Home Hair Removal in All Skin Types with a Combined Radiofrequency and Optical Energy Source Device

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BACKGROUND Home hair removal devices are available for skin types I to IV. Side effects may limit hair removal in darker-pigmented individuals.

OBJECTIVE To evaluate a home hair removal device using combined radiofrequency (RF) and intense pulsed light (IPL) energy for effectiveness and safety with all skin types (I–VI).

DESIGN Two study designs: effectiveness (treating 94 bilateral patient areas weekly seven times, with one side then receiving three additional treatments at 4-week intervals) and safety (37 patient areas treated every 2–4 days for three sessions).

MEASUREMENTS Hairs were counted 3 months after treatment for the first design and 2 months after for the second.

RESULTS In the first study design, 55% hair count reduction was achieved1 month after seven treatments to all sites. The side with no further sessions had 43% hair reduction and the side receiving ongoing treatment had 58% reduction after two further treatments. Side effects were transient and minor. In the second study, with 46% of the patients having skin types V/VI, 2 months after the procedure there was 44% hair reduction. There were no adverse effects reported.

CONCLUSION For the first time, a home hair removal device has been shown to be effective and safe in all skin types using a low-energy RF–IPL device.

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A number of at-home hair removal devices have been developed in the past decade.[1–3] These devices are based on the technology used in office-based devices that selectively heat the hair follicles, minimizing injury to surrounding tissue. Intense pulsed light (IPL) technology has been used in hair removal mainly for skin types I to IV [4–6] and occasionally on skin type V[7] when appropriate cut-off filters were used. At-home devices offer the advantage of constant availability and greater privacy,[8] but as with all heat-producing light sources, these devices are designed to cause biologic damage. As such, there is a level of caution that is necessary when using these laser- or light-based hair removal devices.[9,10] Although clinical results have confirmed the safety and efficacy of hair removal at home in skin types I to IV, use of such home hair removal devices on darker skin types (V–VI) remains a challenge. Combined electro-optical technology, integrating optical (IPL) energy with bipolar radio frequency (RF) energy, has shown significant results in different dermatologic applications, such as hair

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removal and skin rejuvenation.[11–14] The addition of bipolar RF energy enables the use of lower levels of the optical energy, reducing the risk to the epidermis in darker skin types.

A home-use device incorporating this type of electro-optical technology was evaluated. Two different approaches are studied in this multicenter study: one examining primarily safety in all skin types (I–VI) and the second evaluating efficacy and safety.

Materials and Methods

Subjects

Subjects with all skin types (I–VI) were eligible for enrollment into both study approaches for safety and efficacy. Patients had to be aged 18 to 65 and have naturally brown or black hair in the areas intended for treatment. Exclusion criteria included history of keloid scarring, pregnancy, and photosensitivity. An Institutional Review Board approved study protocols, and all subjects provided written informed consent.

Treatment

All treatments were performed using a combined IPL and radiofrequency (RF) device (mē system, Syneron Medical Ltd., Yokneam, Israel) (Figure 1). This home device emits a single pulse at 2 to 4 J/cm^2 through an optical dielectric filter at wavelengths of 550 to 1,200 nm. A simultaneous bipolar RF pulse is emitted only if the two RF electrodes are in contact with the skin. This sensing mechanism uses a RF feedback circuitry mechanism. The RF component operates at 6.78 MHz, with an output power of 2W. A 10- by 30-mm (3 cm^2) optical spot size delivers the energy through a double-glazed, forced-air cooling window assembly. The repetition rate ranges from 0.5 Hz (at a setting of 4 J/cm^2) to 1 Hz (at a setting of 2 J/cm^2), with up to a 6-ms pulse duration. There is at least an 8-second interval before an area is exposed to a second energy exposure.

Figure 1. The mē device is a combined intense pulsed light and radiofrequency device for home hair removal.

