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ORIGINAL ARTICLE

Ultraviolet radiation after exposure to a low-fluence IPL home-use device: a randomized clinical trial

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Abstract The prevailing advice is to avoid sun exposure after intense pulsed light (IPL) hair removal. However, no systematic evaluation of ultraviolet radiation (UVR) after IPL hair removal exits. Therefore, we investigated the occurrence of side effects in subjects receiving solar-simulated UVR after a low-fluence IPL treatment with a home-use device. Sixteen subjects with Fitzpatrick skin types (FST) II-V were enrolled. Three constitutive buttock blocks (4.4×6.4 cm) were each subdivided into four sites, randomized to one IPL exposure of 0, 7, 8, or 10 J/cm^2 (spectral output 530–1100 nm). Blocks were randomized to no UVR or three standard erythema doses (SEDs) UVR either 30 min or 24 h after IPL. Follow-up visits were 48 h, 1 week, and 4 weeks after IPL. Outcome measures were (i) clinical skin reactions, (ii) reflectance measurements of erythema and pigmentation, and (iii) pain. Subjects with FST II–IV experienced no skin reactions up to 4 weeks after IPL, neither erythema, edema, blisters, crusting, textual, nor pigment changes. Reflectance confirmed no change in erythema and pigmentation ($p \geq 0.090$). UVR exposure induced erythema and increased pigmentation. The combination of IPL and UVR induced skin reactions not different to responses from UVR (IPL-UVR vs. UVR, $p \geq 0.164$). Pain was generally low (median 1, range 0–4) and correlated positively with fluence and pigmentation (Spearman's rho≥0.394, $p<0.001$). One subject with FST V experienced perifollicular hyperpigmentation after IPL and slightly more intense when exposed to UVR. A single UVR exposure of three SEDs either shortly or 1 day after low-fluence IPL causes no amplification of skin responses in constitutive skin of individuals with FST II–IV.

Keywords Adverse events · Hair removal · Home-use device · Skin type · Tanning

Introduction

Hair removal using laser and intense pulsed light (IPL) sources has been successfully employed since 1996 and continues to be an effective treatment option for reduction of unwanted hair growth [1, 2]. Initially, professional, high-powered laser and IPL devices (>20 J/cm^2) were introduced, followed more recently by low-fluence devices developed for at-home consumer use (<20 J/cm^2) [3].

The presumed mechanism of action for both professional and home-use hair removal with light-based devices is based on the concept of selective photothermolysis [4]. This hypothesis suggests that wavelengths adjusted to the absorption spectrum of melanin can reduce hair growth through selective thermal damage of cellular targets, i.e., stem cells in the bulge region and dermal papilla of the hair follicle [4, 5]. To this end, pulse durations close to or longer than the thermal relaxation time of melanin maximize efficacy with minimal side effects based on heat diffusion and the spacial separation between the target chromophore, melanin, and the alleged biological target, i.e., stem cells [6].

Light-based hair removal for home use continues to grow in popularity and availability; however, the shift from professional oversight to individual personal use brings concerns of consumer safety [7]. Presently, several home-use devices are

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available for light-based hair removal, operating with a variety of technical settings in terms of wavelengths (e.g., 810-nm diode laser, IPL range 400–1200 nm), pulse durations (e.g., <2–600 ms) and fluencies (e.g., 2–24 J/cm^2) [8]. Five of the available devices have been evaluated for side effects in clinical trials. Due to variations in technical specifications, the prevalence and severity of side effects are inconsistently reported. Overall, the most frequently reported side effects include erythema, edema, pigment change, crusting, and blistering which increase in prevalence and intensity with use of higher fluence level and darker skin pigmentation [8–18].

Since light-based hair removal tends to be performed in visible sun-exposed areas, it is an issue of concern whether ultraviolet radiation (UVR), before or after treatment, may increase the risk of side effects [7, 19, 20]. To reduce the likelihood of such events, it is generally recommended to avoid sun exposure and to use sunscreen before and after light-based hair removal [20]. Whereas this recommendation is regarded as "good advice," no data exist to support or refute any such interaction. Recently, we investigated the impact of UVR before low-fluence IPL and found that natural skin pigmentation (constitutive) and UVR-induced skin pigmentation (facultative) at identical measures of darkness increases the risk of low-fluence IPL-induced side effects to a similar extent [21]. However, the impact of UVR after low-fluence IPL remains to be investigated.

