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מחקרים קליניים בתחום הסרת שיער - מכשיר Silk'n SensEpil

מחברים: Courtney M.L. Elm, BS, Irmina D. Wallander, BA
Susan E. Walgrave, MD, & Brian D. Zelickson, MD

אודות הרופאים שערכו את המחקר

Courtney M.L. Elm, BS

לא נמסרה ביוגרפיה.

Irmina D. Wallander, BA

כיום מנהלת את תכנית המחקר הקליני באוניברסיטת מינסוטה-ערים תאומות. אירמינה קיבלה את התואר הראשון בלימודי תרבות/תיאוריה ביקורתית וניתוח באוניברסיטת מינסוטה-ערים תאומות.

Susan E. Walgrave, MD

לא נמסרה ביוגרפיה.

Brian D. Zelickson, MD

ד"ר זליקסון עוסק כיום בהדרכת רופאים בתכנית למלגת דרמטולוגיה פרוצדוראלית באוניברסיטת מיניאפוליס. ד"ר זליקסון למד באוניברסיטת קולורדו, שם קיבל את התואר הראשון שלו בביולוגיה מולקולרית והתפתחותית, ואחריו תואר דוקטורט בבית הספר לרפואה של מאיו, השתלם בבית הספר לרפואה של מאיו, ותכנית עמיתים באוניברסיטת צפון קרוליינה.

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Clinical Report

Clinical Study to Determine the Safety and Efficacy of a Low-Energy, Pulsed Light Device for Home Use Hair Removal

Courtney M.L. Elm, BS,* Irmina D. Wallander, BA, Susan E. Walgrave, MD, and Brian D. Zelickson, MD
Zel Skin and Laser Specialists 4100 West 50th Street Edina, Minnesota 55424

Background and Objectives: The principle of selective photo-thermolysis has been studied extensively for hair removal applications in a medical setting. A new, portable, hand-held device featuring two filtered Xenon lamps that utilizes pulsed light in low optical fluencies for hair removal has been developed for consumer use. The purpose of this clinical study was to determine the efficacy and safety of this low-energy, pulsed-intense light device intended for home use hair removal.
Study Design/ Materials and Methods: The treatment group consisted of 10 adults with skin types I–IV who possessed unwanted dark hair in the non-facial region. The subjects received between 4 and 6 treatments on a bi-weekly basis with the device by a trained member of the clinical staff. The clinical responses were evaluated by performing manual hair counts using magnified vision and photographs which were obtained prior to treatment and at each subsequent visit.
Results: Mean hair reduction was 36% 4 weeks after the final treatment and 10% 12 weeks after the final treatment. This resulted in a mean hair count reduction of 23% over the two follow-up appointments. There was no definitive correlation between customer satisfaction and hair count reduction. Adverse reactions were limited to transient, localized, post-treatment erythema. No complications were encountered.
Conclusions: This low-energy, pulsed-light device is a quick, safe, and relatively effective at-home hair reduction treatment option in patients with various skin phototypes. Lasers Surg. Med. 42:287–291, 2010.

Key words: at home hair removal; laser hair removal; selective photo-thermolysis

BACKGROUND AND OBJECTIVES

New advances in laser technology have made hair removal more effective, faster, and safer than ever before. The principle of selective photothermolysis has been studied extensively for hair removal applications due to the widespread use of this technology. The light penetrates the epidermis to the dermis and is absorbed by the melanin in the hair shaft. The heat generated by the absorbed light is then dissipated to the follicle and generates local thermal damage, causing a reduction in hair growth [1]. This technology has been used extensively by many devices to generate hair loss using lasers or filtered xenon flash lamps. Most of these devices are used in physician offices in a clinical setting.