Study Design

Two different treatment approaches were used to evaluate the efficacy and safety of the device. The first approach, conducted at five medical centers, measured safety and efficacy for maintenance and no-maintenance treatment sites. Bilateral anatomic regions were treated from the axilla, lower back, leg, forearm, nape of neck, sideburns, jawline, upper lip, and chin. Each treatment area measured approximately 2 by 2 inches (5 × 5 cm). All participants selected an energy setting (low [2 J/cm^2] to high [4 J/cm^2]), based on their level of tolerability. When tolerated, a high setting was recommended for the axilla and facial areas and up to medium (3 J/cm^2) for the other body areas. The treatment protocol was independent of skin type; for example, even patients with skin type VI used high energy as tolerated to treat the axilla. Each area was treated with three to four passes with an 8-second or longer interval between each pass.

Each side of the same anatomic region received seven weekly treatments. One side received three additional maintenance treatments at 4-week intervals (maintenance side), whereas the other side received no additional treatments (no-maintenance side), enabling comparison of the maintenance and no-maintenance treatment protocols. The treatment regimen is shown in Figure 2.

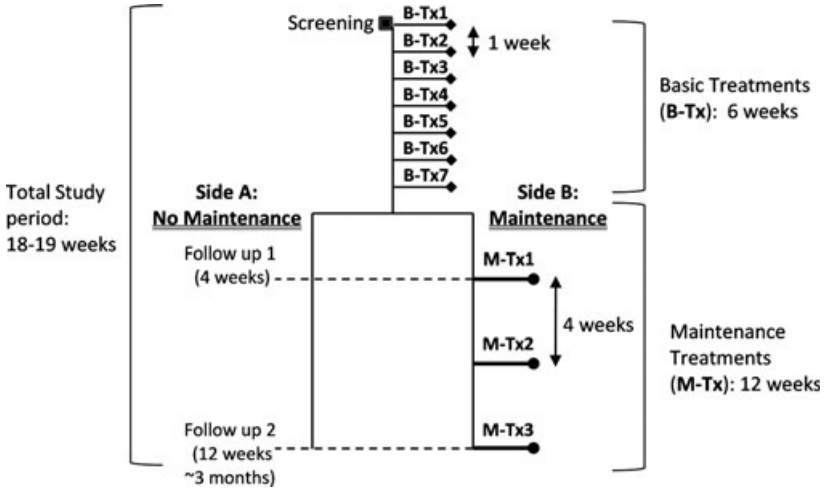

Figure 2. The treatment regimen protocol consisted of seven basic weekly treatments. One anatomic side received three additional maintenance treatments at 4-week intervals (maintenance side), whereas the other side received no additional treatments (no-maintenance side).

Participants underwent treatments at 10 clinic visits; seven treatments at 1-week intervals, followed by three monthly maintenance treatments on one treatment side (left or right), to examine the treatment effect of additional maintenance treatments every month. Generally, subjects self-administered treatments to simulate home use.

Hair Clearance Assessment

The selected treatment areas were trimmed at the screening visit. A close-up photograph of each treatment area was taken before and after trimming using a standardized photography method. Two evaluators experienced in terminal hair counting performed independent third-party hair counts. Quantitative hair counts were made at baseline, at the third office visit, 1 month after the seven basic treatments (first follow-up visit), and 3 months after the seven basic treatments (last follow-up visit).

Hair clearance was defined as percent of terminal hairs cleared in the defined reproducible hair count area within the treatment site, as follows (Equation 1):

$$\text{Hair Clearance}_i = 100 \times \left(1 - \frac{\#\text{Hair}[\text{visit}_i]}{\#\text{Hair}[\text{visit}_0]}\right) \quad (1)$$

where #Hair [visit] = the number of hairs manually counted on visit "i," and visit_0 is the baseline visit. The second approach was a controlled, prospective, single-site study intended to measure safety in all skin types. Subjects had at least two (bilateral) anatomic regions treated from the axilla, lower back, leg, forearm, bikini line, and nape of neck. All participants, including those with darker skin types, randomly treated one side of the selected area using the high-energy setting and the contralateral side with the medium-energy setting. The size of each anatomic treatment area was approximately 1.2 by 1.2 inches (3 × 3 cm).

Participants performed treatments at three clinic visits spaced at an accelerated 2- to 4-day interval. Subjects were evaluated at 2 to 4 days and 1 and 8 weeks after the third treatment (Figure 3).

