Efficiency of Epilaser Pro Home Use Laser Device at 808nm Wavelength for Hair Reduction Treatment

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1 | INTRODUCTION

Long-term removal of unwanted hair is one of the most common cosmetic treatments today. The technology used in the last twenty years for hair removal uses laser and Intense Pulsed Light (IPL). These technologies are based on the scientific principle of selective Photothermolysis. During the treatment, the light energy is absorbed by the hair's pigment (melanin) and transmitted through the hair shaft to the follicle. Conversion of this energy into heat causes a rise in the hair temperature, leading to destruction of the follicle and disruption of the hair growth mechanism[1-4].

Most of the existing over the counter devices work on a principle of IPL since it is safer for domestic use. Laser hair removal, although superior, is not yet adopted for over-the-counter usage, because of the potential risk (except for one system that uses lasers and is FDA approved). Therefore, almost all the devices that are based on lasers are used by professionals in dedicated clinics or beauty salons. The profonde disadvantage of these technologies is the collateral damage to the surrounding skin because of the amount of energy they produce. Although, most of the time the damage is only temporary and includes redness, pain, tingling, and numbness around the treated area for up to 24 hours, sometimes it causes permanent damage, especially when applied in areas with delicate skin1-4.

The proposed project relies on the Epilaser Pro device - a 4 diode laser at wavelength of 808nm with 3 levels of low energy (24, 32, 40 J/cm^2), irradiating an area spot of 1 mm^2. The main advantage of this approach is that the treatment is applied only to the hair follicles without collateral damage of the surrounding skin. Moreover, since the instantaneous treated area is minimal, the laser radiation from the aperture is very low and is defined as a class I laser, allowing development of over-the-counter device. For further precision, Epilaser Pro device contains a vision system for image processing and allow the user to take a picture of the treated skin area and analyze it, resulting in the release of a laser pulse straight into the hair follicle and not into the surrounding skin. It can also detect pigmented spots and avoid releasing a laser pulse into it. Therefore, Epilaser Pro Laser device is safe for treating facial hair, sensitive areas, armpits, and all other areas of the body at home.

The following report describes results of a one-center study, conducted to evaluate the efficacy and safety of the innovative over-the counter Epilaser Pro Laser device. The study monitored hair reduction treatment on 7 patients after 4 months of 2 weekly treatments. The results show 65% hair reduction, without any collateral damage to the skin.

2 | PATIENTS & METHODS

A total of 7 patients, 6 females and 1 male, ages 28-52 years (39.9±11.2), were enrolled to the study after meeting all inclusion/exclusion criteria. The patients' skin types were classified (according to Fitzpatrick skin type classification): Type 2 - 1 out of 7, Type 3 – 3 out of 7, Type 4 - 3 out of 7 ; the hair color consisted of dark brown to black hair. Body areas were the armpits, legs and abdomen. The protocol involved 4 months of 2 weekly treatments and follow-up visit at 1 month following the last treatment. Hair count at the treated area was performed once a month during the active treatment period and at follow-up visit. The treated areas were photographed before the treatment to allow comparison to an untreated control area. Each patient used 2 different levels of energy. For example, patient 1 used 24J/cm^2 on the left armpit and 40 j/cm^2 on the right armpit. During the monthly photoshoot, patients were asked to rate the general pain level which they felt during the treatments. If at any time point during the active treatment period, patients experienced any abnormal skin response including

edema, erythema, hypopigmentation, hyperpigmentation, and textural changes, they were instructed to immediately report it to the study center.

Table 1 Study population

No. of Patients	7
Gender (n)	
Women	6
Men	1
Age (mean±SD)	39.9±11.2
Treatment Areas (n)	
Underarms	2
Pt.1 (L24, R40)	
Pt.5 (L24, R40)	
Pt.6 (L40, R24)	
Legs	4
Pt.3 (L40, R24)	
Pt.4 (L40, R24)	
Pt.7 (L24, R40)	
Abdomen	1
Pt.2 (L40, R24)	

L40 – Left side 40 J/cm², L24 – Left side 24 J/cm²
R40 – Right side 40 J/cm², R24 – Right side 24 J/cm²

2.1 | Treatment Protocol

Local anesthesia and cold gel were not used in all cases due to the painless nature of this treatment modality. The physician approved patients' participation based on the patient's skin type, hair color and lack of tendency to pigmentation. After placing the treatment head perpendicular to the skin, the device was activated to trigger a pulse. The treatment head was moved, and pulses were delivered throughout the designated treatment area. Patients were advised to cover the area twice with laser pulses. Swelling (edema) and/or reddening (erythema) around the hair follicles were considered a normal immediate response, indicative of the effectiveness of the administered treatment.

2.2 | Assessment

The study's efficacy endpoint, i.e. hair clearance rate, was calculated by comparing the number of hairs in the treatment area at baseline and once a month (up to 4 months) after baseline (prior to the treatment) to the number of hairs in the nearby area (control area). To standardize the percentage of hairs left during each check point, the following calculation was performed (Figure 1): 1. Calculation of a "change factor" using the number of hairs on the control area. The "change factor" was calculated by dividing the number of hairs on the control area at the desirable time point (1, 2, 3 & 4 months) with the number of hairs on the control area at baseline (time 0).