Other alternative methods to light and laser-based hair removal treatments include chemical depilators, shaving, or waxing. Depilation is removal of hair above the level of the skin, and includes shaving and chemical hair removal products. These are usually chemically based, often containing the active ingredient calcium thioglycolate, which breaks down the disulfide bonds in keratin. This weakens the hair so that it is easily scraped off where it emerges from the hair follicle in the epidermis. However, as the epidermis is also rich in keratin, the skin may become irritated and sensitive if the preparation is left on for too long. Chemical depilatories are used primarily for the arms and legs, and the effects often last a short time (re-growth of hair begins to appear generally within 2–5 days). Chemical depilatory creams are also generally malodorous and messy to use [2].

Epilation is removal of the entire hair, not just the portion above the dermis. Therefore these methods are often longer-lasting (several days to several weeks). The most common form of epilation is waxing, in which a hot or cold layer of wax is applied and then removed. While this method is effective, it is not permanent and is also very painful and can lead to skin infections [2].

A new hand-held and portable hair removal device has been developed for at-home use (Silk'n™; HomeSkinovations, Kfar, Saba, Israel.) This device uses the principal of selective photothermolysis to permanently remove unwanted hair from the legs, arms, bikini-line or axilla,

Zel Skin & Laser Specialist.
*Correspondence to: Courtney M.L. Elm, BS, 4100 W 50th ST, Edina, MN 55424. E-mail: courtney.elm@gmail.com
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excluding the face. The device uses pulsed light in low optical fluences of up to 5 J/cm^2 and a light spectrum set by the optical filter to 475–1,200 nm, which is highly absorbed by the hair shaft melanin. The use of low optical energy is expected to be safe even on darker skin types, and the ability to control the energy output will allow the user safe and effective treatment. This clinical study investigated the efficacy and safety of this low-energy, pulsed-intense light device intended for home use hair removal.

MATERIALS AND METHODS

The study protocol was approved by the Essex Institutional Review Board (Lebanon, NJ), and informed consent was obtained prior to subject participation. The study inclusion criteria required subjects to have unwanted hair on the body (legs, arms, bikini line, or axilla), to be between 21 and 60 years of age, and to have Fitzpatrick skin types of I–IV. Females were required to be post-menopausal, surgically sterilized, or to use a medically acceptable form of birth control (i.e., oral contraceptives, IUD, contraceptive implant, or barrier methods with spermicide or abstinence) during the study time period. Subjects were excluded if they had malignant lesions, pre-malignant lesions, scarring, or infection in the area to be treated; known photosensitivity, pregnancy, diabetes mellitus, suntan in the area to be treated, use of medication that induces photosensitivity, anticoagulative medication, a thromboemboilic condition, pacemaker or internal defibrillator, use of NSAIDS two weeks prior to or 2 weeks following the treatment, or subjects that use waxing or other methods of photoepilation within 3 months prior to treatment.

Ten subjects were recruited to participate in this study. Prior to treatment, clinical staff obtained informed consent from the qualified subjects, and discussed risks and benefits of participation in the study.

Prior to treatment the patient's initial hair count was recorded on a detailed subject chart. Treatments were performed in the clinic by one of the investigators (S.W.) or by a trained nurse. The treatment parameters were adjusted according to the patient's skin type (see Table 1). A treatment test pulse was performed on the darker part of the area to be treated, and if no significant erythema, blistering, blanching, or edema was noted after 15 minutes, another pulse was performed at an energy level one setting higher than the first pulse. Again, if no reaction was noted, the treatment was performed. If however, side-effects were noted on the test spot after 15 minutes, the energy level was reduced by one setting and another test spot performed. Treatment ensued once a level of energy was found to be suitable for treatment without causing side-effects.

TABLE 1. Skin Types for Treatment and Corresponding Test-Pulse Energy Levels

Skin type	Energy level for test pulse
I–II	3
III	2
IV	1

Prior to treatment, hairs in the area were trimmed to 3/32 inch length (1–2 mm) and the skin was washed with a mild cleanser. The light output window on the device was also cleansed. The energy level was selected and the applicator placed on the area with slight pressure, creating good contact with the skin. The device does not require special eye protection, and the treatment is initiated only when the treatment applicator tip is firmly placed on the skin. Some flashing light is seen around the sides of the treatment area, but it is not harmful to the eyes.

