Low-Energy Intense Pulsed Light for Hair Removal at Home

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ABSTRACT

Low-energy intense pulsed light for hair removal at home was evaluated in this clinical trial. Twenty-two female patients were enrolled into an institutional review board-approved clinical trial. Patients received six biweekly treatments with the device, and clinical results with hair counts and pictures were performed at four weeks and three months following the last treatment. Ninety-five percent of the patients noted hair count reduction at the end of this clinical trial. Overall hair reduction was 78 percent at the one-month follow up and 72 percent at the three-month follow up. No serious adverse events were noted. This clinical trial confirmed the safety and efficacy of this device for hair removal at home. (*J Clin Aesthetic Dermatol.* 2010;3(2):48–53.)

Whether you agree with the notion of using at-home devices for epilation or not, there can be no mistake that there are a myriad of these devices available. If these devices are to receive any merit, then it is the dermatologist's obligation to assess the safety and efficacy of them, as with any device in the research setting.

The use of intense pulsed light (IPL) for hair removal dates back well over 15 years. The first IPL dedicated solely for hair removal was appropriately researched and the findings published on its safety and efficacy following a single treatment, as well as long-term safety and efficacy with one- and two-year results.[1–3] These studies proved that an IPL is a legitimate and useful light source for effective hair removal. Clinical results of the IPL for hair removal on darker skin types were also published, showing that with appropriate cut-off filters, the IPL can be used successfully in all skin types.[4] Other investigators verified these results.[5–7]

As the industry, including established laser companies, began to develop at-home devices for epilation, market research provided a financial projection of billions of dollars annually. Over the years, there have been numerous reports on the safety and efficacy of IPLs for hair removal, which pointed to the IPL as a suitable application to develop for home hair removal.

With this in mind, a clinical trial was designed with the primary objective to assess safety and efficacy of a low-energy IPL specifically designed for home use. The secondary objective of this institutional review board (IRB)-approved clinical trial was to verify previously reported clinical trials of the same device.[8,9]

MATERIALS AND METHODS

Twenty-two female patients were enrolled in this clinical trial, with 20 completing the trial. The patients varied in age from 23 to 60 years of age. All of the study participants reviewed and signed an IRB-approved informed consent form (ICF) prior to the beginning of the trial. All of the participants had to meet predetermined inclusion and exclusion criteria for admittance into the trial. Inclusion criteria included having unwanted hairs on the body (legs, arms, bikini area, or axilla); having Fitzpatrick skin types I–IV; avoiding pregnancy during the study (postmenopausal, surgically sterile, or using a medically acceptable form of birth control, which included oral contraceptives, intrauterine devices, contraceptive implant, barrier methods with spermicide, or abstinence); and having the willingness to follow the treatment care and post-treatment schedule.

Exclusion criteria included having premalignant or malignant pigmented lesions in the treatment areas, a

DISCLOSURE: Dr. Gold has performed research for and speaks on behalf of Home Skinovations. Ms. Foster and Ms. Biron report no relevant conflicts of interest.

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previous history of scarring or previous skin infection in the area to be treated, known photosensitivity to light, pregnancy, a history of either Type I or II diabetes mellitus, sunburn or recent exposure in the area to be treated, taking medication known to induce photosensitivity, taking anticoagulation medications or having a history of thrombolembolic conditions, having a pacemaker or internal defibrillator, and taking NSAIDs two weeks before and two weeks after the treatment. Also, patients were excluded if they waxed or used any other forms of photoepilation in the treatment areas for the three months prior to the treatment session.

During discussions and visits with the subjects, the clinicians continuously reiterated that this device is not recommended for use on the face. Any use on the face was strictly prohibited during the clinical trial period.

All possible risks and potential adverse events that have been recorded from the use of IPLs and other laser systems for hair removal were discussed in length during the consent process. Some of the potential adverse events included pain, skin redness (erythema), swelling (edema), damage to natural skin texture (crust, blister, or burn), changes of pigmentation (hyper- and hypopigmentation), scarring, fragile skin, and bruising.