Safety Findings

For both design approaches, the treated areas were examined for any immediate skin reactions after each treatment. Any skin reactions that occurred during the course of the study were evaluated and reported. At the end of the treatment procedure, the patients graded the tolerability of the treatment according to the tolerability assessment scale, as

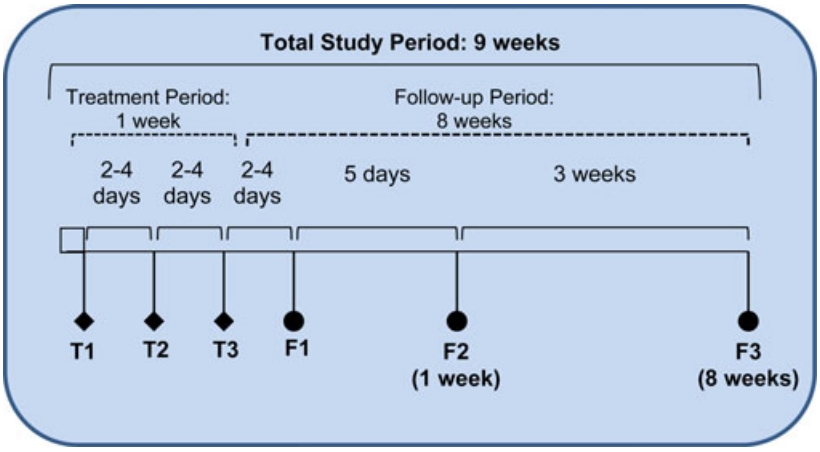

Figure 3. Study design for safety treatment regimen in which three accelerated treatments were performed at a 2- to 4-day intervals. (T = treatment; F = follow-up).

recorded on a 5-point Likert scale (0 [no pain] to 4 [intolerable pain (had to stop treatment)]).

Statistical Analysis

Effectiveness analyses were performed using data from all subjects who had a baseline photograph and at least one postbaseline visit. Safety analyses were performed using data from all subjects who underwent at least one treatment. The primary effectiveness endpoint was mean percentage hair count reduction (as calculated using Equation 1) 1 month after completing the basic treatment protocol. The secondary effectiveness endpoint was mean percentage hair count reduction 3 months after completing the basic treatment protocol. The maintenance and nonmaintenance treated sides were compared for significant differences 3 months after the seventh treatment.

Hair clearance was calculated based on the count of two independent evaluators and then averaged. Areas with a very low hair count at baseline (<7 hairs in the area) were excluded from the analyses. A paired Student *t*-test was used to evaluate the statistical significance of observed differences from baseline to follow-up time-points. Analysis of variance (ANOVA) was performed using SAS version 9.2 (SAS Institute, Inc., Cary, NC) to test treatment effect between study sites.

Results

Ninety-eight subjects (89 female, 9 male; aged 38 ± 9, range 23–60) were enrolled at five medical centers for the efficacy protocol. Four subjects discontinued, resulting in a final sample size of 94 individuals (96%) with data for the primary and secondary evaluation time-points. Of the four dropped subjects, two were discontinued before any treatment because of insufficient hair counts at baseline, one was discontinued because of previous IPL treatment 2 months before screening, and one subject decided not to participate and withdrew consent before treatment. Fourteen subjects (15%) had skin type V to VI, and 80 (85%) had skin type I to IV (26% were skin type IV).

Three hundred thirty-four nonfacial areas (167 left side, 167 right side; 160 axillae, 132 calves/legs, 40 arms, 2 lower back) and 15 facial areas (8 sideburns, 4 jawlines, 2 upper lips, 1 under chin) were treated.

Of the 349 body and facial areas treated, 52 were treated in subjects with skin types V and VI. A total of 2,897 treatments were performed (1,253 bilateral treatments, 496 treatments to the maintenance side); 434 of these were in subjects with skin types V and VI. Ninety-nine percent of treatments on the axillae and 92% of facial treatments were performed using the high-energy setting (4 J/cm^2) and 1% with the

medium setting (3 J/cm^2). Ninety-two percent of treatments of the legs and 100% of treatments of the arms were with the medium energy setting.

Efficacy Results

Overall Hair Reduction

The measured hair count reductions, averaged for all treated areas at each evaluation point, are shown in Table 1 and Figure 4. As evident in Figure 4, mean percentage hair reduction was greater than 40% for the maintenance and nonmaintenance sides at each of the study visits.

