

CONTROVERSIES IN DERMATOLOGY

Medical-Cosmetic Devices for Home Use: Present and Future Considerations

J.L. López-Estebaranz,^{a,*} and E. Cuerda^b

^aServicio de Dermatología, Hospital Universitario Fundación Alcorcón, Alcorcón, Madrid, Spain ^bDepartamento de Anatomía, Campus Ciencias de la Salud, Universidad Rey Juan Carlos, Madrid, Spain

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Abstract

Laser systems and other energy sources for home use are being developed and will have an exponential growth in the coming years. It is in the field of laser hair removal and hair regrowth where these lasers and intense pulsed light systems for home use are gaining most ground. There are few studies supporting their efficacy and safety and there are still no long term studies. Currently these systems do not require medical prescription and can be purchased in the same way as any over-the-counter product. Although they are not a substitute for professional medical systems, they will play an important role in the treatment of medical and cosmetic conditions, and dermatologists should know about them. Technological progress and commercial and market pressures will encourage the development of more sophisticated devices and broaden the cosmetic and medical indications. Appropriate use and rigorous long-term studies would be desirable to better define their safety and efficacy.

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Dispositivos médico-estéticos de uso domiciliario: presente y futuro

Resumen

Los sistemas láser y otras fuentes energéticas de uso domiciliario se están desarrollando y van a tener un crecimiento exponencial durante los próximos años. Es en el campo de la depilación láser y la estimulación capilar donde mayor auge están teniendo estos sistemas láser y de luz pulsada intensa de uso domiciliario. Son escasos los estudios que avalan su eficacia y seguridad y no disponemos aún de estudios a largo plazo. Actualmente estos sistemas no requieren prescripción médica y se pueden adquirir como cualquier producto de venta sin receta. Aunque no sustituyen a los sistemas médicos profesionales, van a desempeñar un importante papel en el tratamiento de las patologías médico-estéticas, por lo que es conveniente el conocimiento de las mismas por parte de los dermatólogos. El desa-

*Corresponding author.

E-mail address: JLLopez@fhalcorcon.es (J.L. López-Estebaranz).

rrollo y avance tecnológico, así como la presión comercial y de los mercados, hará que aparezcan nuevos sistemas más sofisticados y para otras indicaciones dermoestéticas. Su correcta utilización y el desarrollo de estudios rigurosos a largo plazo sería deseable para establecer su eficacia y seguridad de forma más precisa.

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Introduction

Laser and intense pulsed light (IPL) devices are now widely used in dermatological practice to treat a variety of medical conditions and cosmetic problems. The most common products are laser devices for hair removal, the elimination of pigmented spots, and photorejuvenation of the skin. Home-use laser and IPL devices for hair removal, the treatment of acne, the promotion of hair growth, and other cosmetic applications have recently become available. The fact that several multinational consumer product companies have recently become involved in the development and marketing of medical and cosmetic devices for home use means that these products will become available at prices accessible to the general public in the coming years. The major medical laser technology companies are forging alliances with large cosmetic and consumer companies to develop new devices for home use (Palomar and Johnson & Johnson, Gillette and Proctor & Gamble, etc). The large corporations are obviously well aware of the enormous potential of this market in which. in addition to scientific and medical criteria, commercial considerations and marketing will play a key role.

Under current regulations governing the manufacture and sale of cosmetic devices for home use, these systems are over-the-counter products that can be sold without prescription like any other cosmetic product. The efficacy of such systems does not have to be demonstrated by the same types of studies required for medical systems; nor do cosmetic devices have to fulfill the same criteria as medical systems in order to gain approval. The criteria for approving such devices can be found on the websites of the American Food and Drug Administration (FDA) and the European Medicines Evaluation Agency. Although a medical prescription is not required for the purchase of these devices, many are type I and II laser systems and their use is associated with certain risks and entails a number of safety precautions.

The question also arises of whether patients can safely use these systems at home for self-treatment. Patient use of laser hair removal systems has been studied somewhat. In a study of 73 individuals, Rohrer et al¹ found that patients were able to administer their own hair removal treatments. The adverse effects varied, with the development of hyperpigmentation in 4.75%, crusting in 2.35%, hypopigmentation in 1.55%, and blistering in 1.4%. Such studies are important even though they do not replicate the real conditions of home treatment because the patients must be monitored and observed by an expert, who will rescue them from possible errors and explain any doubts they may have.

