"Sensilight"

A Study Report

By Sensica

Introduction

A common technology used in cosmetic phototherapy for long term hair reduction, is the IPL (Intense Pulsed Light). These devices, originally designed for professional use, evolved as OTC (Over-The-Counter) for home use. Such light- based devices for removal of unwanted hair are based on the principle of selective photothermolysis. In this process, the light penetrates into the dermis, the chromophore (melanin) in the hair shaft absorbs the light energy, which dissipates into the surrounding cells of the hair follicle and causes thermal damage to the cells in the root bulb and the root bulge, ultimately leading to reduction in hair growth 1, 2. Two factors play an important role in the optimal long-term hair reduction. The first is the hair growth cycle (Anagen, Catagen and Telogen). Anagen is the growth phase while Catagen and Telogen are the resting phases. Permanent hair reduction can only occur when treatment is performed during the Anagen phase 3. The second parameter is the skin type (commonly assessed according to the Fitzpatrick Scale). Darker skin contains more melanin, which competes with the targeted hair for light's energy absorption. As more light energy is absorbed by the skin, the effectivity of hair reduction will decrease while the risk of adverse effects and potential epidermis damage will increase. Therefore, dark hair color is most suitable for hair removal using phototherapy, as it contains more melanin than light hair (such as blond and grey) 4.

In IPL methodology, noncoherent, polychromatic light energy is emitted at different wavelengths that target specific chromophores. For melanin targeting, long wavelengths are most efficient (475-1200 nm), as these can act selectively on the dense melanin deposits in hair follicles without damaging the epidermis 5. Another common technology for long term hair removal is laser-based. As with the IPL method, laser-based devices target the melanin in the hair shaft. Typically home-use laser devices implement ~800nm wavelength6. Several studies comparing between IPL and laser technologies revealed that both methods are effective and safe for hair reduction. The major advantage of IPL method over the laser hair removal is safety, with fewer side effects and less pain during treatments. In addition, IPL devices cover a larger treatment area per pulse compared to laser devices, enabling faster treatment.5, 7, 8

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Here we present the results of a market survey, using the Sensilight and Sensilight MINI Reactive Pulsed Light™ (RPL™) devices. The RPL family of devices is intended for permanent reduction of unwanted hair regrowth, based on the selective photothermolysis scientific principle, adding a reactive skin tone sensor to the IPL technology. The primary goals of this survey are to assess the user's satisfaction and their subjective evaluation of the extent of hair reduction, during and after completion of a recommended treatment regimen with the RPLTM devices. The results included in this report are after the completion of 8 treatments spread over a period of 5 months.

Sensilight device

Sensilight RPL™ advanced technology uses IPL along with a combination of unique skin condition sensors. The light penetrates the epidermis into the dermis and is absorbed by the melanin in the hair shaft. The heat generated by the absorbed light then dissipates into the follicle and generates local thermal damage, causing a reduction in hair growth.

The Sensilight or Sensilight MINI hand held devices consist of the following main components (as shown in Figure 1):

- External power supply.
- An optical filter composes the optical aperture, which is referred to as Treatment Window. The optical energy (flux of 5 J/cm2) is delivered through that optical filter (when in full contact with the body) for treatment purposes. The size of the treatment window is 3cm2. Next to the Treatment Window, Proximity and Pigmentation sensors that serve as safety features are located.
- User Interface parts: ON/OFF and energy button, the LED indicators for the energy function. An additional LED indicates the device's status.