With respect to the primary measure of treatment efficacy (follow-up 1 month after completing seven treatments), mean hair count reduction from baseline was 54.1% for the no-maintenance side and 56.5% for the maintenance side. The reduction in hair counts was statistically significant for both sides ($p < .001$ for both).

Three months after the final basic treatment (FU3), there was still significant overall hair reduction on the maintenance (58%) and no maintenance (43%) sides from baseline ($p < .001$ for both sides). The 1- and 3-month results within the maintenance arm were similar (56.5% at FU1, 57.9% at FU3), with no statistically significant difference ($p = .77$, paired t-test), but there was a significant difference between 3-month results in the maintenance and no maintenance arms ($p = .0027$).

Hair count reduction as a function of skin type (skin types I–IV and V–VI) was also significant in all skin

TABLE 1. Overall Hair Clearance at Two Evaluation Time Points

Overall Hair Clearance Distribution	*1-Month Visit (After 7 Treatments)*		*3-Month Visit (Third Maintenance Treatment)*	
	No Maintenance, n = *148*	*Maintenance,* n = *150*	*No Maintenance,* n = *145*	*Maintenance,* n = *151*
%, mean	54.1	56.5	43.3	57.9

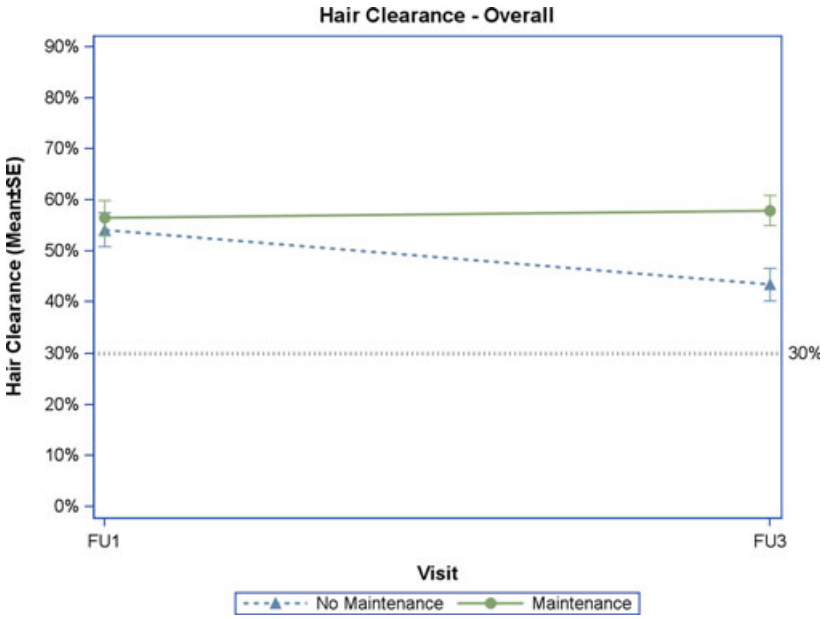

Figure 4. Overall hair clearance on maintenance and no-maintenance sides at the two evaluation periods: follow-up 1 (FU1) and 3 (FU3) months after completing seven treatments. Standard error bars are included above each data point.

types for both sides at all visits (all $p < .01$) (Table 2). Mean hair count reduction at 1-month follow-up was 57% for the no-maintenance arm and 59% for the maintenance arm in skin types I to IV and 40% and 44%, respectively, in skin types V to VI. There was a significant difference between 3-month results in the maintenance and no-maintenance arms for skin types I to IV ($p < .01$) and skin types V to VI ($p < .05$).

As with the overall hair reduction, there were significant differences in hair reduction according to body site from baseline to 1 month (FU1) after the seven basic weekly treatments for the both sides (all $p < .01$) (Table 3). Comparisons of facial sites between the maintenance and no-maintenance sides were not evaluated because of the small sample size. There were significant differences between baseline and 3 months in nonfacial sites that received maintenance treatments (all $p < .01$) (Table 3). There were also significant differences between baseline and 3 months in nonfacial sites for both sides. At 3-month follow-up, the greatest reduction in hair counts occurred on the maintenance side of the legs (74%), followed by the arms (68%), and the axillae (45%). There were statistically significant differences in hair reduction between the maintenance and no-maintenance sides at the 3-month follow-up for axillae and legs ($p < .001$ for both sites) (Figures 5–7).

