

# מחקרים קליניים בתחום הסרת שיער - מכשיר Silk'n Infinity עם טכנולוגיית IPL

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# The Effect of Novel Low Energy Pulsed Light Combined with Galvanic Energy for Home-Use Hair Removal of Dark Skin

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## Abstract

**Background and Objectives:** Permanent reduction of unwanted hair on skin types V and VI is the most challenging procedure among all hair removal technologies based on selective absorption of light or laser. The objective of this study is to evaluate the safety and efficacy of a low energy pulsed-light device combined with galvanic energy, intended for home-use hair removal on dark skin. **Materials and Methods:** Fifteen women with skin types V and VI and dark terminal hair in axillaa-rea self-administrated 6 treatments at 2 week intervals, using a hand-held IPL combined with galvanicenergy device, using HPL (Home Pulsed Light) technology. Hair count and photographs were performed pre-treatment and 1 and 3 months after the last sixth treatment. Adverse events and subject satisfaction scores were recorded. **Results:** All patients showed a positive clinical response to treatment, with reduction of unwanted hair. Hair counts were significantly reduced by 57.3% 1 month following last treatment and by 44.5% 3 months following last treatment. No adverse events were recorded. Subject satisfaction scores of the device usability and the treatment outcome were high. **Conclusions:** Low energy pulsed light combined with galvanic energy may be applied safely and effectively for at-home hair removal for people with dark skin types V and VI.

## Keywords

Hair Removal, Dark Skin, Home-Use, IPL, Galvanic Energy

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## 1. Introduction

Long-term removal of unwanted hair is the most popular skin treatment worldwide. Over the past decade, various light and laser sources have been advocated for use in the office setting with long term results [1]-[3]. Selec-

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tive photothermolysis was established as the mechanism of action of optical sources of light and laser for the selective destruction of hair follicles [4] [5]. However, efficacy and safety of these technologies presented a challenge when dark skin was treated [6]. The disadvantages of in-office based hair removal methods called for the establishment of home-use devices of laser and light sources that enable people to enjoy permanent hair reduction in the comfort of their own home [7]-[11]. The challenge of treating dark skin safely and effectively at home environment still exists, as low fluence light source has to be deployed to protect the dark skin without affecting efficacy of the long-term hair removal. In an attempt to increase absorption of light in the hair melanin, continuous galvanic current has been added. The galvanic current applied that may be as low as 200  $\mu\text{A}$  is widely used in cosmetic treatments for a few decades [12]. Such a low direct electrical current is hardly perceptible and may affect temporarily several skin structures, including pore dilation. Dilation of the pores at the skin surface exposes a bigger portion of the hair shaft to the optical energy, thus increasing the absorption and enabling a low fluence to be efficacious. The combination of radiofrequency electrical current and intense pulsed light (IPL) energy has been previously reported for in-office system [13]. The current study is the first attempt to combine the electrical and optical energies in a home-use device in an attempt to treat dark skin safely and effectively.

## 2. Materials and Methods

### 2.1. Device and Technology

The Infinity Device is a small hair removal home-use device, employing the technology of electrical Home Pulsed Light (eHPL™) (Home Skinovation, Yokneam, Israel). It is a portable hand-held device with spot size of  $1 \times 3$  cm, combining low energy IPL (475 - 1200 nm; 3 - 5  $\text{J}/\text{cm}^2$ ) and 200  $\mu\text{A}$  galvanic energy (Figure 1). IPL may be applied in the rate of 1 pulse every 1 - 2 sec in 5 different levels according to individual skin response, following a test spot. The electrical current is a continuous direct current that depends on full contact with the skin. Failure to have this contact results in automatic inactivation of the galvanic energy by a built-in safety mechanism. This mechanism also inactivates IPL if full contact with the skin is not achieved.

### 2.2. Subjects

Seventeen females, 21 - 60 years old with Fitzpatrick skin type VI who had black hair in their axillae and met the inclusion and exclusion criteria were recruited to the study. Subjects were retained by in office recruitment of existing patients who would be a candidate for hair removal through an IRB (Investigational Review Board) approval study. Fifteen subjects have completed the study. All subjects signed an informed consent form.

