EFFECTS OF FLUENCE AND PULSE DURATION FOR FLASHLAMP EXPOSURE ON HAIR FOLLICLES

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Presented at the 21st Annual Meeting

of the American Society for Laser Medicine & Surgery, April 2001

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SUMMARY

Aim of this work was to optimize parameters of a lamp-based photoepilation system in order to provide highly efficient and safe hair management, while maintaining low system costs. Roles of the short wavelength spectrum cut-off, the spotsize of the beam, and the pulsewidth have been analyzed. The optimal values of these parameters have been established. The choice of the parameters has been substantiated by an *in vitro* study. The latter revealed that by using the optimized set of parameters, a histologically significant damage to the hair bulb could be produced at fluence levels as low as 5 J/cm^2. The optimal set of parameters has been implemented in a prototype lamp-based photoepilation system (Palomar EsteLux). Preliminary *in vivo* studies of the prototype have been conducted. Safety profiles of the treatment and medium-term (up to 4 months) efficacy have been assessed. The feasibility of achieving long-lasting reduction of hair re-growth has been demonstrated.

INTRODUCTION

Since 1996, lasers and high-intensity lamps have been successfully used for hair removal. The procedure can be termed more precisely as hair growth management using light. Hair growth management includes several effects: growth delay, changing of hair growing rate, hair miniaturization, changing of hair pigmentation, and permanent hair loss. It was demonstrated that all these effects could be achieved by light. Growth delay is usually close to hair growth cycle and requires minimal light energy. Higher light energies have to be employed for miniaturization and depigmentation. Finally, for permanent hair loss, one needs maximum light energy that can be delivered into the skin without damaging the epidermis.

Melanin is the principal target chromophore for hair management with light. Since melanin is found not only in hair follicles but also in the epidermis. During photoepilation it is not possible to heat hair follicle without heating the epidermis. A key point of good photoepilation technology is to choose parameters of the procedure in such a way as to produce maximum temperature rise at the hair follicle while maintaining the temperature of the basal layer of epidermis below the cell damage threshold. This requirement can most easily be met for very fair skin and dark hair, because the ratio of the melanin concentration in the hair and in the epidermis is high. The combination of low pigmented thin hair and dark skin, on the other hand, presents a challenge to designers of photoepilation systems. Obviously, the ratio of the melanin concentration in the hair to that in the epidermis is a natural characteristic of a subject and out of the designer's control. However, the problem can be rectified by optimizing the ratio of the light energy density in the hair to that in the epidermis. In contrast to melanin concentrations, energy densities depend greatly on the particular

design of the photoepilation system. Specifically, the light energy density in the hair matrix (depth equivalent to the hair follicle length) and in the hair shaft at the bulge area (depth 1-2 mm) should be maximized with respect to the light energy density in the basal level of the epidermis. This goal can be achieved by careful selection of the wavelength spectrum, size of the light beam, and distribution of the light energy over the cross-section of the beam. These parameters are of paramount importance for safe and effective photoepilation. An additional protection of epidermis can be achieved by cooling the skin surface before treatment (referred to as pre-cooling) and extracting heat from the epidermis during the light pulse (referred to as parallel cooling).

Laser-based photoepilation systems use lasers of several types: ruby, alexandrite, diode, Nd:YAG. Lamp-based systems use flash (arc) lamps. A number of comparison studies aimed at selecting the best photoepilation system have been done. However, different users have different comparison criteria. When performance/cost ratio is the main criterion, it appears that, at the present stage of technology, lamp-based systems may have a competitive edge over laser-based systems.

The aim of this work was to find optimal parameters of the arc-lamp-based photoepilation system. The goal of the optimization was to maximize efficacy and safety of the procedure, while keeping the cost of the system under a reasonable limit. We performed computer optimization of system parameters, including the spot-size, the pulsewidth, the fluence, and the "working" spectrum of the device. In order to substantiate the simulation results, a detailed *in vitro* study of the hair follicle destruction has been done. In this study, an experimental Palomar arc lamp system was used. Damage thresholds for hair matrix and for hair follicle have been established. These thresholds were then used to formulate design parameters for a low cost photoepilation system. The parameters have been implemented in the Palomar EsteLux prototype, which underwent an *in vivo* study. In the first phase of the *in vivo* study, the safety profile of the treatment has been investigated for a selected range of parameters. In the second phase, a preliminary assessment of the efficacy of the hair growth management has been made.