Another question we should ask about these systems concerns their effectiveness in real conditions. The home laser hair removal devices currently on the market emit light at very low fluence levels (2-15 J/cm²). If the primary principle behind hair follicle destruction is selective photothermolysis, the fluence must ideally be high enough to destroy target tissue but not damage neighboring structures. The minimum fluence required to destroy a hair follicle is not known. Using a longpulsed neodymium: yttrium-aluminum-garnet (Nd: YAG) laser, Shulze et al² achieved significant improvement of pseudofolliculitis barbae with a fluence of 12 J/cm². This energy density can be delivered by some of the home-use laser and IPL devices on the market, although such systems deliver this fluence level in much longer pulse durations than the professional systems.³ However, the removal of thinner and lighter hair and the hair in certain areas of the body requires systems that deliver the light at a higher fluence in shorter pulses, a configuration not yet possible in home-use systems. Furthermore, none of these new devices are equipped with skin cooling systems, an omission that reduces their safety and may increase the discomfort of treatment.

In this article, we review the home-use IPL and laser systems currently marketed for hair removal, the promotion of hair regrowth, acne, photorejuvenation, and other cosmetic problems.

IPL and Laser Hair Removal Devices for Home Use

Hair removal is the most popular cosmetic application of laser and other light-based systems (IPL). The mechanism of action of these devices is selective photothermolysis; a light beam can be used to destroy a pigmented structure if the wavelength used targets follicular or chromophore melanin.⁴

Effective hair removal depends on the following factors:

- The hair shaft must absorb more light than the surrounding tissue.
- The light must penetrate deep enough to reach the hair bulb. Depth of penetration is variable and depends on wavelength, spot size, and fluence level.
- The pulse duration must be shorter than the thermal relaxation time of the hair follicle.⁵ The energy delivered should be confined to the follicle and should not dissipate into the surrounding tissue.

The pulsed light hair removal devices used by medical practitioners typically have a number of characteristics in common:

- They emit light at between 5 J/cm² and 120 J/cm². The explanation for the large variation in fluence levels between devices is that manufacturers use different methods to measure energy density.
- The number of treatments required varies, typically between 4 and 12 or more.
- Permanent hair reduction 12 months after the final treatment ranges from 50% to 75%.

These medical systems also have a series of disadvantages:

- Inconvenience for the patient, who must travel to the clinic
- High cost
- Pain when high fluence devices are used
- The risk of adverse effects, such as burns and changes in pigmentation

In recent years, a number of home-use hair removal devices have come onto the market (Figure). Most of these new products are pulsed light systems because these devices are easier to manufacture and maintain, although some laser devices are also available. While they offer users the convenience of self-treatment in the privacy of their own home at a lower cost, the safety and efficacy of these home-use devices have yet to be determined. The following is a description of some of these products.

Silk'n

The Silk'n deoice uses a replaceable lamp cartridge with a life of about 750 shots and is equipped with a safety sensor that prevents flashing unless the unit is pressed to the skin.

In a study of 34 women, Mulholland⁷ carried out 3 treatments and achieved reductions in the number of hair follicles of 74%, 84%, and 64% at 2 weeks, 4 weeks, and 4 and a half months, respectively. The only adverse effect reported was perifollicular erythema, which occurred in 25% of the patients and resolved within 1 hour. The author concluded that the Silk'n pulsed light hair removal device for home use had proved to be a clinically effective tool for long-lasting hair removal and that it was safe, quick, and easy to use.

In a study of 20 patients, Alster et al⁸ evaluated the safety and clinical efficacy of a pulsed light unit for home use on nonfacial sites and assessed the patients' tolerance of treatment. Six months after the last of 3 treatments administered at 2-week intervals the authors observed a



Figure Laser and pulsed light devices for home use.

reduction in hair counts of between 37.8% and 53.6%. The only complication encountered was mild transient erythema in 25% of cases. The author concluded that low-energy pulsed light systems can be used safely and effectively for home hair removal in nonfacial sites and skin phototypes I to IV.

