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מחקרים קליניים בתחום הסרת שיער - מכשירי Silk'n Flash&GO עם טכנולוגיית IPL

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אודות הרופאות שערכו את המחקר

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מנהלת מייסדת של המכון לניתוחי לייזר דרמטולוגיים בוושינגטון ופרופסור קליני לרפואת עור במרכז הרפואי של אוניברסיטת ג'ורג'טאון בוושינגטון הבירה. ד"ר אלסטר קיבלה את תארי ה-B.S. וה-M.D בהצטיינות הגבוהה ביותר מאוניברסיטת דיוק וסיימה את השתלמות הדרמטולוגיה באוניברסיטת ייל.

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רופאת עור מוסמכת להנהלה, פרופסור קליני לרפואת עור בבית הספר לרפואה באוניברסיטת ג'ורג' וושינגטון ומנהלת מייסדת של Capital Laser & Skin Care, וושינגטון די.סי.

ד"ר טנזי קיבלה את תארי ה-B.S. וה-M.D שלה בהצטיינות מאוניברסיטת אפסטייט ניו יורק לרפואה, וסיימה את השתלמות הדרמטולוגיה בבית החולים סנט לוקס רוזוולט.

Effect of a Novel Low-Energy Pulsed-Light Device for Home-Use Hair Removal

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BACKGROUND Removal of unwanted hair is the most popular skin treatment worldwide. Over the past decade, various lasers and light sources for epilation have been advocated for use in an office setting, although most people continue to treat unwanted hair with a variety of temporary physical methods (e.g., waxing, shaving) in a home setting, presumably due to cost and convenience factors.

OBJECTIVES To evaluate the safety and efficacy of a low-energy pulsed-light device intended for home-use hair removal.

MATERIALS AND METHODS Twenty women (skin phototypes I-IV) with dark terminal hair in nonfacial sites (axilla, forearms, inguinal region, legs) self-administered three treatments at 2-week intervals using a handheld intense-pulsed-light device. Matched untreated skin sites were also studied. Hair counts and clinical photographs were obtained pretreatment and at 1, 3, and 6 months after the third treatment. Side effects and patient satisfaction scores were recorded.

RESULTS All patients showed a positive clinical response to treatment, with reduction of unwanted hair. No reduction of hair was noted in untreated matched areas. Hair counts were reduced 37.8% to 53.6% 6 months after the three treatments. Skin region influenced clinical response, with lower legs exhibiting greater hair reduction than arms and inguinal and axillary areas. Mild erythema was experienced in 25% of patients, but no other side effects or complications were encountered. Patient satisfaction scores were high, with all patients stating that they would purchase the device for future home use.

CONCLUSIONS Low-energy pulsed light can be applied safely and effectively for at-home hair removal in a variety of nonfacial locations and skin phototypes I-IV.

The device was loaned by Home Skinovations. Dr. Alster purchased stock options after completion of the study.

Removal of unwanted hair is big business, exceeding $9 billion annually worldwide.[1] The vast majority of this market involves temporary at-home hair removal treatments, including waxing, depilatories, and shaving.[2,3] Since the introduction and widespread acceptance of a variety of laser and light-based hair removal devices that can effect more long-standing hair reduction over the past decade, more people have been pursuing these latter, longer-lasting treatment modalities.[4] The laser and light-based treatments are all based on the theory of selective photothermolysis,[5] in which heat is generated using selective absorption of predominantly red or infrared light within the targeted hair bulge.[6] The localized thermal damage (which includes pleuripotential follicular stem cells) eventuates in follicular unit destruction and reduced hair growth.

Despite the prevalence of unwanted hair and the availability of numerous successful treatments, the majority of the population, because of economic or convenience factors, do not pursue professional laser or light-based treatment. Given the high demand, the need for a safe, convenient, effective, and inexpensive means to produce long-standing hair removal is obvious. This study was designed to determine whether patients could safely and effectively apply a novel handheld intense-pulsed-light device intended for home-use to reduce unwanted hair.