A

B

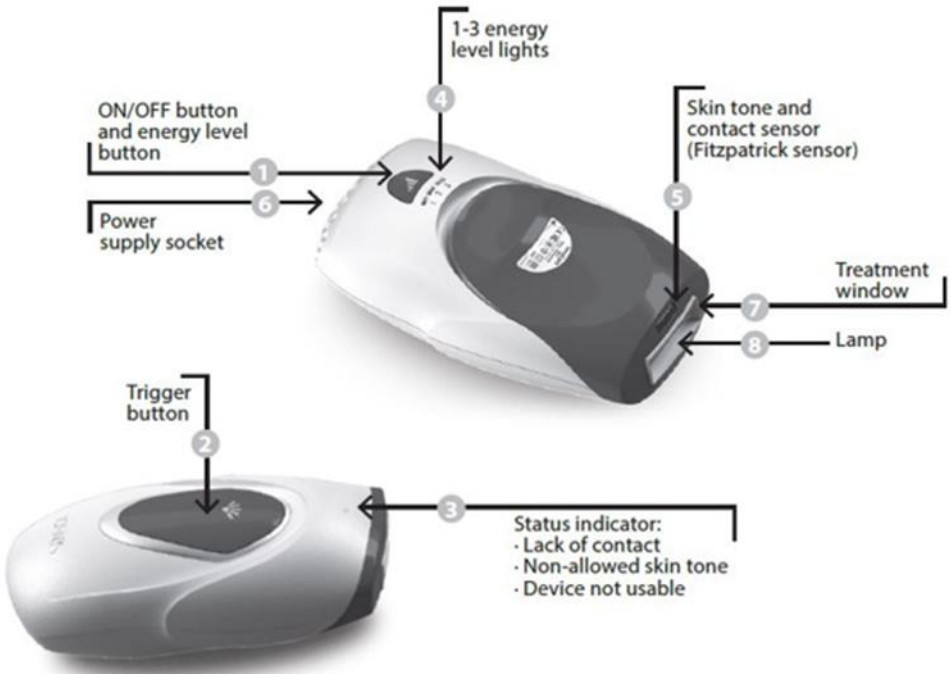

Figure 1. Sensilight (A) and Sensilight MINI (B) devices. The main components are detailed in the images.

The device was designed to allow fast treatment, with one pulse delivered every two-three seconds, resulting in treatment of just few minutes per the desired area. In addition, the life time of the lamp is long enough to enable full body treatment, when taking into account the average number of pulses required per each treatment area. This is promising that the average user will not need to replace the lamp for full body entire treatment regimen.

Note: the term Sensilight device is used for discussing both Sensilight and Sensilight MINI devices, unless indicated otherwise. Both devices operate the same technology and parameters crucial for treatment's success.

Study design

The Sensilight Market Survey was designed as a prospective, single arm study to assess satisfaction of the reduction in hair re-growth followed by 8 RPL™ treatment sessions, performed independently by the participants at their homes.

The primary objective of this study was to evaluate the subjective satisfaction of study participants with the Sensilight and Sensilight MINI devices, when used on the following body areas: legs, underarms, bikini line, arms, back, chest and/or face, according to the participant's own preference. This goal was achieved by collecting subjective feedback from participants during and after the completion of the recommended treatment protocol. The secondary objective was to support participants' feedback regarding the reduction of hair re-growth by objective assessment, of a blind evaluator. This was achieved by hair counts from photographs of the same treatment region having the same size area before, during and after treatments.

37 participants (33 females and 4 males, mean age 37±8, Fitzpatrick skin tones I-IV) were enrolled to the market survey after receiving a detailed explanation on the study. The participants have received a Sensilight or a Sensilight MINI device and were instructed on how to operate and use it based on Instructions for Use.

Results

Up to date 30 participants have finished the recommended treatment regimen of 8 treatments and arrived to a follow up session (T8) that included filling a satisfaction questionnaire and photography. Their demographic data is summarized and presented in table 1. Three additional participants are still awaiting follow-up visit. Four participants have withdrawn from the study, according to their own decision and not due to adverse events or side effects. Data after the 5th treatment of a participant, who failed to come to T8 follow-up, was also taken into analysis. No adverse events occurred during or after treatments.

Table 1. Participant's demographic data

	# participants
Age	Average & (range): 37 (26-63) years
Sex	27 females, 4 males
Fitzpatrick skin tone	
I	2
II	10
III	16
IV	3
Hair color	
Black	7
Dark brown	16
Brown	5
Dark blond	1
Blond	2

Out of the participants who have completed 8 treatments with the Sensilight RPL device, 87% showed >25% reduction in hair regrowth. Maximal hair clearance noticed was 98% .

It is well established that response to phototherapy differs between individuals, depending on biological factors. People with dark hair had better results than participants with blond hair , although it was not found to be statistically significant .

No differences in hair reduction between the Sensilight and Sensilight MINI devices were found.

Discussion & Conclusions

Self-assessment of treatment success

83% of the participants reported that they feel a reduction in hair regrowth after the completion of the treatment regimen. On a scale of -1 to 3, where -1 is worsening (e.g., increase in the number of hairs) and 3 is very significant improvement (e.g., very significant decrease in the number of hairs), the average score was 1.5 (SD±0.93) . 73% have noticed that the hairs that regrew after 8 treatments with the Sensilight device were finer. 87% felt that the hair regrowth is slower after treatments, with

an average of 1.5-2 times decrease in hair regrowth rate. Importantly, no one has reported on increase in hair regrowth, thickness or faster growth cycles.

Interestingly, some participants have even reported noticeable improvement and high satisfaction after only 1 or two treatments (within 2-4 weeks).

