the study (areas of greater surface). The only areas of large surface area included are three male pectoral regions.

It is accepted that adverse effects appear more frequently on the arms and legs than on the areas treated in this study. Nevertheless, in the periphery of the skin of the axillae (more pigmented) or in the perineal region (either due to greater pigmentation or high density of hair) secondary thermal effects also appear with conventional epilation.

Energy was not reduced in more pigmented areas such as the perineum just as it was not reduced in the case of bronzed patients or those with higher phototypes so as not to affect the homogeneity of the study and test the safety contributed by this technology.

Risks may be associated with defects in technique such as inadequate (lack of) movement of the hand-piece leading to a greater number of shots on the same cutaneous region.

The delivery of pulses in movement at least partially prevents the appearance of burns since 72% of the treated areas (266/368) correspond to patients of phototypes IV and V. Due to the high repetition rate of pulses per second (10 Hz), the main care taken when treating was to shift the hand-piece continuously and homogeneously. The few cases in which adverse effects did occur appear to be

Table 4 Immediate skin reaction and adverse effects

			IMMEDIATE SKIN REACTION					SIX-MONTH FOLLOW-UP						
AREA	Slightly tanned	No. of sessions	Erythema	Perifollicular edema	Pain	Pseudofolliculitis	Purpura	1st-degree burning	2nd-degree burning	3rd-degree burning	Hyperpigmentation	Hypopigmentation	Persistent erythema	Hyperpigmentation	Hypopigmentation	Scarring	Paradoxical effect	Other
AXILLA																		
206		1,030	673	651	48	19	0	3	1	0	1	3	0	0	0	0	0	
	0																	
BIKINI																		
93		465	320	195	31	6	0	2	1	0	1	2	0	0	0	0	0	
	71																	
PUBIS																		
55		275	203	195	92	50	0	2	1	0	0	3	0	0	0	0	0	
	0																	
PECTORALS																		
3		15	13	7	5	0	0	0	0	0	0	0	0	0	0	0	0	
	2																	
LOWER ABDOMEN																		
11		55	20	3	4	0	0	3		0	0	3	0	0	0	0	0	
	9																	
368	82	1,840	1,229	1,051	180	75	0	10	3	0	2	11	0	0	0	0	0	

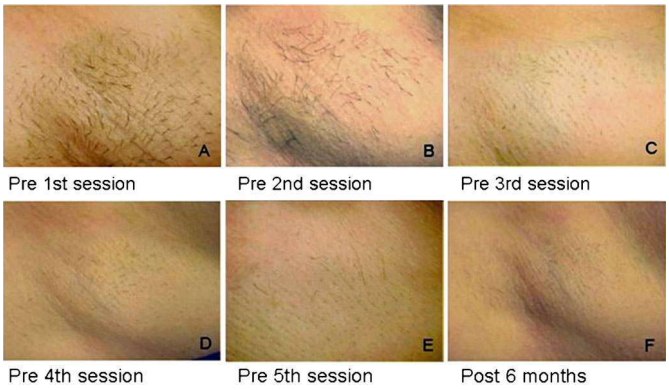

Fig. 3 Laser epilation of the axillae. Progressive hair loss is notable in the before images prior to each laser session and at the 6-month follow-up

Fig. 4 Laser epilation of the axillae. Progressive hair loss is notable in the before images prior to each laser session and at the 6-month follow-up

related to poor technique. Scarce appearance of adverse effects was seen to be related to defective application of the technique.

Efficacy of treatment as judged by patients was very high, with a range of between 75 and 100%. The degree of discomfort during the sessions on successive days was low, and treatment was well accepted.

Photoepilation is a common aesthetic procedure that can be carried out with a variety of laser devices. Laser systems have become solidly established due to their efficacy. A common laser for epilation is the Alexandrite [6], and the procedure is practically risk-free, provided patients present thick, dark hair and light-colored skin. Other lasers, such as the 810-nm diode laser and the 1,064-nm Nd:YAG laser can be used on darker phototypes, but epilation is particularly painful with the latter. Therefore, laser epilation outside its defined boundaries of light skin and dark hair is challenging to practice.

Clinically, the use of a filterless flashlamp-based system delivering fluences in the range of 7.5 J/cm^2 has been reported to lead to partial degeneration of the hair follicle and coagulation in the adjacent tissue [7]. However, intense pulsed light (IPL) devices, when used for epilation, are not exempt from complications such as burns and changes in skin pigmentation. Moreover, IPLs demand a long, steep learning curve to acquire the necessary experience. However, depilation with this non-laser device at low fluences has proved to be effective in in vitro studies [8]. Roosen et al. in their laboratory study have shown that IPL treatment with low fluences leads to architectural changes in hair structure, giving solid information as to the possibility of feasible, efficacious hair elimination in individuals [8].

With the SHR device there is less need for parameterization, since it is only the fluence that needs be considered (5–10 J/cm^2). This automatically associates pulse width and the total time of application (or the total energy delivered).

