

Randomized study of tolerance and efficacy of a home-use intense pulsed light (IPL) source compared to the hot-wax method

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Summary

Background More and more we are seeing depilatory mechanisms based on IPL technology and used at home. As far as we know, these appliance have not undergone either safety or efficacy testing.

Aims The aim of the study was to compare tolerance and efficacy of two depilation methods a medical device in-home-use IPL (E-One) and hot wax.

Materials & Methods Axillae of 63 persons were treated by either IPL (intense pulsed light) or hot wax for 49 weeks. Tolerance was assessed clinically by a dermatologist and efficacy by an independent blinded photographic assessment.

Results Tolerance of the two methods is reasonably good with better results for the IPL treatment. IPL treatment is also much more efficient.

Conclusion This study confirmed good tolerance and excellent efficacy of this first one medical device used at home. Taking into consideration the mechanical action of the IPL and our experience, other cutaneous appliances (against wrinkles (or aging), hyperpigmentation. etc.) could be considered after optimization of the technical parameters.

Keywords: efficacy, hot wax, intense pulsed light, tolerance

Introduction

Intense pulsed light (IPL) consists of high-intensity light sources emitting noncoherent visible light over a very wide spectrum. It has been used for many years to treat vascular and pigmented lesions. More generally, this technology is carried out for the treatment of photoaging including slack skin and wrinkles.¹ Another domain is hair removal where IPL treatments are preferred more

and more to other optical devices because of their versatility.² Efficacy of this kind of treatment for depilation has already been addressed in literature for both professional and home-use devices. Generally, these studies conclude in a good efficacy, even if permanent hair removal needs repeated treatments. Safety is good and only minor side effects (mainly erythema) were reported.³

The present study is relative to the efficacy and tolerance of a new, relatively small IPL medical device, recently developed for home-use. Short- and long-term efficacy and tolerance were assessed versus the most frequently used technique by consumers: "hot wax."

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Material and method

The aim of this study was to assess and compare the tolerance and efficacy between a new IPL device and the usual reference product, hot wax, for depilation of axillae. This was a randomized study based on clinical blinded photographic assessment on photos and self-assessment by the volunteers. Two investigation centers participated in the study: The Sabouraud, Hôpital Saint-Louis Center, Paris and Eurofins/ATS Center for Cosmetic Evaluation, Aix-en-Provence, France. In each center, clinical assessments were carried out by a clinician who followed the volunteers included in the investigation during the whole study (245 days).

Volunteers

Thirty-three volunteers were included in the Aix-en-Provence study and 30 in Paris. Among the 63 persons, 79% were women and 21% men. Concerning their phototypes, 21% were phototype II (13 people), 75% phototype III (47), and 5% phototype V.³ The mean age of the patients was 39.6 ± 9 years. After complete information about the aim of the study, the techniques under investigation, the time schedule, and the detailed protocol, volunteers signed a confidential agreement form.

The IPL device is an innovative compact device called "E-One" (E-Swin, Paris-France). This new technology allows a smaller footprint and lower fluence delivered with the same IPL from the beginning to the end of the flash.

These characteristics are as follows:

- A flash filtered to 580 nm
- An average pulse time of 34 ms

Hot waxing is an effective method of removing large amounts of hair at one time. In this method, the wax is warmed allowing it to be spread easily over the skin with a spatula in the direction of hair growth. When the wax cools and is firm, the hair becomes embedded in it. The wax is then quickly pulled off in the opposite direction of the hair growth, pulling it out of the follicles.

General procedure

Treatments (E-One or hot wax) were randomly attributed to either the right or left axillae of each volunteer. At Day 0, axillae of each person were treated either by E-One or hot wax. The day following D1, photos of axillae were taken and a first assessment of tolerance was recorded by clinicians at each center. The following weeks W7, W14, W21...W49 (corresponding to

49, 98, 147, 196, 245, 294, 343 days after the beginning of the experiment) photos were taken and tolerance assessed. Volunteers received their depilation treatments according to the preestablished randomization table.

Assessment of efficacy

At the end of the study, the totally blinded photos of both patient's axillae were presented successively to two independent clinicians who had not followed the volunteers during the clinical study. Those clinicians were to decide which one displayed the best result in terms of the remaining quantities of hair under each axilla.

Assessment of tolerance

The following signs of irritation were clinically assessed: erythema, edema, and desquamation. A four-grade scale was used: 0, no appearance; 1, weak; 2, moderate; and 3, severe.

Statistics

The Mac Nemar test was used for efficacy. Percentages of success for the two methods were compared versus time with the chi-square test. For tolerance, the chi-square test was also used.