2. Multiply the initial number of hairs on the treatment area at baseline with the "change factor". This enables an estimation of how many hairs would be on the current treatment area if no laser intervention was applied. The result was described as the "estimation factor."

3. Calculation of the percent of hair left after laser treatments. By dividing the number of hairs on the treatment area at the desirable time point (1, 2, 3 & 4 months) with the "estimation factor" and then multiplying the result by 100 to convert it to percentage.

	Months →	0	4
Test area		125	44
Control Area		97	117

1. $\boldsymbol{Change\ Factor} = \frac{117}{97} = 1.21$

2. $\boldsymbol{Estimation\ Factor} = 1.21 \times 125 = 151$

3. $\boldsymbol{Percentage\ of\ hair\ left\ after\ laser}$

$$= \frac{44}{151} \times 100 = 29\%$$

Figure 1 An example for calculation of percentage of hair left after 4 months of laser treatments.

Patient satisfaction with the treatment was assessed on a scale of 1 to 5 when 5 is very satisfied and 1 as dissatisfied.

3 | RESULTS

The present study was designed to evaluate the safety and efficacy of Epilaser Pro Laser device.

As can be seen in Figure 2, average clearance rates of 63% were achieved in this treatment (40 J/cm²) at check point of 1 month follow up (1MFU). 24 J/cm² results are not shown.

No erythema, hypopigmentation, hyperpigmentation, textural changes were reported during the study.

All the patients experienced overall mild pain during the treatments (100%). However, it was described as pinpoint pain – some pulses were more painful than others. Therefore, the overall sensation was experienced as mild pain as more pulses were painless than the ones that did cause pain. Patients were also asked to rate the level of satisfaction of the treatment success. Patient Treatments satisfaction level response was rated as good.

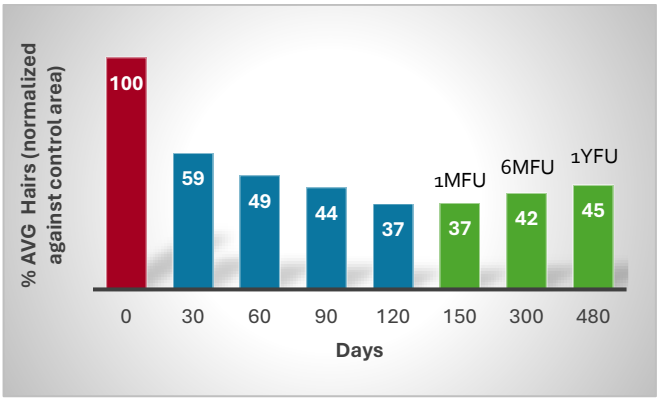

Figure 2 Average Hair reduction rate with 40 J/cm²

At 6 months follow up (6MFU) there is a 5% increase of hair counts and at 1 year follow up (1YFU) there is an additional increase of 3% in hair counts. Making it 8% during most of the follow up period in which, patients stopped using the Epilaser Pro completely.

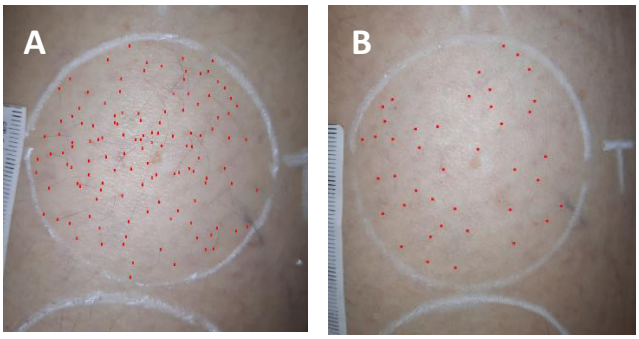

Figure 3 Example for Leg treatment area with 40 J/cm² (Patient 7). (A) Day 0 of treatment, hair count was 125 hairs. (B) Hair count was 41 hairs at 1YFU.

4 | DISCUSSION

The results of this study clearly indicate that Epilaser Pro innovative laser device for home-use offers a non-invasive, effective, safe, and virtually painless hair removal solution for home use. The low energy lasers' beam combined to one spot produces a low energy level, in addition to the devices' vision system enables an effective treatment in comparison to one laser source with high energy. The lower energy and vision system allow safer utilization by all patients at home if the device is used correctly.

The increase of hair counts during the follow up period suggests that it might be beneficial to perform maintenance treatments. Therefore, it is recommended to perform an additional study which also includes a protocol for maintenance treatments. The current device is suitable for skin types 1-4. A planned future study is testing a device with the same configuration but with a longer wavelength laser (for example, 980 nm) for skin types 5-6.

Device-wise, special attention was given to an aesthetic and compact design system, which allows mobility and easy operation. Most importantly, the system's preset parameters enable quick and simple operation by privet users.

Additionally, it is suggested that the system configuration can be used for additional indications such as sunspots, melasma or acne spots as this technology can detect the lesion and then irradiate it with a laser at a suitable wavelength.

5 | CONCLUSION

Epilaser Pro home use laser device at 808nm Wavelength for hair reduction was found to be an effective and safe treatment for patients with skin types 1-4.

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