Fluences automatically apply concrete pulse widths, 10 ms for 5 J/cm^2 and 20 ms for 10 J/cm^2. Since the hair of the study areas was predominantly thick (92.12%), all sessions were conducted at 10 J/cm^2 and a repetition rate of 10 Hz.

With the high-speed pulse repetition of the laser used in this study, in SHR mode, epilation is done with the continuous movement of the hand-piece over the skin. By delivering laser pulses in motion, energy is prevented from concentrating on a single point, and thus, burning is avoided.

During the continuous movement of the hand-piece, 10-J/cm^2 pulses are delivered at a frequency of 10 Hz so that the low-energy pulses heat the skin and the melanin as its prime chromophore. Given the faster thermal relaxation of the epidermis, combined with the constant cooling by the chilled contact tip and cold air flow, the epidermis remains cooler that the dermis and hair follicle throughout treatment.

Due to progressive dermal heating caused by thermal propagation from the hair structure, the dermis becomes a heat reservoir that ends up hindering the thermal diffusion of the heat generated in the follicle. As a consequence of the preferential absorption of the melanin present in the follicle before emission at 810 nm, the latter heats progressively more than the dermis in each repeated shot (due to the fact that it releases heat more slowly in a hot environment). Gradually, an increase of follicular temperature is brought about which enables this system to achieve efficacy and to impair the function of its biological condition.

By using low-level laser fluences, effective thermal induction to hair follicles occurs, with cytopathic changes and also vacuole formation at the basal layer as noticed in our histologies. Interestingly, trials were conducted with the device of this study and with the settings used which validate the efficacy of this form of laser epilation [9]. A low rate of short-width pulses at high fluence in traditional epilation increases the chance of violent saturation of the melanin- hair follicle. This will be the cause of pain and burns, which do not occur during epilation with the laser method presented here, as it produces bearable symptoms of pain and heat sensation and, moreover, warns the therapist not to burn the skin.

A gradual increase in temperature in perifollicular tissue by the chromophore melanin absorption, gives a chance for preferential thermal damage to occur. Heat is released from the heated follicle relatively slowly, maintaining a high thermal gradient for longer than in the case of standard laser epilation. The high average power obtained with the various laser pulses and the sweeping of the hand-piece leads heat to accumulate in the dermis as a consequence of the equation of high pulse rate and various passes (time). In addition, the depth of penetration of the 810-nm diode laser increases the temperature in the dermis, as well as in the melanin chromophore of the hair follicle, due to its higher density in melanin content [9].

Phototype V patients and recently tanned areas were epilated without noticing complications, and treatment was conducted with no extra discomfort. This shows that it is possible to perform epilation with the 810-nm diode laser at low energy per pulse without adverse events.

The settings of laser emission in the windows of the hand-piece give the opportunity of a large spot size, determining homogenous energy density at low fluence per area. Because the hand-piece is slid over the skin at approximately 10 cm per second and since the shot frequency is 10 Hz, each shot means a similar functional impact of the spot size (10×12 mm). Besides, the large beam diameter and the 810-nm wavelength have a direct impact on laser light penetration.

Skin phototype III patients with fairer hair were noticed to respond slightly less to epilation than dark-haired patients. Hypothetically, this may be because the melanin targeted by the laser is scarcer, and patients complain more rapidly of pain and burning sensation during the laser session.

However, these patients were also satisfied with the results of epilation and none presented any long-term adverse effects.

Treatment performed over a relatively long time during which energy accumulates is important. Energy received per unit of area is related to unit of time, i.e., 10×10 cm correspond to an area of 100 cm^2 designed for epilation at which a total flux of energy given to the tissue becomes critical. The system does not include an emission time counter. It does value the "total energy delivered". We have used the "end point" of reaching a total of 9.6 kJ of total energy per area of 100 cm^2 as a way of regulating treatment (measuring total time of emission). With this system, emitting for 80 s is the same as emitting 9.6 kJ, which is far higher than with conventional laser epilation [10].

The high amount of energy accumulated in tissue with the constant motion technique is free of long-term adverse effects as described in our study. This is a point of consideration when compared to traditional one-pass high fluences at low repetition pulse rate with diode laser epilation [11].

Conclusions

This 6-month study on epilation using an 810-nm diode laser pulsed at 10 Hz at low fluence provides efficacy, safety, and comfort with a high degree of patient satisfaction. The 368 areas epilated in patients phototypes III to V over a total of five sessions, every 2 months, at the final follow-up 6 months no longer presented any adverse signs. The results show an absence of significant lesions in the epidermis and no permanent adverse events. Treatment is easily implemented and comfortable, but requires adapting the movement of the hand-piece to avoid such risks as burning. The results show efficacy without hair re-growth for a longer period than that of hair growth, being a safe, convenient therapeutic resource for patients of high skin phototypes.

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