Silk'n™ - A novel device using Home Pulsed Light™ for hair removal at home

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Abstract
A small, light-weight, low-energy, and low-cost IPL system designed for home use (Silk’n™; HomeSkinovations, Kfar, Saba, Israel) was tested for efficacy and safety on 34 test individuals and 92 sites. Each of the patients underwent informed consent and performed self-treatment at the clinic supervised by an experienced laser hair removal nurse. The pre- and post-treatment hair counts were performed and the reduction counts were analyzed by a blinded observer.

Key Words: Home hair removal devices, intense pulsed light hair removal, laser hair removal, photoepilation

Introduction
Since the first laser was approved for long-term hair reduction by the FDA in 1995, laser, light and electro-optical removal of unwanted hair has grown to become the number one medical aesthetic procedure. The laser and light-based devices all work through the selective absorption of photon-based energy by the melanin chromophore in the hair shaft, causing heat injury to the surrounding internal and external root sheet and damage to the mitotically active cells in the root bulb or the precursor cells in the bulge. This selective thermal process was introduced by Anderson in 1983 (1).

In order to safely and effectively heat the hair shaft and damage the surrounding cellular structure in the root sheath, three conditions of selective photothermolysis need to occur:

1. Light absorption by the hair shaft should be higher than the surrounding tissue. There are many wavelengths of laser and pulsed light that can achieve this – 694 nm (ruby), 755 nm (alexandrite), 810 nm (diode) and 1064 nm (Nd:YAG) are the most common, whereas intense pulsed light systems commonly deploy cut-off filters and use a broad spectral range.

2. Light penetration into the skin has to be deep enough to penetrate the full depth of the hair follicle. Depth of penetration is achieved through longer wavelengths of light, large spot sizes, and higher fluences.

3. The pulse duration of the light/laser should be less than the hair follicle thermal relaxation time. The energy that is delivered by the optical pulse should be confined to the hair follicle and not dissipate to the surrounding tissue.

The various laser systems need to create a critical thermal threshold in the bulb and bulge structures for a critical duration in order to achieve some permanent/long-term hair reduction. All of the common infra-red hair removal lasers, from 694 nm to 1064 nm, can accomplish permanent reduction and hair clearance, prolongation of the anagen–telogen cycles, micronization of the remaining hair follicles, and synchronization of the growth cycles (2–4).

The typical in-office medical laser/light-based systems deploy energy densities of 20–120 J/cm², depending upon the wavelength of light and the skin type of the patient. Treatment protocols involve six to 12 treatments over many months and the cost can vary between $75 on the low end per treatment for a small zone up to $1000 to $1500 per treatment for large zones. Across the spectrum of all companies, devices, wavelengths and fluences, the permanent reduction data (percent of hair showing no re-growth 12 months after the last treatment)
ranges between 50% and 75% reduction after a series of treatments (6–8).

The disadvantages of in-office-based laser/light hair removal include:

1. the inconvenience of travel to the clinic for multiple sessions
2. the cost of the treatments $500–$5000 or more
3. discomfort with the high fluence devices
4. risks of pigmentation issues and scars.

If a home light-based device was available that could demonstrate significant efficacy and a high degree of safety, then home-based light/laser hair removal may add significant benefit to patients suffering from hypertrichosis.

Study objective

The objective of this study was to assess the clinical efficacy, safety and patient tolerance of a low-energy, light-weight, portable, pulsed light, home hair removal system (Silk’n™; Homeskinovations, Kfar, Saba, Israel).

Materials and methods

A total of 34 patients were selected for an efficacy study. All patients were female (average age of 22.4 years) and the most common treatment sites were the bikini (38), axilla (36) and lower leg (18). Skin types ranged from type 1 (three), type 2 (23), skin type 3 (seven) and skin type 4 (one).

Informed consent was obtained from all study participants. The body sites that were to undergo the hair removal treatment were photographed. Each treatment site was randomly divided into two: 50% of the area to receive treatment and the remaining 50% to act as an untreated control. Standardized close-up pictures were taken pre-treatment, at each subsequent visit, and 3 months after the last treatment.

The protocol called for three treatment sessions, each 2 weeks apart, and then a follow-up session 3 months after the last treatment. All photographs had the hair counts for each region scored by a blinded observer.

The Silk’n device specifications

The device is a small, portable, low-cost, low-energy HPL™ (Home Pulsed Light™) system (Figure 1) with the following specifications:

- Wavelengths: 475–1200 nm
- Max energy density: 5 J/cm²
- Spot size: 20×30 mm²
- Pulse rate: 1 pulse every 3.5 seconds.

The Silk’n hair removal device was then applied to the 50% treatment region. The energy level for all patients was set to level 1 at the first treatment and with each follow-up treatment was increased by one level as long as no side effects were noted. The skin of the treatment site was treated using approximately 20% overlap of the Silk’n applicator and without the use of topical gel. The patients did not use topical anesthetic cream during the study.

After the third session, patients were followed-up at 3 months and standardized, close-up photography was performed. All photographs were then submitted to a blinded dermatologist observer, experienced in laser hair removal treatments, who calculated the hair density for each of the two regions (treated and untreated) in each photograph. The observer was blinded to which zone in each photograph had been treated with the Silk’n device.
Results

The device was simple to operate and ergonomically efficient. The patients perceived some very slight discomfort on emission of the light, but none requested for treatment to be stopped nor asked for topical anesthetic cream.

Immediate response

The immediate cutaneous response from the Silk’n device was a mild peri-shaft erythema and a faint perifollicular edema that appears within 5–10 minutes. There was an immediate carbonization of the hair shaft and the aroma of thermal hair shaft coagulation.

Hair clearance success

Hair clearances were calculated as the ratio between the hair count at baseline taken before any treatment and the count taken at each follow-up visit.

The 2-week hair reduction after the first treatment was 74% for the treatment region and no significant reduction for the untreated area. The 2-week hair reduction after the second treatment was 84% for the treated zone and no significant reduction for the untreated area. In all, 95% of study participants experienced hair clearance 3 months after the third treatment. The average percent clearance and hair reduction 3 months after the third Silk’n hair treatment was 64%.

Figure 2 shows typical Silk’n hair removal results achieved in an axilla.

Complications

There were no long-term complications in the study. Some 25% of the study patients had pre-follicular erythema that resolved after 1 hour.

Discussion

The worldwide hair removal industry is estimated to be worth approximately US$ 8.6 billion. The vast majority of hair removal is performed with razors and depilatories with no long-term clearance achieved. Electrolysis had formerly been the gold standard of long-term hair removal clearance until the arrival of medical grade high-fluence lasers and intense pulsed light systems. The worldwide in-office medical laser hair removal industry is perhaps now worth US$ 2.9 billion per year, is reasonably expensive and offers a good retail proposition of permanent reduction and long-term hair clearance for large, medium, and small hair zones.

The Silk’n system is the first low-cost, lightweight, portable and clinically effective pulsed light hair removal system developed. It has been proven to be clinically effective at achieving long-term hair clearance, it is easy to use, fast and safe, with no long-term complications observed.

Conclusions

We have demonstrated in a large, randomized, blinded study the clinical efficacy and safety of the Silk’n hair removal device. The Silk’n device was able to produce hair clearance results that rival those of the in-office, high-fluence, ‘big box’ devices.

The Silk’n device proved to be not only effective, but safe and relatively painless. The only post-treatment reaction that was observed on 25% of the patients was a mild erythema that self-resolved within 1 hour.

The efficacy, safety profile, comfort, portability, and ease of use of the device confirms the clinical and commercial reality that HPL hair removal will be eminent and may alter how hair removal is conducted.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

References