There were no significant differences in hair reduction rates between the five centers when comparing average overall hair clearance 1 and 3 months after treatment ($p > .05$, ANOVA test).

TABLE 2. Overall Hair Clearance at Follow-Up Visits for Both Skin Types

	1-Month Visit	*3-Month Visit*
Skin Type	*Mean Percentage (95% Confidence Interval)* p-*value**	
I–IV		
No maintenance	56.6 (47.2–66.1) <.001 (*N* = 126)	45.2 (36.0–54.5) <.001 (*N* = 127)
Maintenance	58.5 (48.8–68.1) <.001 (*N* = 129)	57.9 (49.2–66.5) <.001 (*N* = 133)
V–VI		
No maintenance	39.7 (16.3–63.2) <.01 (*N* = 22)	35.2 (14.7–55.8) <.01 (*N* = 18)
Maintenance	44.1 (17.9–70.1) <.01 (*N* = 21)	58.2 (36.6–80.0) <.001 (*N* = 18)

*Evaluation of mean change from baseline at each follow-up time, per side and for each skin type [paired *t*-tests].

TABLE 3. Hair Reduction at Follow-Up Visits by Body Site

	1-Month visit		*3-Month visit*	
	Mean percentage (95% confidence interval)	p-*Value**	*Mean percentage (95% confidence interval)*	p-*Value**
Body Site				
Legs				
No Maint.	71.3 [62.7–79.9] (*N* = 56)	<.0001	57.4 [47.9–66.9] (*N* = 54)	<.0001
Maint.	71.9 [62.6–81.2] (*N* = 56)	<.0001	74.0 [65.9–82.1] (*N* = 56)	<.0001
Arms				
No Maint.	55.3 [24.5 -86.1] (*N* = 15)	.0017	54.5 [38.2–70.8] (*N* = 13)	<.0001
Maint.	62.5 [38.0–84.2] (*N* = 15)	<.0001	67.7 [37.5–97.9] (*N* = 13)	.0014
Axillae				
No Maint.	40.4 [31.1–49.7] (*N* = 72)	<.0001	35.4 [26.2–44.6] (*N* = 72)	<.0001
Maint.	43.9 [33.1–54.7] (*N* = 72)	<.0001	44.5 [36.4–52.6] (*N* = 72)	<.0001

Maint., maintenance.
*Evaluation of mean change from baseline at each follow-up time, per side and for each body site [paired *t*-tests].

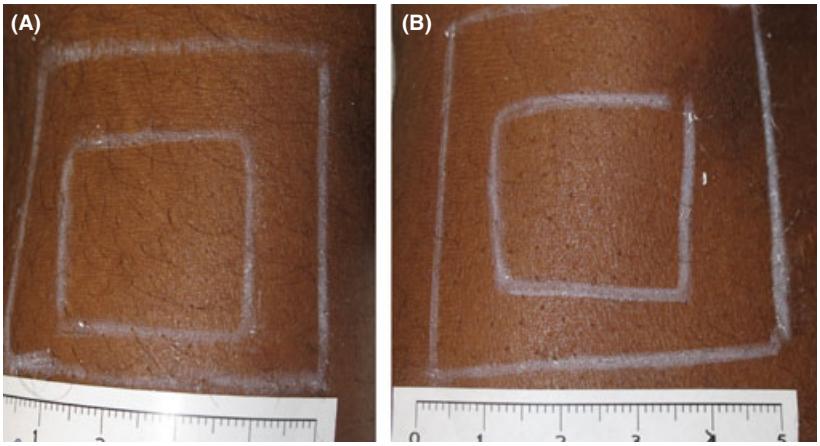

Figure 5. Twenty-year-old man with skin type VI. The outer and inner white squares are drawn using white eyeliner, indicating the treatment area and hair count area, respectively. (A) Left forearm before trimming and treatment (averaged hair count 53). (B) At 1-month follow-up after seven weekly treatments (before maintenance treatment), showing 61% hair reduction (average hair count 22).