The pulsed treatment was then initiated, with the treatment parameters varied in the range of energy level from 2 to 5, dependent on skin type. The maximum treatment energy level of 5 corresponds to 5 J/cm^2. The full area was treated with the device with an overlap of approximately 15%. One to two passes were completed.

Treatments were preformed on a bi-weekly basis in the clinic for 4–6 treatments, and two follow-up visits were attended by all subjects at 4 and 12 weeks after the final treatment session. At each treatment session and at each follow-up hair were performed and the subjects were assessed for side-effects.

Post-treatment instructions were provided to subjects. These instructions allowed the patients to shave the treated area if needed but instructed them not to use any other hair removal method, including plucking, waxing, epilation, or chemical treatments.

Photographs were taken of the treatment areas utilizing the D80 Nikon (Nikon Inc. Melville, NY) camera with standard positioning techniques. These were obtained at baseline, 4 week and 12 week follow-up visits.

Statistical Analysis

Statistical analysis was performed using the Analysis ToolPak statistical package for Microsoft Office Excel 2007 (Microsoft Inc., Redmond, WA). For statistical testing, a one-sided paired t-test and nonparametric Sign test for median were used and P-values <0.05 were considered statistically significant. A confidence interval of 95% was selected for all data. The null hypothesis was that the Silk'n device provided equal to or less than a 10% reduction in the number of hairs in the area treated. Hair counts were taken from the first screening treatment as a baseline for comparison. Subsequent hair counts were then taken at each of the two follow-up treatments. These hair counts were tabulated and also evaluated as ratios of the number of hairs seen at baseline to the number of hairs seen at follow-up. These ratios were then represented as percentages. Additionally, the average percent improvements at both 4 and 12 weeks were tabulated.

RESULTS

Ten subjects, mean age of 39 (range age 25–49), and skin types II–IV, participated in the study. One subject was lost to follow-up at 12 weeks. Of the 10 subjects in the study, 6 had type II skin, 3 had skin type III skin, and 1 had type IV skin. Seven subjects chose to have the axilla area treated, 1 chose the bikini area, 1 chose the forearm, and 1 chose the leg below the knee as the area for treatment with the device.

TABLE 2. Summary of Patients Who Participated in the Study

Patient no.	Skin type	No. of treatments	Area of treatment
201	2	6	R axilla
202	3	4	R leg below knee
203	3	4	R axilla
204	2	6	R forearm
205	2	5	R axilla
206	3	4	R bikini
207	2	4	L axilla
208	4	6	L axilla
209	2	6	R Axilla
210	2	4	L axilla

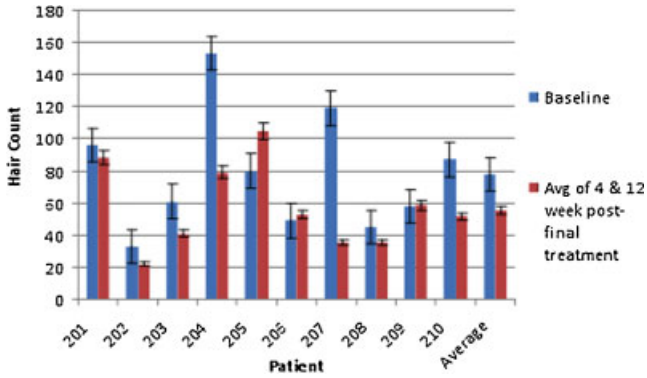

Fig. 2. Hair counts averaged over the 2 follow-up treatments compared with baseline values.

The number of treatments, the subjects received varied between 4 and 6 treatments, with 5 subjects receiving 4 treatments, 1 subject receiving 5 treatments, and 4 subjects receiving 6 treatments. All subjects were evaluated again at the 4 and 12 weeks marks post-treatment for follow-up. A summary of the patient data can be seen in Table 2.

Treatment parameters with the device were dependent on the subject's skin type, as seen in Table 2. With the darker skin type (IV), a less intense treatment was utilized until the safety of the device was assured. Therefore, the patient with skin type IV was begun at treatment level 2, while skin types II and III were begun at level 3. All patients eventually were treated at the highest energy level of 5.