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 • Published by Wiley Periodicals, Inc. • ISSN: 1076-0512 • Dermatol Surg 2009;35:483–489 • DOI: 10.1111/j.1524-4725.2009.01089.x

Materials & Methods

Twenty women meeting the eligibility criteria were enrolled in this institutional review board–approved study (Table 1). Only nonfacial areas (e.g., legs, arms, axilla, inguinal) and dark terminal hair (brown or black) were included for study. A variety of skin phototypes (I-IV) were included, but enrollment and treatment were denied if a suntan was evident. Subjects were excluded from study entry if infections, scarring, or malignant or premalignant pigmented lesions were present in the skin areas to be treated. Other exclusion criteria were known photosensitivities; anticoagulative or oral retinoid therapy; and use of waxing, electrolysis, or other methods of photoepilation within 3 months of study entry.

After informed consent was obtained, baseline photographs of each treatment area and matched (untreated) skin sites were taken using identical patient positioning, lighting, and camera settings. The average of three independent manual hair counts within templates measuring 2 or 3 cm^2 was recorded from each treatment and control (untreated) area. Identical template position was determined at subsequent treatment sessions using digital photography. Hairs longer than 2 mm were shaved with a safety razor immediately before each patient's self-application of the study device.

The portable, handheld device (Silk'n, Home Skinovations, Kfar Saba, Israel) involves the delivery of intense pulsed light at 475 to 1,200 nm, with a maximum energy of 5 J (range 3–5 J/cm^2, pulse duration <1 ms) through a 2- $\times$ 3-cm treatment tip. The finger-activated safety sensor tip can only be fired when the handpiece is in complete contact with the skin. (Figures 1 and 2) A safety mechanism prevents its firing when uniform pressure is lacking over the entire 2- $\times$ 3-cm treatment tip (thereby eliminating accidental discharge). No cooling mechanism is necessary. Because the light is self-contained within the device, no protective eyewear is necessary. Written instructions regarding proper device application were provided to the patients immediately before treatment. Study participants were instructed to initiate treatment at a low energy setting (3.0–3.5 J) and progressively increase to the highest setting tolerated at each visit (4.0–5.0 J). A nurse assessor was present during the self-application of the device by each patient at each of the three sessions to record side effects or other difficulties related to treatment.

TABLE 1. Study Patient Characteristics

Location	*Patients, n*	*Age, mean (range)*	*Skin Phototype*
Legs	5	44 (35–41)	II–IV
Arms	3	43 (35–55)	II–IV
Axilla	7	45.3 (32–56)	II–III
Inguinal	5	35.4 (32–55)	II–III

Figure 1. Silk'n handheld device with finger-activated safety tip.

No particular post-treatment skin care was prescribed except for application of a broad-spectrum sunblock (on arms and legs) and avoidance of sun exposure to the treatment areas. Patients returned at 2-week intervals for retreatment and clinical photographs. Follow-up clinical photographs and manual

Figure 2. Silk'n device can only be fired upon complete contact of device tip with skin.

hair counts were obtained 1, 3, and 6 months after the series of three treatments.

Results

All patients experienced clinical hair reduction in the treatment sites. (Figures 3A, B, and 4A, B) Two-sample Wilcoxon rank-sum (Mann-Whitney) tests revealed significantly greater hair loss in all treatment areas at each of the follow-up periods (1, 3, 6 months) than in the untreated control sites (Table 2). Hair reduction at 1 month was more pronounced on the legs (73.5%) than on the arms (59.0%) and axillary or inguinal areas (47.8% each). This continued to be evident at 3 months, with 61.0% hair reduction on the lower legs and 57.8%, 42.3%, and 40.4% reduction on the forearms and the axillary and inguinal regions, respectively. At 6 months, hair reduction was 53.6%, 49.0%, 38.2%, and 37.8% in the lower legs, forearms, inguinal, and axillary regions, respectively. No decrease in hair was noted within nontreated control skin sites.