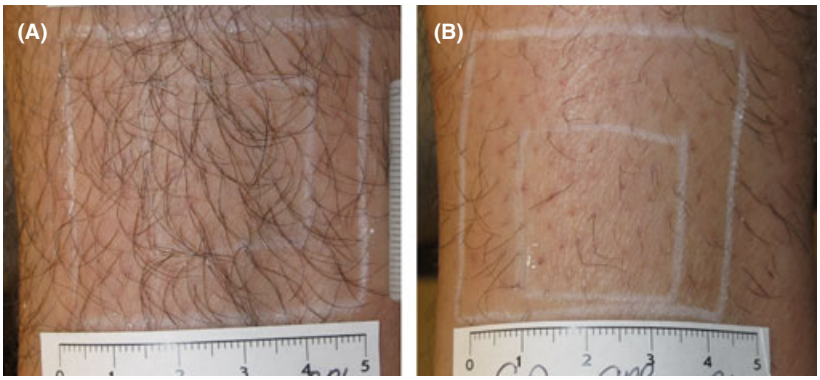

Figure 6. Twenty-two-year-old man with skin type IV. (A) Left lower leg before trimming and treatment (average hair count 54). (B) At 3-month follow-up after seven weekly treatments (no additional maintenance treatments), showing 54% hair reduction (average hair count 24).

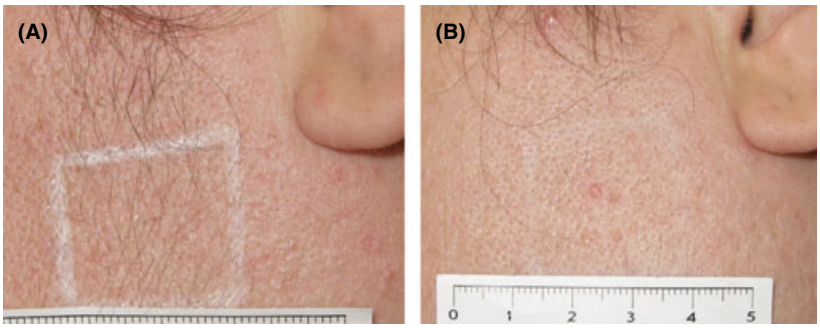

Figure 7. Forty-year-old woman with skin type III. (A) Left sideburn before trimming and treatment (average hair count 70). (B) At 3-month follow-up after seven weekly treatments and two monthly maintenance treatments showing 44% hair reduction (average hair count 39).

For the majority of treatments (88% for nonfacial and facial treatments), subjects reported no pain. Subjects reported mild pain for 10% of nonfacial treatments and 8% of facial treatments and moderate pain for 2% of nonfacial treatments and 4% of facial treatments. There were eight reports of severe pain (0.3% of treatments) from two subjects (1 skin type III, 1 skin type V), reported for two to three treatments to both axillae. Neither subject discontinued because of the pain or required medical intervention. Both subjects reported no pain or mild pain (0 and 1 on the 5-point Likert scale, respectively) with successive self-administered treatments.

The observed immediate post-treatment side effects included transient erythema in 4.6% of subjects, edema in 1%, and pruritus or itching in 1%. All immediate post-treatment side effects were reported as mild and resolved spontaneously within 24 hours. One subject (skin type III) experienced mild blistering in the axillae that resolved spontaneously within 1 week. There were no reports of other skin reactions, including scarring, skin textural changes, infection, ulcers, and skin pigmentation changes, for any study subjects. Thus, overall skin reactions occurred in less than 1% of the 2,897 nonfacial and facial treatments. There were no reports of skin reactions in subjects with skin types V and VI.

Safety Protocol

Thirty-seven patients (31 female, 6 male; aged 33 ± 8, range 19–57) were enrolled in the safety protocol portion of the study at a single center. Two subjects discontinued after undergoing at least one treatment. Twenty subjects (54%) had skin type I to IV, and 17 (46%) had skin type V to VI.

One hundred fifty-four areas were treated (54 arms, 50 axillae, 40 legs, 4 napes of the neck; 4 lower backs, 2 bikini lines). All 154 areas underwent at least one treatment, 150 (97.4%) underwent at least two treatments, and 138 (89.6%) underwent three treatments. Four hundred forty-two treatments were performed throughout the study.