Device operation and treatment regimen

Regarding the ease and comfort of using the Sensilight and Sensilight MINI devices, for 93% of the participants it was easy and clear how to use the devices. Treatment regimen was also found to be appropriate according to the participants' feedback, with 97% stating that the time each treatment takes was reasonable and 90% feeling that the total treatments time (8 treatments) is reasonable. All participants found that both Sensilight and Sensilight MINI devices are comfortable to hold and use during treatments, for most of the treatment areas. The average scores of the above issues on a scale of 0 to 3, where 0 is not comfortable/easy/reasonable at all and 3 is very comfortable/easy/reasonable, are summarized in figure 3.

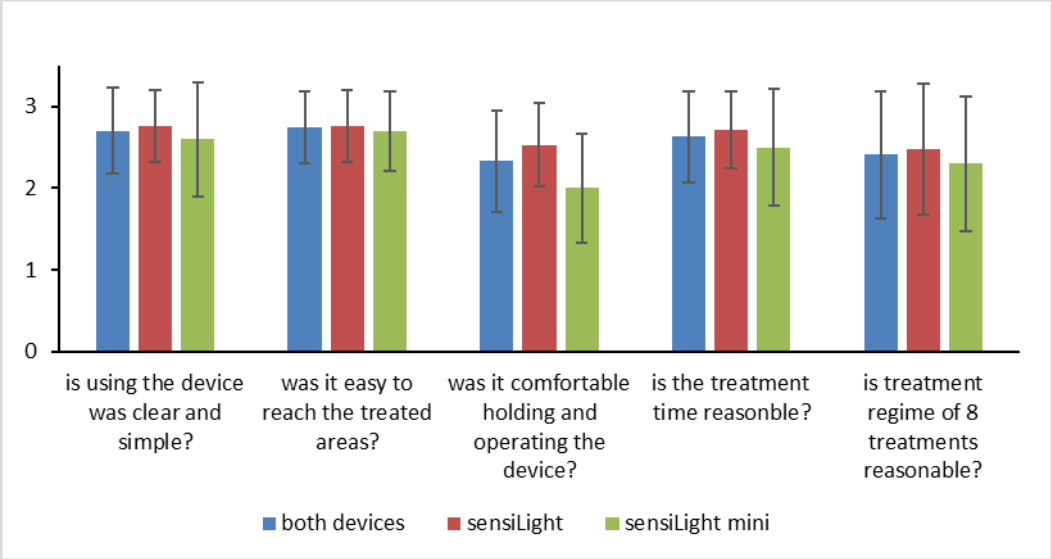

Figure 3. Sensilight and Sensilight mini devices operation and comfort in use. Error bars represent SD.

Satisfaction

Most users, 86%, were satisfied with the device, following 8 treatments with the Sensilight devices. 87% of the responders would prefer to use Sensilight over other devices available on the market and 80% would rather use Sensilight at home than undergoing similar treatments in a saloon/clinic. Moreover, 83% of the participants declared that they would buy and recommend the Sensilight device to a family member or a friend.

When asked regarding discomfort, pain or adverse events, if any, participants have reported only minor side effects appeared, such as temporary redness, resolving spontaneously within few hours. Neither adverse events nor pain were reported by the users.

No differences between Sensilight and Sensilight mini devices were found in any of the parameters/questions asked and here presented.

To summarize the Sensilight's users were satisfied with the results and the device. Users have also expressed their satisfaction with phrases such: "perfect device", "really fun to use, especially when seeing a significant improvement", "very convenient that it's a home use device" , "compact and friendly device, so easy to use and doesn't hurt at all!", "I've got even better results than in a professional hair removal saloon" and more.

Participant	Before	After
IS-EG-001		
IS-EG-011		

Unwanted hair removal from bikini line/inguinal region.
Photographs of (baseline, T0) of two female participants and after 8 treatments (T8) with Sensilight.

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Participant	Before	After
IS-EG-016		
IS-EG-025		

Unwanted hair removal from axilla. Photographs of (baseline, T0) of two female participants and after 8 treatments (T8) with Sensilight. Reduction of hair regrowth is seen after treatments in both subjects

Participant	Before	After
IS-EG-012		

Reduction in hair regrowth on male back after 8 RPL treatments. Before (baseline, T0) and the same region after 8 treatments (T8) with the Sensilight device. Very significant reduction of hair regrowth is seen after the treatments.

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Participant	Before	After
IS-EG-017		
IS-EG-018		
IS-EG-036		

Unwanted hair removal from the legs. Photographs of three female participants of (baseline, T0) and after 8 treatments (T8) are presented. Participant IS-EG-017 was photographed after 5 treatments only and had 93.5% hair reduction in the treatment area. Participants IS-EG-018 and IS-EG-036 showed 90% and 82% hair reduction, respectively.

* Treatments were performed around the tattoo and never on it.

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