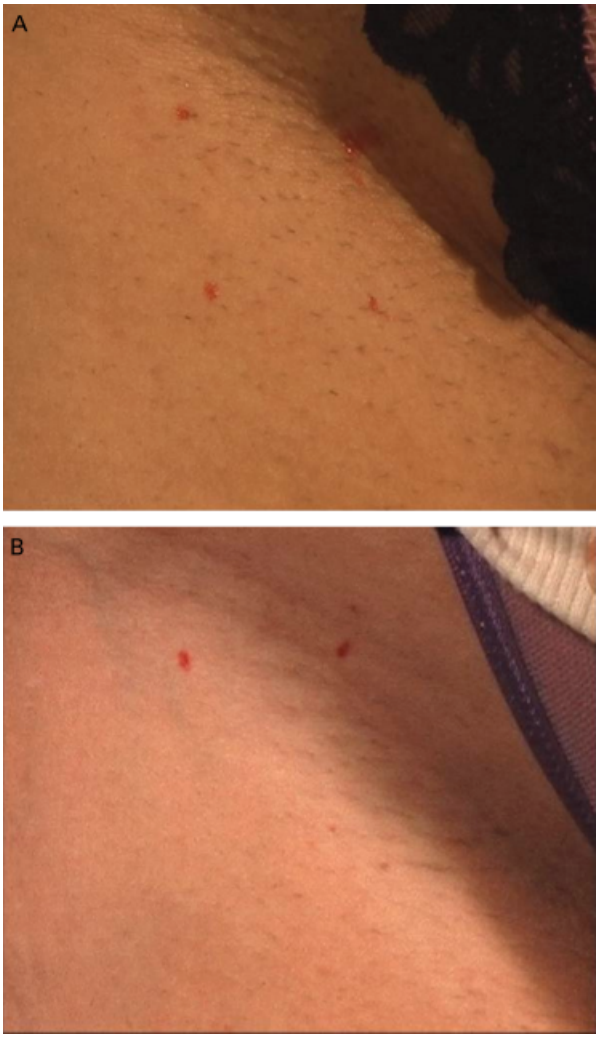

Figure 3. Inguinal hair at baseline (A) and 6 months after third treatment (B).

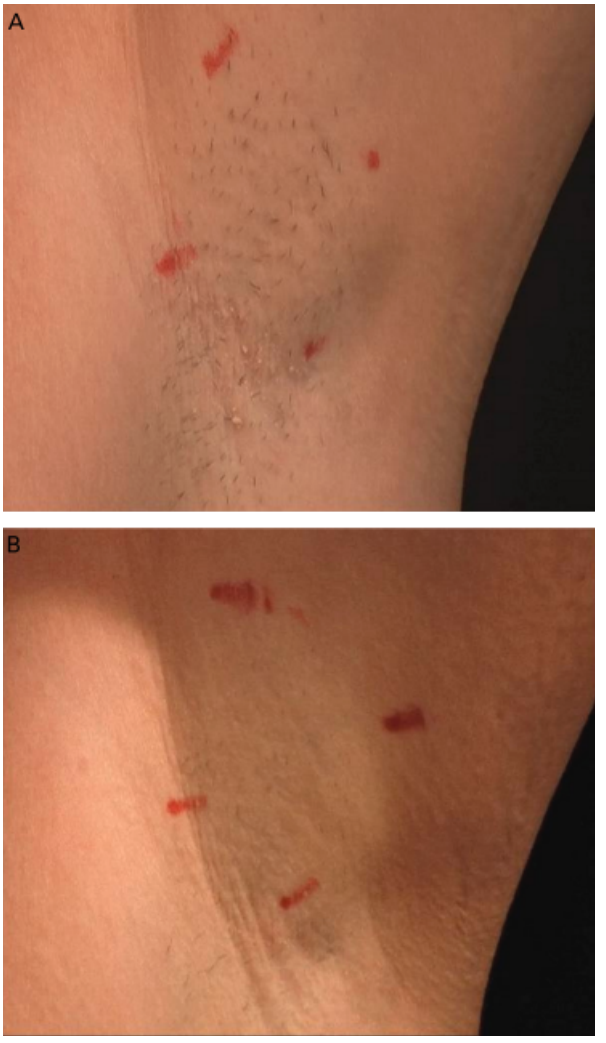

Figure 4. Axillary hair at baseline (A) and 6 months after third Silk'n treatment (B).