Spa touch

Spa touch is a home-use pulsed light device that has a 400 to 1200 nm cutoff filter, a spot size of 22×55 mm², an energy density of 7.5 to 10 J/cm², and a pulse duration of 35 ms.⁹

In a study of 73 patients who self-administered 2 treatments separated by a 4-week interval, Rohrer et al¹ reported mean hair reductions of 33.6%, 44.3%, and 32.3% at 4, 6, and 12 weeks, respectively. The adverse effects reported were as follows: transient erythema (47.5%), edema (5%), hyperpigmentation (4.75%), crusting (2.35%), hypopigmentation (1.55%), and blistering (1.4%). All these side effects had resolved by the 12 week follow-up. The authors concluded that patients could, with adequate training, effectively use this hair removal system at home.

No!No!

Although, unlike the other devices described in this article, No!No! is not a light-based hair removal system, we considered it of interest to include this product because it was designed and is marketed by an IPL manufacturer and has enjoyed great commercial success in spite of the fact that its efficacy is more than doubtful.

The system is based on a filament that is heated electrically to a high temperature. When the device is moved across the skin, the heat is transmitted from a minimum distance of 2 mm burning the body hairs as it goes, leaving a residue of burnt hair on the skin. The device is equipped with a wheel that detects when the unit is in motion and an internal mechanism that separates the heated wire from the skin by a distance of 4 mm when the device is not in motion to prevent epidermal burns. The manufacturer uses the term "Thermicon" to describe this technology, by which hair growth is altered when heat is conducted from the hair down the hair shaft to the follicular bulb.⁹ There is, however, no clinical or scientific evidence supporting the effectiveness of this thermal treatment in terms of permanent hair reduction.

In a study by Spencer¹⁰ that enrolled 20 patients, only 12 completed the study. Following a 6-week course of twice-weekly treatments, hair reduction 12 weeks after the final treatment varied depending on the area treated. Reduction was 43.5% on the legs and 15% in the umbilicus-bikini area. Mild and transient erythema was reported in 25% of the patients studied, and the author concluded that the efficacy of No!No! was comparable to that of laser systems used by medical personnel.

Other Products

A number of other devices have recently come onto the market in Spain. Of these, the following are of particular interest: Satinlux,¹¹ an IPL device marketed by Philips; and

Table 1 Laser and Intense Pulsed Light Hair Removal Devices for Home Use	inse Pulsed Light Ha	air Removal Devic	ses for Home	Use					
Model	iPulse Personal	No!No!	Rio Salon Laser	Rio Scanning Satinlux Laser	g Satinlux	Spa Touch	Silk'n	Teny Epil Flash	Tria
Manufacturer	CyDen Ltd	Radiancy	Dezac Ltd Dezac Ltd	Dezac Ltd	Philips	Radiancy	Home Skinovations	GHT Innovations	SpectraGenics
Advertised fluence level 7.7 and 10 J/cm ² 5-8 J/cm ²	7.7 and 10 J/cm ²	5-8 J/cm ²	I	1	$2-6.5 J/cm^{2}$	7.5-10 J/cm ²	5 J/cm ²	$20 J/cm^2$	6-24 J/cm ²
Advertised pulse duration	25, 40, 60 ms		I	I	I	35 ms	I	24-33 ms	125-600 ms
Advertised spectrum 530-1100 nm	530-1100 nm	400-1200 nm	808 nm	808 nm	475-1200 nm	400-1200 nm	475-1200 nm	600-950 nm	810 nm
Advertised number	10 000	Replaceable	Unlimited	Unlimited	I	Unlimited	750 per	20 000	>250
of shots		heads					cartridge		
Spot size	3 cm ²	255 mm long	0.0019 cm^2	0.14 cm^2	3 cm ²	12.10 cm^2	6 cm ²	2.64 cm ²	0.785 cm^2
Repetition rate	6.1 s	I	6.3 s	I	I	I	4.1 s	8.3 s	2.2 s
Skin phototypes	III-	I-VI	- ∨	 - ∕	-I<	I	I-IV	VI-I	I-IV
Eye protection	No	No	No	No	No	Yes	No	Yes	No
Weight, g	1500	200	300	700	290	5000	1150	I	750
References	11	None	None	None	11	None	7 and 8	None	12

Tria, an 810-nm diode device with an energy density ranging from 6 to $24 \text{ J/cm}^{2.12}$ Although not sold in Spain, a number of other products can be purchased on the Internet. Their characteristics are summarized in Table 1.