Once all of the inclusion and exclusion criteria were determined and the informed consent executed, the initial treatment was performed by trained staff, as the subject observed. The device utilized was the Silk'N (Home Skinovations, Kfar Saba, Israel) (Figure 1). The Silk'N home hair removal device is a small, portable, low-energy IPL. The traditional term, IPL, has been put aside for this handheld device, and instead is referred to as HPL (home pulsed light). The specifications for the device include wavelengths of light from 475 to 1200nm, a maximum energy density of 5J/cm^2, a spot size of 20x30mm^2, and a pulse rate of one pulse every 3.5 seconds. The device can only be "fired" when the hand piece is in direct contact with the skin surface. Complete contact with the hand piece's entire treatment tip is required as a mechanism to prevent premature discharge of the device. Cooling of the skin is not required because of the low energy utilized with this device. Protective eyewear is not required with this HPL device because the light delivered is self-contained within the device.

All treatments were performed by a trained professional from the Tennessee Clinical Research Center in Nashville, Tennessee. Energy levels were first determined by the patient's skin types: Types I and II received energy level 3 for the test pulse; Type III received energy level 2 for the test spot; and Type IV received energy level 1. This treatment test pulse was performed in a darker part of the area that was selected for treatment with the Silk'N. If no reaction was noted after 15 minutes, a second test pulse was performed at one level higher than the first pulse. If once again no skin reaction was noted, the subject then received the first of six treatments.

In the area to be treated, the hairs present were trimmed to 3/32 of an inch in length (1–2mm) or were shaved three days prior to the treatment. Hair counts were determined prior to the first treatment and standardized digital photography was obtained to document the treatment area. The skin in the area was cleansed with a mild cleanser. The applicator was checked to make sure that the light output window was clean before the device was switched on and the appropriate energy level set on the device. The applicator was placed on the treatment site and slight pressure was applied. With the light window in complete contact with the skin, the trigger is switched to emit the light pulse. The applicator is then moved to the next spot to ensure full coverage to the treatment area. Three pulses were given and the skin was again checked for reaction. After 15 minutes, if no unexpected adverse skin reaction was noted, the treatment was continued over the entire predetermined treatment area. Transient erythema and follicular edema are normal skin reaction endpoints for photoepilation as is the smell of burnt hairs.

Figure 1. Silk'N device (Home Skinovations, Kfar Saba, Israel)

Once the treatment was completed, a moisturizer was applied to the treatment area and the patients were educated on the proper use of sunscreen with a sun protection factor of greater than 15. The patients were asked to avoid direct sun exposure to the treatment areas for at least two days after the treatment session. Tanning was to be strictly avoided.

The subjects were then asked to return to the research center biweekly (one treatment every other week) for a total of six treatments, which were to occur over a 16-week study period. Photographs were taken, as noted, at baseline and at four weeks and 12 weeks after the last treatment session. Hair counts were performed at each session in the same areas each time. All adverse events, whether expected or unexpected, were recorded at each visit.

RESULTS

Of the 20 female patients who completed the clinical trial, 19 (or 95% of the subjects enrolled) noted reduction