There were no incidences of erythema, edema, inflammation, blistering, or pruritus or itchiness, and there were no adverse events reported during the study for the 442 treatments performed.

Subjects assessed pain tolerability after each treatment. After the first treatment (n = 154), 86% of the subjects reported no pain, 11% reported mild pain, and 3% reported moderate pain. Greater tolerance occurred with successive treatments, with less pain. There were no significant differences in pain according to treatment area (Fisher exact test p = .71).

Discussion

Safety and efficacy were evaluated using a combination RF and IPL home hair removal device. Patients of all skin types were treated, including for the first time with an over-the-counter device, skin types V and VI. An accelerated rate of therapy was evaluated for safety.

Overall, the two study approaches demonstrated a favorable safety profile. All immediate postprocedural side effects were mild and transient. These effects, such as erythema and edema, are anticipated in all hair removal devices, but with the low energies used with this device, the highest being 4 J/cm^2, and the double-glazed cooling of the contact exposure site, even erythema occurred in only 4% of the cases. Previously reported effective pulsed-light home-use hair removal units have used slightly higher energies (5 J/cm^2) and, more importantly, a broader range of wavelengths (475–1,200 nm), shorter pulse duration (<1 ms), and a larger spot size (2 × 3 cm), all potentially contributing to greater epidermal effect, especially in darker skin types.[8,15] There was only one case of blistering in 3,339 treatment sessions, which healed without any sequelae. There were no delayed or persistence adverse effects wither either of the study approaches.

A total of 120 sites were treated in both study approaches, which were skin types V and VI. These

sites received over 600 treatment sessions. There were no reported immediate or delayed adverse effects. It is possible that mild changes in erythema or edema were less perceptible in darker-skinned patients. In addition, pigmentary changes, which are more readily seen in these skin types, did not occur.

Safety, especially with darker skin types, remains of paramount concern. Because our study evaluated all skin types, we also investigated the safety profile of the study device with objective measurements of skin temperature increase after single and repeated exposure to IPL pulses using the highest settings of 4 J/cm^2 combined with 2-W RF in subjects with skin types IV (n = 11) and VI (n = 10). Skin temperature measurements were compared with those after single IPL pulses of 7 to 8 J/cm^2 using another commercially available home hair-removal device (i-Light Pro System, Spectrum Brands, Inc., Madison, WI), which the Food and Drug Administration has cleared for skin types I to IV, in 11 subjects with skin type IV. The average skin temperature increase was considerably less after a single pulse with the study device, as well as after several passes with the study device, than with the commercial device with a single pulse only (2.3, 2.6, and 6.2°C, respectively) for the 11 subjects with skin type IV. Moreover, the average temperature increase in 10 subjects with skin type VI, after exposure to the study device with several passes, was still considerably lower (3.8°C) than with the commercial device (6.2°C) for the 11 subjects with skin type IV (with a single pulse).

When evaluating hair reduction effectiveness, overall hair reduction of nearly 60% was achieved for the treatment areas (axilla, arms, and legs) in the maintenance side of the study. The nonmaintenance side had 44% hair reduction at 3 months, less than the maintenance side but still a significant percentage. These data demonstrate that, although the initial results in both groups were similar, the effect of maintenance was to better sustain or prolong the hair removal results. It appears that continued maintenance may allow the patient a better ongoing clearance rate. As seen in the study by Wheeland,[16] home devices can be associated with permanent hair reduction.

Effectiveness did not appear to depend on skin type. Skin types I to IV and V to VI had similar outcomes for the maintenance side of the study. Legs and arms responded better than axillae, which may reflect a slower growth cycle.

Although home-use devices are considered to have lower efficacy than office-based lasers and light devices, the results from self-administered use are impressive.[17–19] In this study, 74% clearance was reported for legs that received maintenance treatments with the RF–IPL home hair-removal device.

Combining an optical source with a RF source for low-energy photoepilation has proven to provide safe and effective hair reduction treatment for all skin types, even skin types V and VI, in a home device. Further studies are needed to evaluate long-term hair reduction with this system. As these home devices become available, clinicians should familiarize themselves with the various available options to help patients assess their clinical choices. The clinical trials described herein support safe and effective use of a home hair-removal device for the first time for all skin types.

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