Results

Results concerning tolerance for the two methods are detailed in Table 1. It can be noted that there was neither grade 3 nor grade 2 during the length of the study for edema and desquamation. For grade 1, there were only a few cases occurring at Day 0. Finally, there was no statistical difference between the two methods concerning edema and desquamation.

Concerning erythema, there was a significant difference at D0: treatment by E-One was less irritating than hot wax ($P = 0.014$). This difference was no longer significant at the end of the study except at week 7, where E-One treatment was significantly less irritating than hot wax ($P = 0.03$).

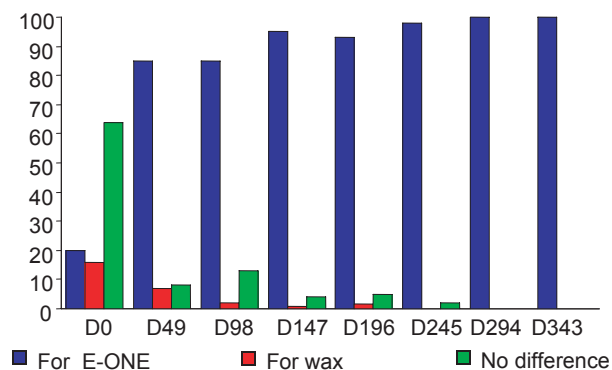
Results of efficacy are summarized in Figure 1 where the percentage of choice for the preferred methods (E-One better, hot wax better, equivalent) is plotted versus time. It clearly appears after the first day where the methods are assessed "equivalent" ($P = 0.65$), the E-One method was found more efficient than the hot wax ($P < 0.001$).

Table 1 Detailed results of the Tolerance study (continuous line indicates that there was no statistical difference between treatments)

	Intensity	D0 after first epilation (%)		D1 (%)	
		E-One	Wax	E-One	Wax
Erythema	0	79	43	97	93
	+	21	46	3	7
	++	0	11	0	0
	+++	0	0	0	0
Desquamation	0	86	96	100	100
	+	14	4	0	0
	++	0	0	0	0
	+++	0	0	0	0
Edema	0	93	86	100	100
	+	7	14	0	0
	++	0	0	0	0
	+++	0	0	0	0

Comparison	D0 after first epilation	D1
E-One vs. Wax		
Erythema	Significant difference for E-One ($P = 0.014$)	ns
Desquamation	ns	No abnormal clinical sign for both groups
Odema	ns	No abnormal clinical sign for both groups

No more significant at the end of the study expected at week 49 ($P = 0.03$, E-One treatment less irritating than hot wax).

**Figure 1** Percentage of choice of the most efficient method versus time. There was no difference between methods at D0. E-One was found more efficient ($P < 0.0001$) for all the following weeks.**Table 2** Percentage of agreement between the two clinicians for the duration of the study

	D0 (%)	D49 (%)	D98 (%)	D147 (%)	D196 (%)	D245 (%)	D294 (%)	D343 (%)
E-One	20	85	85	95	93	98	100	100
Hot Wax	16	7	2	1	2	0	0	0
No difference	64	8	13	4	5	2	0	0

Comparison between the two clinicians in terms of their choice of the best efficacy is displayed in Table 2. Their agreement is relative at D0 (68%) but quite good (>80%) at W7 reaching 95% at W14.

Discussion

To our knowledge, it is the first time that a home-use IPL device was compared with a widely used method for hair removal, i.e., hot wax. In terms of tolerance, this study confirms previous ones relative to the use of the IPL device for hair removal. Several studies have shown that mild and reversible erythema was the main clinical sign appearing posttreatment.^{3,4} Compared to the hot-wax method, our study demonstrates a better tolerance of the E-One system during the course of the study. In all cases, erythema was mild with no consequences of edema and desquamation.

In the present study, efficacy of the methods was not tested in terms of partial hair or definitive depilation. Only comparative results between the two methods were recorded during the study to determine which method was the most efficient. Importantly, the new IPL method was compared with the well-known method generally usually used by consumers "in home." If we exclude the

**Figure 2** Illustration of the difference of efficacy at W14 between the two methods: left, hot wax; right, E-One treatment.

first day, results show that areas depilated by the IPL device display less hair than symmetric areas treated by hot wax and with no exception during the full year of treatment. An example of such a result is presented in Figure 2.

The majority of studies carried out with IPL for nonfacial body areas conclude in a reduction ranging from 41 to 81% of hair removal after repeated treatment, figures depending mainly of skin phototype and of the total fluence received.^{4,5} Even if definitive epilation is not obtained completely with IPL techniques today, partial results are made possible for a majority of people with reasonable tolerance. Compared to the hot-wax method, the E-One device is a good alternative for both tolerance and efficacy.

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