Skin reactions induced by low-fluence IPL are predominantly transient, i.e., erythema, which indicates that IPL-exposed skin might be most vulnerable to UVR exposure shortly after treatment. We therefore designed a randomized clinical trial to investigate the occurrence of side effects in subjects receiving UVR shortly after exposure to a low-fluence IPL home-device and further investigated whether a potential risk would be reduced when UVR is given 1 day after IPL.

Materials and methods

Subjects

Sixteen healthy males and females were recruited. Inclusion criteria were 18 years of age or older and Fitzpatrick skin types (FST) II-V [22]. Exclusion criteria were moles, freckles, tattoos, suntan, or previous hair removal in the test areas and immunosuppressive medication within 30 days of inclusion. Subjects were given verbal and written information about the study and signed informed consent prior to inclusion. The study was approved by the Danish National Committee on Health Research (H-2-2013-103) and conducted at the Department of Dermatology, Bispebjerg Hospital, from August to October 2013.

Study design

The study was designed as a blinded physician evaluated, randomized intra-individual controlled trial with three buttock blocks per subject. As illustrated in Fig. 1, each block (4.4× 6.4 cm) was divided into four sites, randomized to receive one IPL exposure of 0, 7, 8, or 10 J/cm^2. After IPL exposure, blocks were further randomized to receive no UVR (Fig. 1a), three standard erythema doses (SED's) of solar-simulated UVR 30 min (Fig. 1b), or 24 h (Fig. 1c) after IPL, resulting in a total of 12 interventions (Fig. 1). Randomization of IPL fluencies and UVR vs. no UVR was performed separately by computer-generated sequences, and allocations were contained in opaque, sequentially numbered, concealed envelopes.

Follow-up visits were conducted at 48 h, 1 week, and 4 weeks after IPL exposure. The clinical evaluator (A.M.E) and study subjects were blinded for IPL fluence and UVR.

Reflectance

Skin erythema and pigmentation were measured objectively by reflectance spectroscopy using UV-Optimize Scientific 558 (Chromo-Light, Espergaerde, Denmark). The spectroscope measures skin reflectance at peak wavelengths of 558 and 660 nm where the discrimination between light absorption in melanin and hemoglobin is maximal [23]. Skin erythema and pigmentation were quantified on a linear scale from 0 to 100 %. Zero percentage pigmentation corresponds to no pigmentation and 100 % to the darkest skin possible with no light reflected, whereas 0 % skin erythema corresponds the reflectance from a blood-drained skin area and 100 % skin erythema to a highly vascular skin lesion, i.e., naevus flammeus. The methodology is previously described in detail [24].

UVR exposure

A single UVR dosage of three SED was given to each subject at 30 min and 24 h after IPL, using a Solar Simulator (Chromo-light, Espergaerde, Denmark). Three SEDs correspond to 30-min sun exposure in the middle of a summer day in Denmark and is considered a clinically relevant dosage, i.e., enough to elicit a noticeable skin response [25]. The UVR spectrum is illustrated previously [21]. Radiation intensity was measured with a spectro-radiometer (Sola-Hazard; Solatell, Cornwall, UK).

IPL exposure

IPL exposures were performed with "iPulse/Smooth Skin Plus" home-device (Boots UK Limited, Nottingham England NG2 3AA). The device is a filtered broadband system that delivers IPL at 530–1100 nm through a spot size of