TABLE 1. Clinical trial results

PATIENT	AREA TREATED	BEFORE	2 TX	3 TX	4 TX	5 TX	6 TX	1-MONTH FOLLOW UP	3-MONTH FOLLOW UP	ADVERSE EVENTS	2 TX %	3 TX %	4 TX %	5 TX %	6 TX %	1-MONTH FOLLOW UP %	3-MONTH FOLLOW UP %
EDZ	R AX	49	31	37	9	7	3	4	6	None	63%	76%	18%	14%	6%	8%	12%
KSS	L +RAX	62	65	36	24	18	4	3	10	None	105%	58%	39%	29%	6%	5%	16%
LB	R+L AX	27	18	15	13	9	4	2	3	None	67%	56%	48%	33%	15%	7%	11%
PH	R+L AX	30	11	2	3			2	0	None	37%	7%	10%	0%	0%	7%	0%
JLH	R+L AX	36	24	29	19	22	14	3	7	None	67%	81%	53%	61%	39%	8%	19%
CMC	R+L AX	14	15	12	7	4	11	8	5	None	107%	86%	50%	29%	79%	57%	36%
KML	R+L AX	33	26	5	19	13	7	3	3	None	79%	15%	58%	39%	21%	9%	9%
EAR	BL	57	17	12	18	32	20	16	20	None	30%	21%	32%	56%	35%	28%	35%
LAB R+L	AX	48	36	20	29	21	14	12	6	None	75%	42%	60%	44%	29%	25%	13%
I-N R+L	AX	53	33	14	23	10	10	7	4	None	62%	26%	43%	19%	19%	13%	8%
AGB R+L	AX	58	67	39	37	35	43	28	30	None	116%	67%	64%	60%	74%	48%	52%
AMM R+L	AX	26	10	6	9	8		15	12	None	38%	23%	35%	31%	0%	58%	46%
LHW R	AX	18	21	10	10	10		5	14	None	117%	56%	56%	56%	0%	28%	78%
D-N R+L	AX	23	19	10	4	15	7	5	11	None	83%	43%	17%	65%	30%	22%	48%
MRG R	AX	19	13	8	5	19		2	3	None	68%	42%	26%	100%	0%	11%	16%
L-P R	AX	38	17	12	5	6		4	7	None	45%	32%	13%	16%	0%	11%	18%
CGS R	AX	23	13	7	7	3	3	5	5	None	57%	30%	30%	13%	13%	22%	22%
AGG R	AX	44	39	23	10	15	10	10	12	None	89%	52%	23%	34%	23%	23%	27%
JTR R	AX	29	25	8	8	14	2	3	10	None	86%	28%	28%	48%	7%	10%	34%
JFS R	AX	22	10	10	8		6	8	14	None	45%	45%	36%	0%	27%	36%	64%
Average Clearance																22%	28%

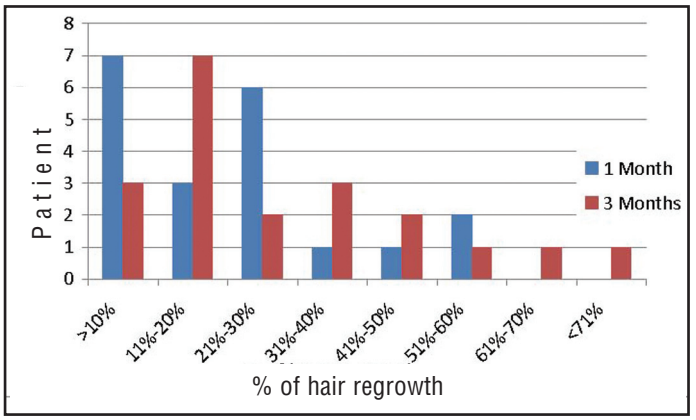

Figure 2. Clinical trial results summary

in hair removal as a result of participation in the clinical trial. Fifteen of the patients completed all six of the treatment sessions and all of the patients participated in the one- and three-month follow-up sessions. The results are shown in Table 1 and Figure 2.

The Silk'N device resulted in hair reduction in the majority of subjects, including observation of long-term reduction.

At the one-month follow-up visit, seven patients were found to have up to 90-percent hair reduction, three patients between 81- and 90-percent hair reduction, six patients between 71- and 80-percent hair reduction, one patient between 61- and 70-percent hair reduction, one patient between 51- and 60-percent hair reduction, and two patients between 41- and 50-percent hair reduction. The overall average hair reduction was 78 percent at the end of one month following the last treatment.