Mild, transient erythema was the only side-effect noted and was observed in all subjects (100%) immediately post-treatment. However, there was erythema present after every treatment in only 7 subjects (70%). In two subjects, erythema only appeared after they were treated with the highest energy setting (5 J/cm^2). Erythema resolved completely in all subjects (100%) by the 4-week follow-up after the last treatment. Edema was not noted as side-effect of this device.

Figure 1 shows the baseline hair counts in the areas of treatment, as well as the follow-up 1 (4 weeks post-treatment) and follow-up 2 (12 weeks post-treatment) hair counts. The average hair count including all participants at baseline was 78 ± 6 hairs. The average hair counts 4 and 12 weeks after the final treatment were 48 ± 3 and 63 ± 4 hairs, respectively. This resulted in a statistically significant $36 \pm 2\%$ reduction in the number of hairs on average at the 4-week follow-up (P-value $= 0.02$). However, with only a $10 \pm 1\%$ reduction in the number of hairs at the 12-week follow-up, the 12 week benchmark did not yield a statistically significant result (P-value $= 0.14$).

The average hair count improvement over the two follow-up appointments was tabulated in Figure 2. The overall average reduction in the number of hairs in the area treated was 56 ± 3 hairs. This corresponds to a statically significant ($P = 0.04$) result in the area of hair count reduction.

Figure 3 shows the average percentage improvement seen over the two follow-up appointments. Overall, a statistically significant average improvement ($P<0.05$) was seen, with an average percentage improvement overall of $23 \pm 1\%$ (Fig. 3). There were outliers such as patient 205 who had a negative overall improvement with use of the device of $31 \pm 1\%$.

Subject photographs shown in Figures 4 and 5 depict the most successful examples of the Silk'n device hair removal,

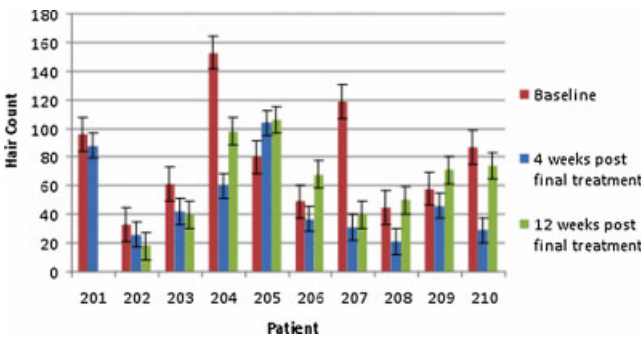

Fig. 1. Baseline and follow-up hair counts at both 4 weeks and 12 weeks post-final treatment.

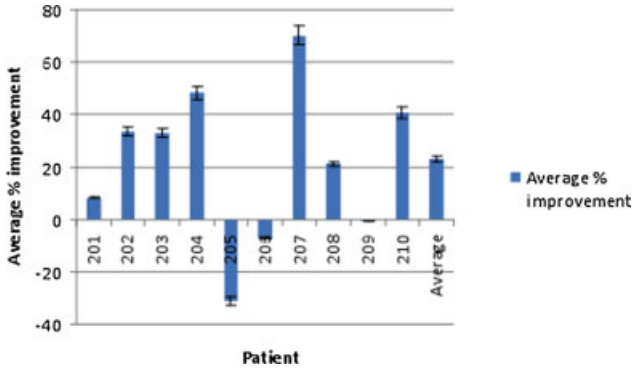

Fig. 3. Average of the 2 follow-up appointments hair count represented as percentage improvements from baseline.