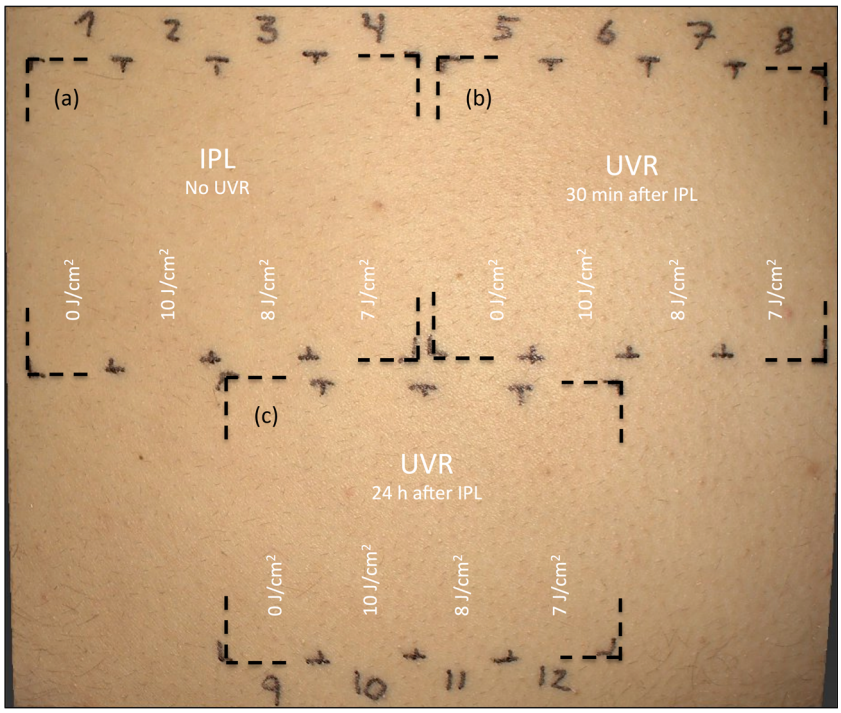

Fig. 1 Photograph illustrates the study setup. Three buttock blocks (**a**–**c**) were each divided into four sites, randomized to receive IPL of either 0, 7, 8, or 10 J/cm^2. Blocks were further randomized to receive 0 (**a**) or 1 solar-simulated UVR either 30 min (**b**) or 24 h (**c**) after IPL exposure

3 cm^2 using fluence levels of 7 J/cm^2 (i.e., 74-ms double pulse 17 ms on, 40 ms off, 17 ms on), 8 J/cm^2 (i.e., 45-ms double pulse 15 ms on, 15 ms off, 15 ms on), and 10 J/cm^2 (i.e., 40-ms double pulse 15 ms on, 10 ms off, 15 ms on). All exposures were performed by D.T.P.

Outcome measures

Clinical skin reactions

Blinded on-site evaluation of erythema, edema, blisters, crusting, textural, and pigment changes was performed immediately, 30 min, 24 h, 48 h, 1 week, and 4 weeks after IPL exposure. Each skin reaction was assessed using a 4-point scale (i.e., none, low, medium, high intensity). Photos were taken under standardized conditions and used for documentation.

At the same time-points, skin reflectance measurements of erythema and pigmentation were performed. For each intervention, change in reflectance measurements was calculated by the following equation: $\text{Change} = \text{Reflectance} - \text{Reflectance}_{(\text{Baseline})}$.

Pain

Subjects quantified pain intensities during IPL exposure immediately after treatment for each fluence level separately, using a visual analogue scale (VAS) in which 0=no pain and 10=worst imaginable pain.

Statistics

A minimal relevant difference of 20 % was expected for erythema with an SD of 25 %. A total of 13 subjects were required to complete the study, using a significance level of 5 % and a power of 80 % in a paired setting. Because a drop out of approximately 15 % was anticipated, we included a total of 16 subjects.

Non-parametric statistics was used, and descriptive data were presented with medians and ranges. For each block separately, change in reflectance measurements after 7, 8, and 10 J/cm^2 IPL was compared to change after 0 J/cm^2 IPL (control), using Wilcoxon matched-pairs test. Spearman's rank correlation was used to analyze correlations. *P* values less than 0.05 were considered significant. All statistics were performed using SPSS version 20.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Study population

All 16 subjects completed the study protocol. The participants consisted of 13 males and 3 females with a median age of 25 years (range 18–34). FST distribution included FST II (n=7), FST III (n=4), FST IV (n=4), and FST V (n=1) with a median of 12 % skin pigmentation at baseline (range 3–51 %). The subject with FST V was evaluated separately since he was the only FST V. Demographics are shown in Table 1.