At the three-month follow-up time period, three patients were noted to have up to 90-percent hair reduction, seven patients between 81- and 90-percent hair reduction, two patients between 71- and 80-percent hair reduction, three patients between 61- and 70-percent hair reduction, two patients between 51- and 60-percent hair reduction, one patient between 51- and 60-percent hair reduction, one patient between 61- and 70-percent hair reduction, and one patient between 41- and 50-percent hair reduction. The overall average hair reduction was 72 percent at three months after six treatments.

During the course of the study, adverse events were evaluated at each treatment visit. No unexpected adverse events were reported during the course of this clinical trial. An example of the effects of the Silk'N device can be seen in Figure 3.

DISCUSSION

Hair removal with lasers and light sources has become a mainstay in many physician and nonphysician offices all over the world since the first description of the use of a long-pulsed ruby laser showed efficacy for hair removal. Since then, a variety of lasers including the ruby, the long-pulsed alexandrite, and the neodymium: yttrium, aluminum, and garnet (Nd:YAG) lasers have shown efficacy in the reduction of unwanted hair. IPL devices also have

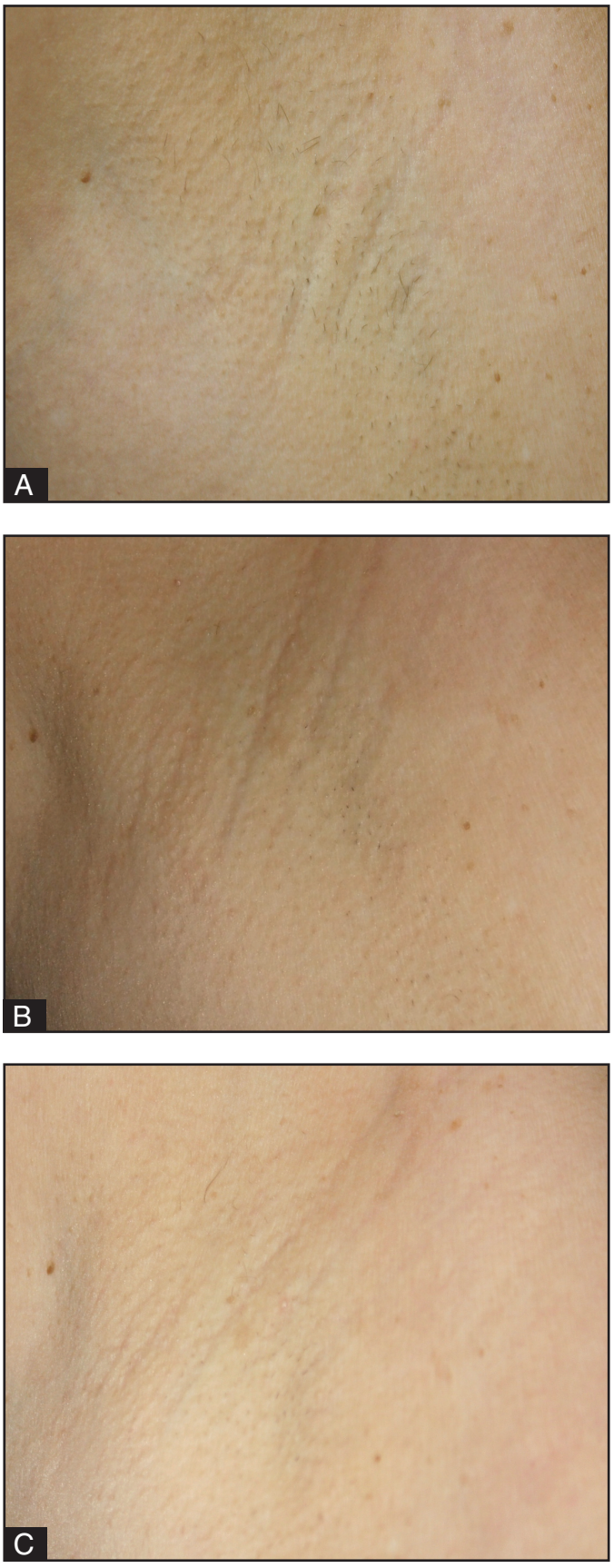

Figure 3. Clinical example of the effects of the Silk'N device as seen in a 50-year-old woman. Right axilla at baseline (A), one month after six treatments (B), and three months after six treatments (C).