Comments

Scientific studies in peer-reviewed journals are available for very few of the systems on the market. Moreover, the few studies that have been carried out with home-use hair removal devices have included only 3 to 4 months of follow-up, making it impossible to talk about permanent hair removal. Studies with laser devices have shown that it takes 3 to 6 months to stabilize hair reduction. We can state that some of the home use hair removal devices only afford temporary hair removal and that not all of them are equally safe and effective. None are equipped with skin cooling devices or automatic calibration systems.

For some devices, a recent report found differences between the energy densities claimed by manufacturers and the actual fluence levels emitted, adding that such discrepancies could cause problems related to both safety and effectiveness.¹³

These home-use devices offer patients savings in terms of both time and money, a benefit that will tend to increase the user's adherence to treatment. They are probably effective in the removal of thick dark hair on nonfacial sites in patients with light skin phototypes. Their use is indicated in skin phototypes I to IV and on all areas of the body except the face and neck. These devices only function when they are in contact with the skin in order to prevent possible eye damage. Although they are class I laser devices (Table 2), proper information and instruction is essential to ensure correct use. Abusive or incorrect use of these devices may cause adverse effects. Paradoxical growth or regrowth of hair is one side effect that should be taken into account with these low-energy systems. Another unwanted effect is leukotrichia, a condition that can be difficult to eliminate. In our opinion, professional medical laser systems continue to play a key role in the permanent elimination of unwanted body hair even though they may be complemented by these home-use systems.

More studies are required to identify the optimum parameters (fluence level, wavelength, duration of treatment) for home-use devices and to establish safety and reliability mechanisms.

Hair Regrowth Devices

There is evidence to suggest that low-energy light applied at wavelengths between 650 and 900 nm can stimulate hair growth. $^{\rm 14-18}$

The mechanism by which such treatment promotes hair growth is not presently understood, although a number of theories have been advanced, as follows:

- Stimulation of resting follicles with low-energy fluence levels (as in the paradoxical growth observed with the use of hair removal laser devices)
- Synchronization of the hair growth cycles by direct light stimulation ¹⁹
- Activation of the mitochondrial respiratory chain that intervenes in the production of adenosine triphosphate (ATP). Although such activation has been demonstrated in several studies, the manner in which ATP intervenes in hair growth is still poorly understood.²⁰

HairMax LaserComb

HairMax LaserComb, the best-known hair growth device, is approved by the FDA for the treatment of male androgenetic alopecia classified as grade IIa to grade V on the Norwood-Hamilton scale. The comb has 9 class 3R diode lasers with an output of up to 20 mW and a wavelength of 655 nm ($\pm 5\%$).²¹

Several studies have demonstrated the effectiveness of this product.²² Leavitt et al²³ recently published a study of 110 men with androgenetic alopecia who used this device and were assessed at 26 weeks. They reported a greater increase in terminal hair density in the treatment group than in the control group with no adverse effects.

In a 2009 study of 7 patients with androgenetic alopecia, Avram and Rogers²⁴ observed an increase in both shaft diameter and the number of terminal hairs in patients treated twice weekly for 3 months. They concluded by saying that low-level laser therapy may be a promising treatment option, but that more controlled studies were needed to confirm this.

There are a number of other home-use devices on the market for the stimulation of hair growth, including Laser Hair Brush (Sunetics International), Revage Hood, and

Class	Wavelength, nm	Exposure to the Beam	Output Power, W
Class I	0-13 000	Supposedly "inherently safe," but eye exposure should be avoided	Maximum allowed, 10 ⁻³
Class II	400-700	Eye exposure: 0.25 seconds. Protect the eyes	10 ⁻⁶ -10 ⁻³
Class IIIa	0-13 000	Eye exposure: should be fully assessed	10 ⁻⁹ -0.5
		Protect the eyes. Skin exposure: protect	(approximately)
Class IIIb	0-13 000	Should be fully assessed. Protect the eyes.	10 ⁻⁹ -0.5
		Skin exposure: protect	(approximately)
Class IV	0-13 000	Should be completely avoided	0.75-10
			(approximately)

Table 2 Classification of Laser Types

ProXtra Hair Brush. However, no studies have yet been published on the safety and effectiveness of these devices.