Table 1 Subject characteristics

Subject ID	Age (years)	Gender (M/F)	FST (II–IV)	Baseline reflectance	
				Pigment %	Erythema %
1	22	M	II	2.9	28.7
2	21	M	II	3.8	30.0
3	19	M	II	6.7	27.0
4	22	M	II	7.2	27.0
5	21	M	II	8.0	25.3
6	18	F	II	8.4	25.1
7	25	M	II	9.5	22.8
8	22	M	III	9.7	29.0
9	28	M	III	14.1	23.9
10	22	F	III	15.6	24.4
11	21	F	III	15.8	22.0
12	22	M	IV	17.0	21.7
13	21	M	IV	18.2	20.5
14	30	M	IV	26.9	21.5
15	21	M	IV	35.0	10.3
16[a]	34	M	V	51.3	6.5
Median	25			11.8	22.8
Median (FST II)			n=7	7.2	27.0
Median (FST III)			n=4	14.9	24.1
Median (FST IV)			n=4	22.6	21.0
Median (FST V)			n=1	51.3	6.6

M male, *F* female, *FST* Fitzpatrick skin type

[a] Subject 16 is evaluated separately throughout the paper

Clinical skin reactions

As illustrated in Fig. 2, subjects with FST II–IV experienced no clinical skin reactions up to 4 weeks after a single IPL exposure of 7, 8, or 10 J/cm^2. Reflectance measurements confirmed no significant change in erythema or pigmentation up to 4 weeks after IPL (IPL vs. no IPL, $p \geq 0.090$). Skin exposed to UVR responded with erythema and increased pigmentation, validated by reflectance ($p \leq 0.001$). Reactions in skin exposed to UVR, either 30 min or 24 h after IPL, were not different from those produced by UVR alone, neither clinically nor by reflectance (UVR vs. IPL-UVR, $p \geq 0.164$). Clinical skin reactions are visualized in Fig. 2, and reflectance data are presented in Table 2.

One subject with FST V experienced mild erythema 48 h after IPL exposure of 10 J/cm^2, which resolved with mild perifollicular hyperpigmentation at 1-week follow-up. Skin reactions were slightly more intense in skin exposed to UVR either 30 min or 24 h after IPL of 10 J/cm^2.

Pain

Pain intensities during IPL exposure are presented in Table 3. Pain reached low to moderate intensities (median 1, range 0–4) and correlated positively with IPL fluence (spearman's rho=0.667, $p<0.001$), FST (spearman's rho=0.394, $p<0.001$), and skin pigmentation, measured by reflectance (spearman's rho=0.402, $p<0.001$). The subject with FST V experienced pain intensities of median 3 (range 2–5).