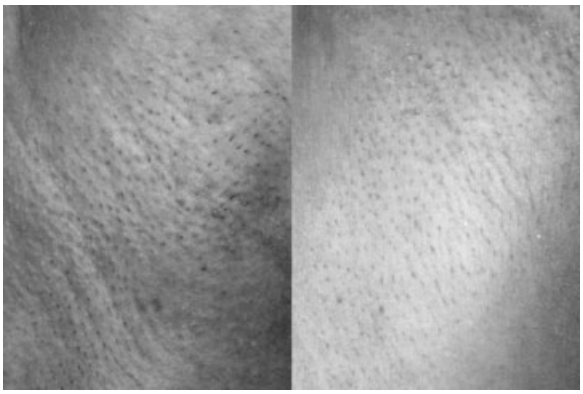

Fig. 4. Baseline (left) and 4-week follow-up (right) axilla photos.

with an average improvement of $70 \pm 1\%$ over the 4 and 12-week follow-up visits. At 4 weeks, the percentage improvement in hair count reduction was $74 \pm 1\%$, and at 12 weeks was $66 \pm 1\%$.

Subject Self-Assessment

Many of the subjects had beneficial results from the device other than reduction in the number of hairs in the region treated. Three subjects commented that treated hairs were lighter, finer, and much less visible when compared to baseline and/or the other untreated side of the body, especially near the end of the scheduled treatments and at the 4-week follow-up visit. One subject noted a 50% reduction in hairs after treatment 3. However, one subject did note that although the reduction in the number and visibility of the hairs was noticeable at the 4-week follow-up, by the 12-week follow-up visit many of the hairs seemed to return to baseline (see page 6 Figure 1).

Subject Satisfaction

Subjects in the study were given a chance to obtain the Silk'n device at the end of the study free of charge or receive \$25 for each visit and an additional \$50 when they completed the study. Four of the 10 participants choose to receive a free device over the monatary compensation for the study. A table of all the participants and their average hair count percentage improvement is shown in Table 4.

When the average percent improvements between those who chose to receive the Silk'n device and those who chose to take the compensation are evaluated, it can be shown that those who decided to receive a free device had a $3.9 \pm 0.3\%$ larger reduction in hair counts. This does not show a definitive correlation between customer satisfaction (measured in who requested to have the device instead of compensation) and hair counts. These results are shown in Table 5.

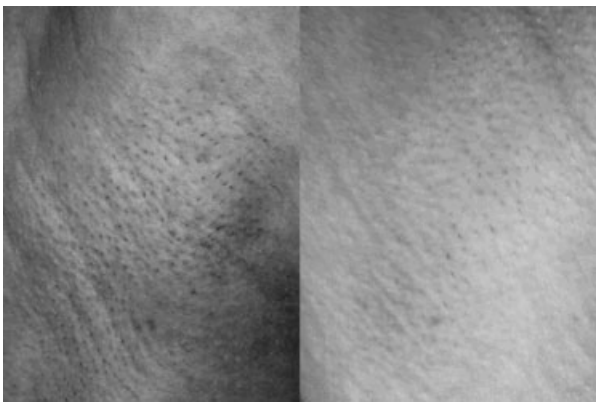

Fig. 5. Baseline (left) and 12-week follow-up (right) axilla photos.

DISCUSSION

This clinical study examined the efficacy and safety of a low-energy, pulsed-intense light device intended for home use hair removal. This device was FDA cleared in 2008 for the permanent removal unwanted hair from the legs, arms, bikini line, or axilla, excluding the face.

Indeed, this device appears to be safe at the treatment parameters utilized in this study. All subjects noted some transient erythema immediately post-treatment. The erythema resolved completely in all subjects by the 4-week follow-up visit after the last treatment. There were no cases of edema, hyperpigmentation, infection, hypopigmentation, or scarring.

The overall reduction in the number of hairs in the area treated was significant ($P<0.05$), with an average reduction in the number of hairs of a 56 ± 3. This leads to an overall average percentage hair reduction of $23 \pm 1\%$. Additionally, subjects had beneficial results from the device other than reduction in the number of hairs. Three subjects commented that treated hairs were lighter, finer, and much less visible when compared to baseline. One subject noted a 50% reduction in visible hair after 3 treatments.