Figure 4. SensEpil device (Home Skinovations, Kfar Saba, Israel)

shown both safety and efficacy in hair removal. These devices have received US Food and Drug Administration (FDA) clearance for permanent hair reduction.[10]

The major drawback for the use of both lasers and IPL devices under physician direction tends to be the cost associated with the procedure. The ability to cut costs has led to the development of home-use devices. Consumers must be properly educated on which of these numerous devices in the market actually work.

Hair removal with home devices has become a reality. Whether or not they impact the in-office hair-removal business has yet to be determined. Many of the home hair-removal devices available in the market are listed in Table 2, although only a few have controlled clinical trials that document their safety and efficacy.

The first home-use device available in the United States is known commercially as the Tria. It is an 810nm, diode, hair-removal device manufactured by SpectraGenics Inc., Pleasanton, California. The Tria is a battery-powered, handheld device with one clinical trial to its credit. In the study by Wheeland,[11] the Tria laser was effective in hair reduction with an average reduction of 41 percent at the six-month follow-up time period. The subjects received three treatments at three-week intervals. The device has a 1cm spot size and was found useful in this study.[11]

The Silk'N device has been evaluated by several previous investigators using slightly different clinical protocols than the current study. In the first evaluation, by Mulholland,[8] 34 individuals utilized the device on 92 sites. Each subject received three treatments at two-week time periods and were followed for three months after the last treatment. The two-week hair reduction was noted to be 74 percent. Two weeks later, the hair reduction was noted to be 84 percent. At the three-month follow-up period, 95 percent of all of the patients noted improvement with an average reduction of 64 percent. Mild, transient, perifollicular erythema was noted in 25 percent of the patients.

A second published clinical trial by Alster and Tanzi[9] evaluated 20 women for hair removal with the Silk'N device. As in the previous study, three treatments were given and subjects were followed for one, three, and six months following the last treatment session. All of the subjects in this clinical trial showed a response to the Silk'N device. Hair reduction was noted to be from 37.8 to 53.6 percent six months after three treatments. Side effects were minimal with 25 percent of the subjects noting mild erythema following the treatment session. Overall patient satisfaction scores were high in this clinical trial.

Of note, the overall experience and patient satisfaction were high in all of the clinical trials with the Silk'N device. The results of the clinical trial in discussion support the positive results seen in both previous studies by Mulholland[8] and Alster and Tanzi.[9] The 78-percent hair reduction at one month and 72-percent hair reduction at three months following the last treatment are consistent with the results already presented. The importance of properly using any at-home device must be prominent in the consumer marketplace, as patient responses to these devices will differ by device and training.

Recently, the Silk'N has undergone a major upgrade, and has been renamed the SensEpil (Figure 4). Although the appearance of the SensEpil device is significantly different than the original Silk'N used for this study, it has the same characteristics and has replaced the Silk'N at retail centers.

Other home hair-removal devices are available primarily

TABLE 2. The most common home use hair-removal devices in the United States and Europe

LASERS	IPLs
Tria (Tria Beauty)	Silk'N/SensEpil™ (Home Skinovations, Kfar Saba, Israel)
Rio Salon (The Dezak Group Ltd.)	CyDen, iPulse™ Personal (CyDen Limited)
Rio Scanning Laser (The Dezak Group Ltd.)	Teny Epil-Flash (GHT Innovation)
	SatinLux (Philips)

outside the United States and will not be covered in this manuscript. Dermatologists need to assure that as these home hair-removal devices make their way to the US market, their claims match their clinical outcomes.

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