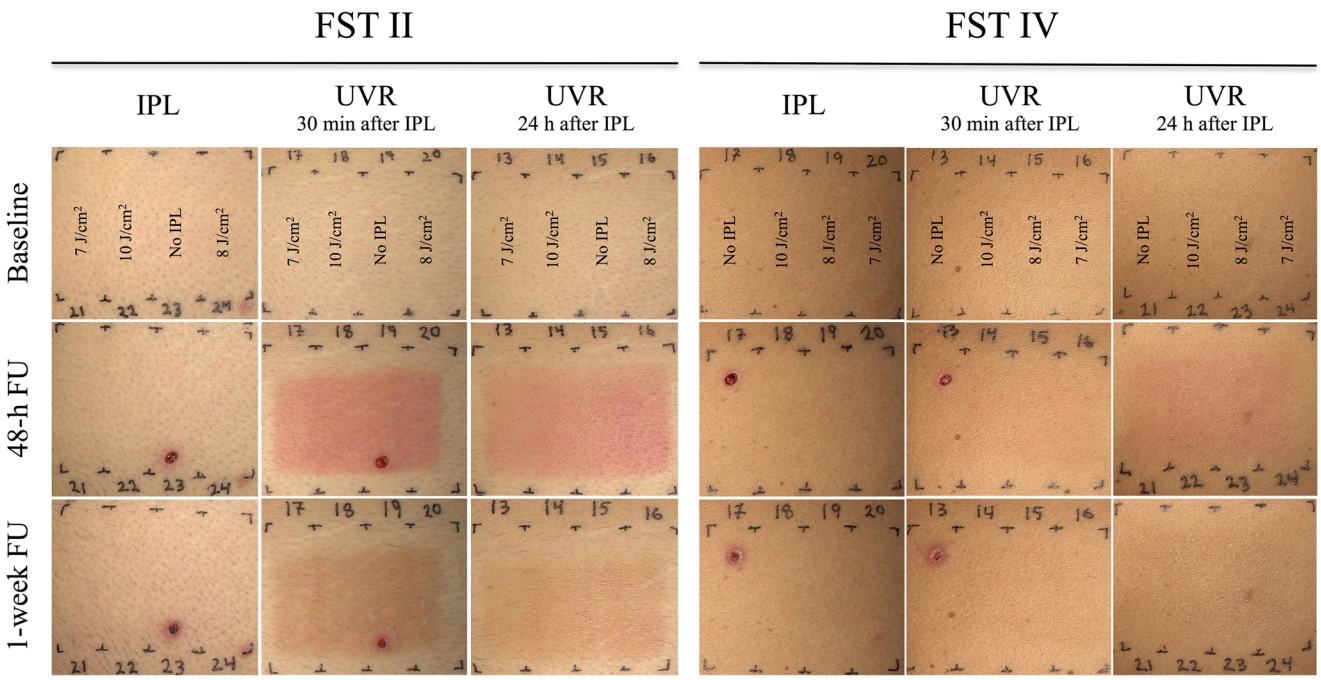

Fig. 2 Photographs show test blocks at baseline, 48 h, and 1 week follow-up (FU) in Fitzpatrick skin types (FST) II and IV. No skin reactions are seen after IPL of 7, 8, or 10 J/cm^2. Skin erythema and skin pigmentation increased significantly after UVR (no IPL). A combination of IPL and UVR either 30 min or 24 h after IPL induced skin reactions similar to skin responses from UVR

Table 2 Reflectance measurements in FST II–IV

	UVR 30 min after IPL				Compared to no IPL	UVR 24 h after IPL				Compared to no IPL
	No IPL	7 J/cm^2	8 J/cm^2	10 J/cm^2		No IPL	7 J/cm^2	8 J/cm^2	10 J/cm^2	
Erythema (%)										
Baseline	24.3	25.2	23.7	24.3		24.4	23.8	24.3	24.3	
24 h follow-up	40.9	40.5	39.1	41.7		25.0	23.8	26.4	24.5	
Change	16.6	15.0	14.1	15.0	$p \geq 0.552$	0.2	0.0	0.3	−0.2	$p \geq 0.337$
48 h follow-up	36.3	36.9	35.6	38.0		35.9	39.5	38.4	37.9	
Change	7.4	9.3	9.9	12.3	$p \geq 0.261$	12.1	12.5	13	13.4	$p \geq 0.334$
Pigment (%)										
Baseline	10.1	13.0	11.5	12.2		12.0	10.2	8.9	9.3	
1 week follow-up	14.5	15.0	14.1	15.9		16.4	17.6	16.4	16.1	
Change	4.3	4.3	3.4	4.5	$p \geq 0.167$	3.8	3.7	3	5.1	$p \geq 0.164$
4 weeks follow-up	14.5	15.4	16.6	17.2		14.6	15.5	14.7	16.2	
Change	1.9	3.2	2.8	2.3	$p \geq 0.183$	3.4	2.7	3.0	2.7	$p \geq 0.237$

The table shows median skin erythema % and skin pigment % at selected follow-up visits. Raw data from blocks randomized to ultraviolet radiation (UVR) at 30 min and 24 h after IPL is presented. *p* values represent Wilcoxon test results comparing reflectance changes in skin exposed to UVR at 30 min or 24 h after IPL of 7, 8, and 10 J/cm^2 to changes in skin only exposed to UVR (no IPL)

Discussion

This is the first blinded, randomized controlled trial to investigate the impact of a single UVR exposure after low-fluence IPL in constitutive skin of subjects with FST II-V. Under circumstances in the present study, we found no amplification of skin responses in constitutively pigmented skin of subjects with FST II–IV, when exposed to three SEDs of solar-simulated UVR 30 min or 1 day after low-fluence IPL. These findings suggest that home-use, low-fluence IPL treatment may not sensitize skin to damage from incidental sun exposure. However, in accordance with current recommendations from authorities including American Academy of Dermatology and Skin Cancer Foundation, avoidance of sun exposure and use of sunscreen are recommended for all individuals to help diminish the adverse skin effects of UVR [26].

