

מחקרים קליניים בתחום הסרת שיער - מכשיר Silk'n SensEpil

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אודות הרופא שערך את המחקר

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ד"ר מולהולנד למד בבית הספר לרפואה של אוניברסיטת טורונטו, התמחה בבית החולים סנט מייקל, שהה באוניברסיטת טורונטו והוא חבר בבית החולים סאניברוק. ד"ר מולהולנד ייסד את מרפאת SpaMedica (טורונטו) בשנת 1997, שם הוא עדיין מטפל באופן פעיל בחולים.

Silk'n™ - A Novel Device Using Home Pulsed Light™ for the Removal of Facial Hair at Home

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ABSTRACT

A small, lightweight, low energy IPL system designed for home use (Silk'n SensEpil™ from Home Skinovations, Yokneam, Israel) was tested for the removal of unwanted facial hair. Efficacy and safety were monitored on 42 test subjects. Informed consent forms and training was provided to each patient, which permitted them to perform a series of self-treatments on their face, below the cheek line. Most of the treated areas were the chin or upper lip. All study volunteers used the device at clinics supervised by an experienced laser hair removal nurse. The pre and post treatment hair counts were performed and the reduction counts analyzed by a blinded observer.

Introduction

Electro-optical removal and photo-epilation of unwanted hair using lasers or pulsed light devices, has grown to become the number one medical aesthetic procedure. All photo-epilation devices work through the same principle: selective absorption of light by the melanin chromophore in the hair shaft, causing heat injury to the follicle. This selective thermal process was introduced by Rox R. Anderson in 1983⁽¹⁾.

In order to safely and effectively heat the hair shaft and damage the surrounding cellular structure at the root sheath, three

conditions of selective photothermolysis needs to occur:

(i) ***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 uses broad spectral range.

(ii) ***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.

(iii) ***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.

Various laser devices demonstrated the ability 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 infrared hair removal lasers, from 694nm to 1064 nm can accomplish permanent reduction and hair clearance, prolongation of the anagen-telogen cycles, diminishing 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 on the wavelength of light and skin type of the patient. Treatment protocols involve 6-12 treatments over many months and the cost can vary between \$75 for treatment of a small zone upwards to \$1,500 for treatment for large zones. Across the spectrum of all companies, devices, wavelengths and fluences the permanent reduction data (percent of hair showing no significant re-growth 12 months after the last treatment) ranges between 50-75% reduction after a series of 6 to 8 treatments.

In the past 2 years Home Pulsed Light (HPL) based device, sold in Silk'n or Silk'n SensEpil units, demonstrate significant efficacy and a high degree of safety, offering users similar results as in-office procedures.

Study Objective

The objective of this study was to assess the clinical efficacy and safety of Silk'n SensEpil users using the device to treat facial hairs.

Materials and Methods

42 patients were selected for an efficacy study, 38 of patients were female, and 4 were male. The average age of the group was 30.3 years old. Treatment sites were split between the women who treated the upper lip and chin area, while the men were treated in the neck area. Each treatment site was randomly divided into 50% of the area that would be treated and the remaining 50% that would act as an untreated control.

Informed consent was obtained by all study participants. In addition, photography further documented the body sites that underwent the hair removal. Standardized close up pictures were taken pre treatment, at each subsequent visit and 6 months after the last treatment.

The protocol called for a total of 8 sessions. The first three sessions occurred every two weeks and subsequent session occurred when hair growth would appear. All photographs had the hair counts for each region, scored by a blinded observer.

The Silk'n SensEpil Device Specifications

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

- Wavelengths: 475nm-1200nm
- Max energy density: 5 J/cm²
- Spot Size: 20 X 30 mm²
- Pulse Rate: 1 pulse every 3.5 seconds



Figure 1. Silk'n SensEpil Home Pulsed Light Hair Removal Device

Silk'n Treatment Technique and Protocol

The protocol involved 8 HPL treatment sessions, each two weeks apart. During each treatment session, standardized

photography of the zone was performed prior to shaving. Each zone was then again divided to the predetermined equal treatment and control regions and the hair shaved 1-2 days prior the treatment.

The SensEpil hair removal device was then applied to the treatment region. 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 or strong discomfort were noted. The skin of the treatment site was treated with approximately 20% overlap of the SensEpil applicator and without the use of topical gel or other solutions. The patients did not use topical anesthetic cream during the study.

After the 8th session patients were followed up for 6 months and standardized, close up photography was taken. All photographs were then submitted to a blind reviewer 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 did not know which zone in each photograph had been treated with the SensEpil device.

Results

Immediate Response

The immediate cutaneous response from the Silk'n SensEpil 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 Results

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

Average 6 months hair reduction after the last treatment was 54% for the treatment region and no significant changes for the untreated area.

95.2% of study subjects experienced hair reduction at the follow up session.

Figure 2 shows a typical SensEpil hair removal results achieved in the chin.



Figure 2. Chin hair clearance

Complications

There were no long-term complications in the study. Fifteen percent (15%) of the study patients had pre-follicular erythema that resolved after one hour.

Conclusions

The Silk'n SensEpil system is an affordable, lightweight, and portable device that shows clinically effectiveness on facial hairs. Results are proven for long term removal of facial hairs in the upper lip and chin.

This large, randomize, blinded study demonstrates the clinical efficacy and safety of the Silk'n SensEpil Hair Removal Device for facial hair. The device was able to produce hair clearance results that rival those of the in-office, high fluence, "big box" devices.

The Silk'n SensEpil device proved to be not only effective, but safe and relatively painless. The only post-treatment reaction that was observed on 15% of the patients was a mild erythema that resolved with in one hour.

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

References

1. Anderson R. R., Parrish J.A. Selective photohermolysis: Precise microsurgery by selective absorption of pulseRadiation, *Science* 220:524, 1983
2. Grossman M.C., Dierickx C, Farinelli W, Flotte T, Anderson R. Damage to hair follicles by normal mode ruby laser pulses. *J Am Acad Dermatology* 1996, 35:889-894.
3. Lou, W.W, Quintana, R.G., Geroneumus, M.C., Grossman M.C. Prospective study of hair reduction by diode laser (800nm) with long term follow up. *Derm Surgery* 2000, 26:428-432.
4. Goldberg, D.J., Marmur E.S. and Hussain, M. reatment of terminal and vellus non-pigmented hairs with an optical/bipolar radiofrequency energy source - with and without pre-treatment using