### 2.3. Acceptance Criteria

Inclusion criteria included healthy females between 21 - 60 years of age with skin type VI, having unwanted



Figure 1. The Infinity Device.

black hair in their axillae and willingness to follow the study protocol. Exclusion criteria included pregnancy and lactating throughout the study period, concurrent severe diseases and history of malignancy, diseases that may be stimulated by light, such as epilepsy and lupus, scarring, inflammation or infection of the area to be treated, history of skin disorders such as keloids and abnormal wound healing, a pacemaker or internal defibrillator device, poorly controlled endocrine disorders as diabetes or PCO, history of bleeding coagulopathies or constant use of anticoagulants, previous photo-epilation hair removal or waxing and plucking in the treatment area during the last three months, history of known photosensitization or the use of a medication known to induce photosensitization; tanned skin in the treatment area within four weeks of the study, and presence of tattoo in the treatment area.

## 2.4. Study Design

Subjects were given the Infinity device and the instructions for use and were asked to perform the first self-treatment in the investigator's clinic in the supervision of a qualified trainer who determined the fluence used for each individual following a test spot procedure. Baseline measurements included demographic data, laboratory tests to rule out pregnancy, and initial photography and hair counts in both axillae. Subjects conducted 5 more sessions of self-treatment (total 6) at home at 2 weeks intervals. Follow-up sessions were held in the investigator's clinic 1, and 3 months following the last treatment. At each follow-up session the treated area was photographed and hair count conducted in a similar way to baseline. Photographs were taken with Nikon D100 camera with 60-mm micro lens. Hair count was done on a predetermined  $2 \times 2$  cm ( $4 \text{ cm}^2$ ) area, using a small sticker. These stickers have a central cut out area that is a reproducible  $2 \times 2$  cm in size. The axillae with the stickers were also photographed to ensure count in the same area. Furthermore, a transparency sheet was placed over each axilla of the subject, and anatomic locations (such as nevi, freckles, tags, scars) were marked to facilitate reproducibility of count area in the various visits. The duration of the entire study for each subject was up to 7 months.

## 2.5. Treatment Procedure

Hair was shaved and treatment was performed by applying light pressure on the treatment area with the Infinity device, to achieve complete contact with the skin and pressing the trigger button. The applicator was then moved to the next spot without overlap and with full coverage of the treated area. Post-treatment care included the application of cold Aloe Vera cream and a moisturizer cream and the patients were instructed to protect the treated areas from sun exposure and tanning throughout the whole study. After each treatment subjects were instructed to evaluate any adverse event and attend the clinic for its assessment. At each follow-up session subjects were asked to rate their satisfaction level in a scale of four: 0—Not satisfied; 1—Slightly satisfied; 2—Satisfied; 3—Very satisfied.

## 2.6. Statistics

Sample size was 30 treatment sites of 15 subjects. Hair count p values were performed using paired t-test analysis. Values  $< 0.001$  were regarded statistically significant.

## 3. Results

All 15 subjects who enrolled and completed the study were females with an average age of 42 years, with skin type VI that were treated on both axillae for unwanted black hair. Energy levels used (out of 5 levels) were 1 - 3 with a mean value of 2.3.

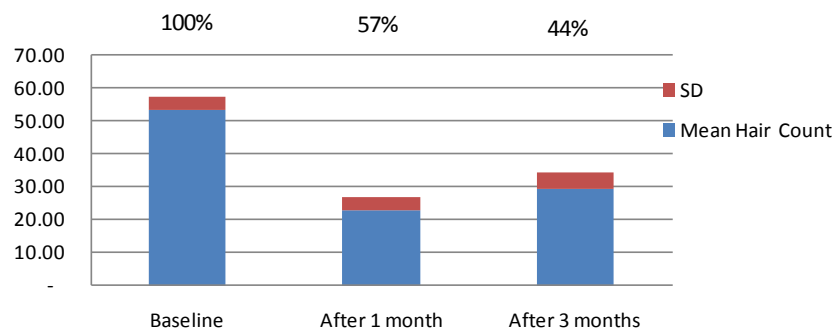
Results of the clinical study and demographic data are given in **Table 1**. The Results show that the mean hair count per at baseline was  $53.4 \pm 3.9$ . At the 1 month follow-up visit, the mean hair count significantly decreased to 22.8 (SD = 4.4), by 57.3% ( $p < 0.001$ ). At the 3 month follow-up visit, the mean hair count was decreased to a lesser degree 29.7 (SD = 4.8) which was still significantly lower than baseline count in 44.5% ( $p < 0.001$ ).