In the present study, individuals with FST II-V and hair of various colors, thickness, and quantity were exposed on healthy constitutively pigmented buttock skin to an IPL home-device with spectral output of 530–1100 nm, pulse durations of 40 to 74 ms (double pulse), and fluence levels of 7 to 10 J/cm^2. Subjects with FST II–IV experienced no skin reactions up to 4 weeks after IPL; however, one subject with FST V responded with mild erythema and mild perifollicular post-inflammatory hyperpigmentation after IPL of 10 J/cm^2. This indicates that settings used in the present study are safe in FST II–IV and further suggests a threshold for side effect at 10 J/cm^2 in FST V. In a previous study, Emerson et al. investigated the efficacy and safety of an IPL home-use device similar to the one used in the present study [11]. A total of 29 individuals with skin types I-III and dark to medium brown hair received three weekly IPL treatments and experienced significant hair reduction of 44 % at 3 months and 41 % at 6 months after the final treatments. The authors reported that no side effects were observed during or immediately after treatment and neither reported later by study participants. Only mild erythema was noted immediately after IPL exposure, further supporting that settings used in the present study are safe in fair to moderately pigmented individuals. However, studies evaluating safety of low-fluence laser and IPL home-devices with technical specifications that differ from the device in the present study report cases of erythema, edema, pigment change, crusting, and blistering which increase in prevalence and intensity with use of higher fluence level and darker skin pigmentation [8–18].

Table 3 Pain intensities during IPL in FST II–IV

		0 J/cm^2	7 J/cm^2	8 J/cm^2	10 J/cm^2
FST II	n=7	0 (0–0)	0 (0–1)	0 (0–1)	1 (0–2)
FST III	n=4	0 (0–1)	1 (0–2)	1 (0–3)	2 (1–4)
FST IV	n=4	0 (0–0)	1 (0–2)	2 (1–3)	2.5 (1–4)
FST II–IV	n=15	0 (0–1)	0 (0–2)	1 (0–3)	2 (0–4)

FST Fitzpatrick skin type

To reduce the risk of side effects after IPL, it is generally recommended to avoid sun exposure light-based hair removal [20]. To investigate this potential interaction, we exposed individuals to three SEDs of UVR 30 min and 24 h after a single exposure of low-fluence IPL. Subjects with FST II–IV responded with erythema and increased pigmentation, but more interestingly, these skin reactions were similar to responses induced from UVR alone, regardless of whether UVR was given 30 min after or 24 h after IPL. However, it is important to note that these individuals experienced no clinical skin

reactions after IPL exposure. Interestingly, one subject with FST V responded with mild erythema and perifollicular post-inflammatory hyperpigmentation after 10 J/cm^2 IPL, which were slightly more intense in skin exposed to UVR after IPL. These findings indicate a possible risk of UVR exposure to skin with IPL-induced erythema and after low-fluence IPL in dark skin complexions (FST V-VI). Importantly, subjects in the present study only received a single IPL exposure, while multiple IPL treatments are required to maintain IPL-induced hair removal. Since UVR increases the amount of epidermal melanin, UVR after IPL will most probably compromise successive IPL treatments due to competitive light absorption by epidermal melanin [21]. Thus, UVR exposure after low-fluence IPL does not amplify skin responses but may theoretically increase the risk of side effects at following IPL treatments due to UVR-induced skin pigmentation [21].

Post-inflammatory hyperpigmentation has previously been associated with UVR after IPL, based on anecdotal evidence and a single retrospective case study [7, 19, 20, 27]. Under the standardized controlled settings used in the present study, we found no such relation. There are several possible study limitations that might limit extrapolation of our findings: Treatments were performed on healthy, non-UVR-exposed buttocks, and thus, results do not represent situations where treatments are performed on diseased skin, e.g., melasma, or on facultative, UVR-exposed skin. No subject with FST II–IV experienced clinically visible skin reactions after IPL, and results therefore may differ in skin with visible, IPL-induced reactions. Because results from one subjects with FST V showed a tendency of interaction between IPL and subsequent UVR, inclusion of more subjects with darker skin complexions might have altered results from the present study. We exposed subjects to a fixed UVR dosage of three SEDs and different doses as well as multiple exposures of UVR after low-fluence IPL might increase the occurrence of side effects. Future studies have to clarify whether observations found in the present study are also true in skin with clinical IPL-induced skin reactions, in darker skin complexions (FST V-VI), in facultative skin, and for other home-use devices as well as professional devices using different technical specifications and higher fluencies.

In conclusion, we found that a single UVR exposure of three SEDs either shortly or 1 day after low-fluence IPL causes no amplification of skin responses in constitutive skin of individuals with FST II–IV. However, due to the carcinogenicity of UVR, we still believe that UVR should not be recommended.

Conflict of interest D.T.P., A.M.E., P.A.P., and H.C.W. have no conflicts of interest.

J.F.N. and F.B. are employees at The Procter & Gamble Company.

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