Other Dermoesthetic Systems for Home Use

A number of other devices for the home treatment of dermoesthetic problems are now being marketed. Many are based on light emitting diode (LED) technology. These LED devices produce noncoherent light and have many applications. The earliest systems of this type were developed by the US National Aeronautics and Space Administration to accelerate wound healing in space. LED devices are also used as a light source in photodynamic therapy. The theoretical mechanism of action is photobiostimulation and there is still much debate concerning their effectiveness.²⁵ Photobiostimulation has been observed to increase the expression of a number of genes, thereby producing increased cell migration and modulation in levels of growth factors and cytokines, leading to an anti-inflammatory effect.^{26,27} These devices reduce levels of metalloproteinases and p53-mediated apoptosis. Other theoretical effects are antibacterial activity, induction of fibroblast differentiation into myoblasts, and increased fibroblast motility.

These LED devices have been used by physicians for a variety of purposes, including photorejuvenation, wound healing, the treatment of diseases such as acne and rosacea, the reduction of postinflammatory melasma and hyperpigmentation, and as a method of photoprotection.²⁸⁻³⁰

The 2 primary applications of LED devices for home use are facial rejuvenation and the treatment of acne, although some devices are advertised for the treatment of hyperpigmentation.

The following LED light-based treatment systems have been approved by the FDA:

- Omnilux Clear U for the treatment of acne ³¹ with 2 peak wavelengths—415 nm at 40 mW/cm² and 633 nm at 70 mW/cm²
- New U, also an Omnilux product, which is used for rejuvenation³²
- Tanda, a device equipped with 2 LEDs, one that emits 414 nm blue light for the treatment of acne and another that emits 660 nm red light for skin rejuvenation³³
- Rejuvawand³⁴ with 2 LED light sources, one delivering 627 nm red light at 9 J/cm² and the other 850 nm infrared light at 9 J/cm².

In all these LED systems, daily 20- to 30-minute sessions are recommended for rejuvenation and twice weekly sessions for the treatment of acne.

The main difference between the home-use devices and those used by medical practitioners is that the former are smaller and have a lower concentration of diodes. This means that, in theory, longer treatment sessions are required. There is as yet no evidence from rigorous scientific studies to support the use of these home-use devices.

LED devices designed to eliminate pigmented areas and treat vascular lesions (980 nm diode lasers) will come onto

the market in the future, and some products of this type have already been announced.

Future Prospects

Home use of laser and IPL devices to treat dermoesthetic problems will undoubtedly become more common and widespread in the coming years. The safety and efficacy of these systems will vary. In addition to the products for hair removal and acne currently on the market, we will see the introduction of other device for photorejuvenation and the treatment of cellulite, varicose veins, and other cosmetic problems. In the case of medical applications, laser devices for home treatment of vitiligo and psoriasis and photodynamic therapy systems will also very probably enter the market. Equipment rental services will provide users with an alternative to purchase in the case of disorders and conditions that do not require indefinite treatment.

Further technological advances will lead to new systems, mainly for hair removal, the promotion of hair growth, and the treatment of acne because these are the markets with the greatest potential. The new devices will be easier to use and more effective. Moreover, they will incorporate skin cooling systems, automatic calibration, and safeguards against accidental injury. Probably, many of these new devices will complement the systems used in dermatological practice. That home devices will be used for diseases and conditions for which they are not intended will be unavoidable, however, and it will not be possible to prevent their use in ways that do not conform to the manufacturer's recommendations and that may give rise to adverse or unwanted effects.

Conclusions

Consumer laser and IPL devices for medical and cosmetic uses in the home are already a reality and their use will increase exponentially in the coming years. There is, as yet, scant scientific evidence to demonstrate their efficacy and safety under either clinical or real-life conditions. Double-blind, controlled trials and postmarketing studies are needed to establish both effectiveness and safety of these devices. Although these products have to date been developed primarily for laser hair removal and the promotion of hair regrowth, in the future we will see new devices for many other medical and cosmetic applications.

Conflicts of Interest

The authors declare they have no conflicts of interest.

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