The graphic presentation of hair count and percent hair reduction distribution is given in **Figure 2**.

Representative photographic illustrations of hair reduction in the two follow-up sessions as compared with baseline photographs are presented in **Figure 3**. Results of hair reduction on three axillae of three different patients with skin type VI are comparing baseline to 3 month follow-up (**Figure 4**). Both, hair count results and

**Table 1.** Hair count and percent hair reduction distribution at baseline and at 2 follow-up sessions, 1 and 3 months post 6 treatments.

Subject ID	Axilla	Age	Energy Level	Hair Count per 2 cm <sup>2</sup> Mean ± SD			Response
				Baseline	1 Month	3 Months	
1	Left	50	2	47	30	37	Slight erythema
1	Right		2	49	28	34	Slight erythema
2	Left	28	1	49	19	23	None
2	Right		1	49	21	25	None
3	Left	44	3	55	17	27	Slight erythema
3	Right		3	53	21	24	Slight erythema
4	Left	25	3	51	18	27	Perifollicular edema
4	Right		3	55	28	30	Perifollicular edema
5	Left	59	2	49	26	37	None
5	Right		3	47	21	37	None
6	Left	45	2	48	25	27	Perifollicular edema
6	Right		2	54	26	29	Perifollicular edema
7	Left	33	2	50	21	33	None
7	Right		2	57	19	31	None
8	Left	42	1	56	28	28	None
8	Right		2	57	30	35	None
9	Left	21	2	59	27	34	Perifollicular erythema
9	Right		2	53	27	30	Perifollicular edema
10	Left	54	3	53	25	31	Perifollicular erythema
10	Right		3	55	27	30	Perifollicular erythema
11	Left	55	3	47	17	25	None
11	Right		3	50	17	23	None
12	Left	60	1	55	19	30	None
12	Right		1	58	20	23	None
13	Left	28	2	59	29	37	None
13	Right		2	59	25	32	None
14	Left	32	3	51	17	25	None
14	Right		3	50	19	22	None
15	Left	49	3	57	25	34	Perifollicular edema
15	Right		3	56	21	35	Perifollicular edema
<b>Mean Hair Count</b>		42.1	2.3	53.4	22.8	29.7	
<b>SD</b>				3.93	4.37	4.78	
<b>Mean % Hair Reduction</b>					57.3%	44.5%	
<b>p-Value</b>					2.3502E-24	5.64221E-20	



**Figure 2.** Graphic distribution of hair count and percent hair reduction at baseline and at 2 follow-up sessions, 1 and 3 months post 6 treatments.



**Figure 3.** Photographic illustration of hair reduction in axillae of subject 1 at baseline (left), at 1 month follow-up session (center), and 3 months post last treatment (right).

photographs indicate that percent hair reduction after 3 month is smaller than after 1 month.

Subject Satisfaction Score is presented in **Table 2**. Satisfaction included subjects' impression from the results and from the usability of the device. All subjects rated the usability that reflects ease of use as "very satisfied". Regarding treatment outcome, eight subjects scored their satisfaction as "very satisfied" at the two follow-up sessions. Six subjects rated their satisfaction as "satisfied" after 1 month and 5 of them changed their rating to "very satisfied" at the 3 months follow-up sessions. One subject started at "slightly satisfied" at the 1 month follow-up and changed to "satisfied" after 3 months. Altogether, satisfaction rate of both usability of the device and hair reduction outcome is very high (2.5 - 3.0). All subjects expressed their will to purchase the device following the study for home-use treatments and recommend to their friends.