Mild transient erythema, follicular edema, and skin warmth at the skin sites were experienced immediately after treatment in 25% of patients and resolved spontaneously within minutes. No prolonged

TABLE 2. Average Hair Counts

Location	*Sites,* n	*Baseline Hair Count* *Mean ± SD (Range)*	*1-Month Hair Count*	*Hair Reduction (1 Month)* *%*	*3-Month Hair Count* *Mean ± SD (Range)*	*Hair Reduction (3 Months)* *%*	*6-Month Hair Count* *Mean ± SD (Range)*	*Hair Reduction (6 Months)* *%*	p-*Value*
Legs									<.001
Treated	10	58.2 ± 2.9 (53–63)	15.2 ± 3.4 (10–20)	73.5	23.2 ± 4.6 (16–32)	61.0	27.4 ± 4.5 (20–34)	53.5	
Control	10	58 ± 2.8 (54–64)	58.3 ± 3.8 (52–65)		58.4 ± 3.0 (53–63)		58.4 ± 2.7 (54–62)		
Arms									.004
Treated	6	53.8 ± 3.1 (50–59)	22.3 ± 3.1 (18–26)	59.0	23.5 ± 2.81 (20–28)	57.8	28.0 ± 3.0 (24–32)	48.1	
Control	6	54.5 ± 3.1 (52–60)	55.0 ± 3.0 (52–59)		55.2 ± 3.1 (53–61)		59.8 ± 3.1 (52–60)		
Axilla									<.001
Treated	14	77.9 ± 5.9 (67–86)	40.9 ± 5.6 (34–54)	47.8	45.2 ± 6.3 (35–58)	42.3	49.3 ± 6.4 (40–63)	37.2	
Control	14	78.5 ± 4.9 (70–85)	78.4 ± 6.5 (69–88)		78.3 ± 5.9 (70–87)		78.3 ± 5.2 (70–85)		
Inguinal									<.001
Treated	10	4.1 ± 5.6 (41–60)	25.8 ± 3.4 (21–31)	47.8	28.9 ± 4.5 (23–38)	40.4	31.3 ± 5.0 (23–41)	36.7	
Control	10	49.0 ± 5.2 (39–58)	49.4 ± 4.8 (41–57)		49.4 ± 5.2 (40–59)		49.3 ± 4.9 (41–58)		

erythema or edema was observed. No incidences of blistering, scabbing, scarring, skin dyspigmentation, or other untoward side effects or complications were encountered. Patients did not report any discomfort with the treatment at any energy setting used.

All patients were able to self-apply the handheld device without assistance. Average time for treatment ranged from 2 to 3 minutes for the axillary and inguinal areas and 15 to 20 minutes for the forearms and lower legs. As patients became more proficient at handling the device (e.g., using the finger tip to discharge the light pulse, placing the treatment tip footprint side by side on the skin), treatment times shortened. No complaints were registered, and patients were pleased overall with the clinical effects obtained. Upon end-study questioning, each patient reported that, if available, she would purchase the device for future treatment.

Discussion

The management of excess unwanted hair remains a challenge, despite the number of readily available over-the-counter, prescription, and in-office therapies. Comparative studies have shown that, regardless of whether a long-pulsed red or infrared laser (e.g., ruby, alexandrite, diode, neodymium-doped yttrium-aluminum-garnet) or intense pulsed light (yellow or red filter) is used, decreased hair reduction averaging 50% to 80% is typical after a series of two or three monthly treatments.[7,8] Although selective destruction of hair follicles using these lasers and light sources leads to significant, long-lasting epilation, the cost and inconvenience of office treatment remains a major obstacle for most people. The potential for at-home laser and light sources is obvious, but their safety and effectiveness in a home setting have only recently been studied.