Treatment with the device resulted in a statistically significant $36 \pm 2\%$ reduction in hair on average between all 10 subjects at the 4-week follow-up visit. However, hair reduction at the 12-week follow-up was on average $10 \pm 1\%$ taking into account all subjects. With a minimum hair count reduction of 10% required for clinical efficacy, this result does not indicate a statistically significant reduction in hair at 12 weeks post-treatment.

The follow-up hair count results revealed a trend of improvement at the 4-week follow-up visit and relapse at the 12-week follow-up visit. Additional treatments using the device may be advised to occur before 12 weeks after their last treatment.

Subjects in the study were given a chance to purchase the Silk'n device at the end of the study free of charge or receive monatary renumeration when they completed the study. Forty percent of the study particpants choose to receive a free device over the monatary compensation at the conclusion of the study. There was no definitive correlation between customer satisfication (measured by purchase of the device) and hair count reduction. Those who purchased the device had on average a $3.9 \pm 0.3\%$ greater reduction in

TABLE 3. Skin Type and Device Treatment Level

		Device setting					
Skin type	Area treated	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6
II	R axilla	3	4	5	5	5	5
III	R leg	3	4	5	5	N/A	N/A
III	R axilla	3	4	5	5	N/A	N/A
II	R forearm	3	4	5	5	5	5
II	R axilla	3	4	5	5	5	N/A
III	R bikini	3	4	5	5	N/A	N/A
II	L axilla	3	4	5	5	N/A	N/A
IV	L axilla	2	3	4	5	5	N/A
II	R Axilla	3	4	5	5	5	5
II	L axilla	3	4	5	5	N/A	N/A

hair, however, those who bought the device had a range between $8 \pm 1\%$ and $33 \pm 1\%$ improvement. Several subjects had a greater reduction in hair (up to $70 \pm 1\%$ improvement), but did not choose to purchase the device. This suggests other factors (likely financial) were of greater motivation in the choice of remuneration.

Better results have been seen in previous clinical trials using comparable treatment parameters [3–5]. Alster and Tanzi reported all 20 women in their study showed a positive clinical response to treatment, with reduction of unwanted hair. Hair counts were reduced 37.8–53.6% 6 months after the 3 treatments. In this study treatment region influenced clinical response, with lower legs exhibiting greater hair reduction than arms and inguinal and axillary areas. Emerson and Town revealed that after individuals were given three sequential weekly treatments on a total of 31 body and facial areas including: the axilla, bikini area, abdomen, neck, chin, and upper lip, that the mean reduction in terminal hair counts was 47% at 4-week follow-up and 41% at 6-month follow-up. In this study, overall, 84% of participants showed a significant percentage of hair reduction at the 6-month follow-up, with a mean of 51% (range 25–86).

A new model of the device has been released that utilizes identical technologies and produces the same hair removal efficiency and efficacy. The area treated is identical ($2\,\text{cm} \times 3\,\text{cm}$) and the effective level of energy, up to $5\,\text{J/cm}^2$, is the same. However, this new model, the *SensEpil*, has a sensor built into the lamp so it will not flash on skin types V and VI. This was initiated to provide increased safety for dark skinned individuals. Clinical trials with this device are currently underway.

TABLE 4. Participant Data on Compensation for Completing the Study and Hair Reduction Improvement

Patient no.	Choose a free device?	Avg. % improvement ($\pm 1\%$)
201	Yes	8
202	Yes	33
203	Yes	33
204	No	48
205	No	−31
206	No	−7
207	No	70
208	Yes	21
209	No	−1
210	No	40

TABLE 5. Comparison in Overall Hair Count Reduction Between the Two Compensation Groups

Chose device over compensation, average % improvement ($\pm$ 0.3%)	23.9
Chose compensation over device, average % improvement ($\pm$ 0.3%)	20.0

CONCLUSIONS

The Silk'n low-energy, pulsed-light device was demonstrated to be safe for various skin phototypes in a variety of nonfacial locations with minimal downtime and unwanted side-effects. Subjects were satisfied with their clinical improvement with respect to hair count reduction. This small study shows that continued maintenance treatment may be needed for durable clinical results.

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