No adverse events were noted during the study. Slightedema in the perifollicular sites was experienced by 33.3% of the subjects and resolved within 2 hours. This was a desirable and expected response of treatment endpoint.

#### 4. Discussion

The current study demonstrated 57.3% hair reduction 1 month after 6 sessions every other week that was reduced to 44.5% after 3 months and was also demonstrated in the photographs (**Figure 2**, **Figure 3**). These results indicate that a maintenance session may be required after ~2 months following the treatment regime.

Long-term hair removal performed in-office by optical technologies of lasers and IPL have presented an average efficacy of 60% - 80% following a multi-session treatment [3] and with follow-up periods of 1 - 2 years [1] [12]. Home-use devices based on IPL technology proved to be efficacious on body areas [7] [10] and on the face [8] in a similar efficacy as in office-based IPL systems by using lower fluence but more frequent sessions. Thus, 83% hair reduction was demonstrated on the face after 1 month and 78% after 3 months following 6 sessions every other week [7]. Percent hair reduction on the body was lower and reached 78% after 1 month and 72% after 3 months following 6 sessions [8]. In another study [10] average percent hair reduction observed on body





**Figure 4.** Photographic illustration of hair reduction in axillae of 3 subjects at baseline (Left) and 3 months post last treatment (Right). Top to bottom: subjects 3R, 10R, and 11R.

areas after 3 months following 3 treatments was 64%. The three studies were conducted on light skin types, up to Fitzpatrick skin type IV.

In an attempt to adjust the home-use hair removal device to dark skin type (V-VI), lower fluence was applied to the dark skin to ensure safety (energy levels 1 - 3), but efficacy was increased by the simultaneous addition of galvanic energy. Nevertheless, as expected, percent hair reduction was lower than on lighter skin, using a similar device. As the studies described above were conducted with a similar IPL device [7]-[9] on light skin, it is important to note that using lower level energy on dark skin types may require more treatment sessions. Therefore, to achieve similar efficacy to results on lighter skin, it is expected that treatment of darker skin types may require up to 12 treatments every other week.

**Table 2.** Subject satisfaction scores.

Subject ID	1 Month FU		3 Month FU	
	Usability	Outcome	Usability	Outcome
1	3	2	3	2
2	3	3	3	3
3	3	3	3	3
4	3	2	3	3
5	3	2	3	3
6	3	1	3	2
7	3	3	3	3
8	3	3	3	3
9	3	3	3	3
10	3	2	3	3
11	3	2	3	3
12	3	3	3	3
13	3	3	3	3
14	3	2	3	3
15	3	3	3	3
Mean	<b>3.0</b>	<b>2.5</b>	<b>3.0</b>	<b>2.9</b>

O = Not Satisfied; 1 = Slightly Satisfied; 2 = Satisfied; 3 = Very Satisfied.

Despite the lower efficacy achieved by the Infinity home-use device on dark skin, when compared to light skin, subject satisfaction was very high. All subjects found the device ergonomic and easy to use. Most of the subjects were very satisfied with the treatments outcome in hair reduction.

In another study [9], a similar home-use device was used for only 3 sessions bi-monthly. As a result, lower percent hair reduction (40.4%) was noted in the axillae 1 month after last treatment and it was reduced to 37.8% at 6 months follow-up. The skin types treated on axillae were II-III. According to this study, it may be worthwhile to check the percent hair reduction of the current study after 6 months.

No adverse events were recorded, like all IPL hair removal home-use devices that were reported to be safe. Some of the devices, however, had impaired efficacy due to safety [10]. In the current study efficacy was not affected, as the low optical energy was compensated by the galvanic energy used in the Infinity device. The galvanic energy which is applied in a continuous wave enables better absorption of the IPL pulses in the hair shaft by widening the skin pores [11]. As a result, less optical energy is needed to destroy the hair follicle, without creating damage to the surrounding dark skin.

## 5. Conclusion

Low-fluence pulsed light combined with galvanic energy, using the novel technology of eHPL™ may be applied safely and effectively for at home hair removal for subjects with dark skin type of V-VI. All patients (100%) showed a reduction in hair removal at 1 and 3 months, with zero adverse effects.

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