Our study confirms that the at-home intense-pulsed-light device described herein can be applied safely and effectively to reduce unwanted hair. In fact, the clinical results obtained in our study are surprisingly close to the low end of the range typically reported after in-office laser and light sources applied at higher energies. Six months after three consecutive treatments, an average 43% hair reduction was observed across all body regions. These results appear to be long standing, with only a 10% to 20% increase in hair regrowth noted between 1 and 6 months post-treatment.

Other at-home devices have also shown hair reduction comparable with that achieved with in-office treatment. Patients used a battery-powered handheld portable diode laser (810 nm Tria, SpectraGenics Inc., Pleasanton, CA) to treat unwanted hair in a study reported by Wheeland.[9] The laser was effective at reducing hair regrowth (average 41% reduction at 6-month follow-up) with minimal side effects after three treatments delivered at 3-week time intervals. Similar to the device reported in our study, patients were able to apply the device without difficulty after reviewing written and video instructions. Treatment energies were patient-selected based on low, medium, and high settings (with the highest tolerable setting preferred for improved clinical results). Typical treatment time for an average axilla was 10 to 20 minutes (as opposed to 2 to 3 minutes with the study device reported herein). It is most likely that the longer treatment time of the diode laser system is a consequence of the small spot size (1 cm) of the treatment tip, compared with the 6-cm^2 tip area of the device used in our study.

Another handheld self-treatment hair removal device (no!no! Thermicon, Radiancy Inc., Orangeburg, NY) consisting of a replaceable thermal filament has been reported to reduce lower leg and inguinal hair by 43.5% and 15.0%, respectively, 3 months after 12 twice-weekly treatments.[10] Because the hair follicle is heated using simple thermal conduction down the hair shaft, the device should presumably work for a variety of different hair and skin colors. This latter presumption needs clinical confirmation, but the report is of interest insofar as another viable home hair-removal device has hit the mass market and appears to be of some clinical benefit.

The at-home intense-pulsed-light device evaluated in our study has several potential advantages over the two aforementioned devices. First, its lightweight, compact design makes it user friendly. Its use of regular household current omits the need for replacement batteries. In addition, the large treatment tip leads to faster treatment sessions, taking in most cases no longer than the time it takes to shave. A single replaceable treatment tip can be used to treat a large area (upper and lower legs) or can be applied for several treatments to a smaller region (inguinal or axillary).

The design of this study was limited to treatment of individuals with light to medium skin phototypes. The commercial device that will eventually be sold over the counter will incorporate a sensor that will detect the user's skin tone such that only appropriate fluences will be delivered. In the meantime, dispensing of these at-home consumer units will be made through physician prescription in an effort to familiarize physicians and the public with them.

There are disadvantages associated with the use of any laser or intense-pulsed-light device, even at low treatment fluences. Although higher treatment energies have been shown to cause superficial burns, vesiculation, crusting, scarring, and pigmentary alteration, low energies have produced a "paradoxical effect" on hair growth.[11–14] The increase in hair growth sometimes seen in close proximity to areas of skin that have received treatment (particularly in women with olive skin tones and facial hirsutism) has been conjectured to be the result of subtherapeutic indirect light that simulates (via radiant heat) the adjacent dormant hair follicles. Because the clinical effect of our study device was not tested on facial skin, the risk of this side effect was not determined, but its occurrence over the years in large numbers of patients remains low. Nonetheless, this risk should be disclosed to anyone attempting at-home laser or light treatment, particularly on the face, given the application of low fluences.

Conclusions

A novel low-energy pulsed-light device can be used safely and effectively to remove unwanted nonfacial black or brown hair in a variety of areas and on a variety of skin phototypes. Additional advantages include its portability, cost-effectiveness, speed, and ease of application and the privacy and convenience that home use provides.

The study reported herein represents the beginning of a major trend in laser dermatology. The fact that non-medically trained users can successfully apply smaller, inexpensive, safe, and clinically effective lasers and light sources will open the door for the development of additional at-home devices for a multitude of other clinical applications.

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