THEORETICAL CONSIDERATION

Main Differences Between the Lamp and the Laser

Both laser and lamp can be effective tools for photoepilation. When broad spectral output of the lamp is limited with a band-pass filter to a yellow through near-infrared wavelength range (between 550 and 1200 nm), the efficiency of its absorption by melanin becomes similar to that of the alexandrite laser (755 nm). That compares favorably with the diode laser (800 nm), and even more favorably with the neodimium laser (1064 nm). However, with equal initial spotsizes, incoherent light from the lamp typically penetrates into the skin not as deep as laser radiation, because of the high divergence and the rapid attenuation of the short-wavelength components. But when the spotsize of the lamp beam is made significantly larger than that of the laser beam, penetration becomes comparable.

Figure 1 shows a typical raw output spectrum of a lamp (blue curve) and the "working" spectrum produced by filtering (red curve). On the short wavelength side, it is limited by an absorbing or reflecting filter, which is incorporated into the handpiece.

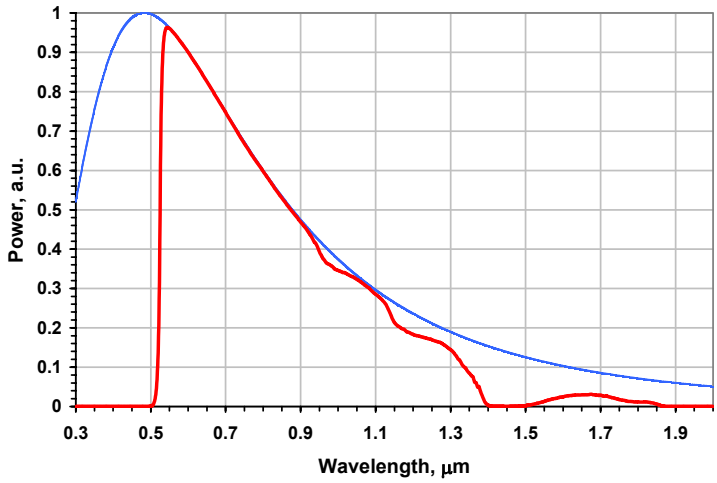


Figure 1. Raw lamp spectrum (blue curve) and spectrum of the same lamp after filtering with a 2 mm water filter and a longpass filter with the cut-off wavelength λ_s of 525 nm (red curve). The color temperature of the lamp plasma is 6000 K.

The cut-off wavelength λ_s can be adjusted by changing the longpass filter. On the long wavelength side, the optical absorption of melanin decreases dramatically after 1200 nm. Therefore, the long-wavelength components of the lamp spectrum do not contribute significantly to the energy deposition at a melanin target. However, this infrared light can produce non-selective heating of the dermis and subdermal tissues due to water absorption. Highly absorbable components of the infrared spectrum ($1300nm<\lambda<1500nm$, $\lambda>1800nm$) should be removed because they are absorbed in the epidermis and shallow dermis and can produce significant pain. A water filter is used for this purpose.

Figure 2 demonstrates the thermal effect on a melanin-rich target as a function of the cut-off wavelength λ_s. For comparison, the thermal effects of ruby, alexandrite, diode, and neodymium lasers on the same target are also shown.

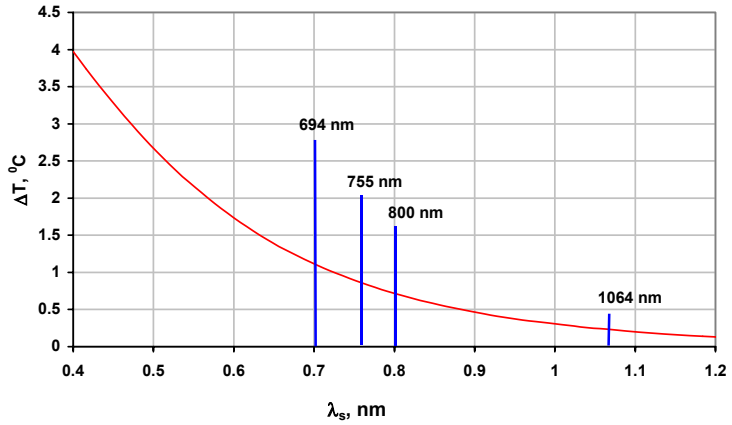


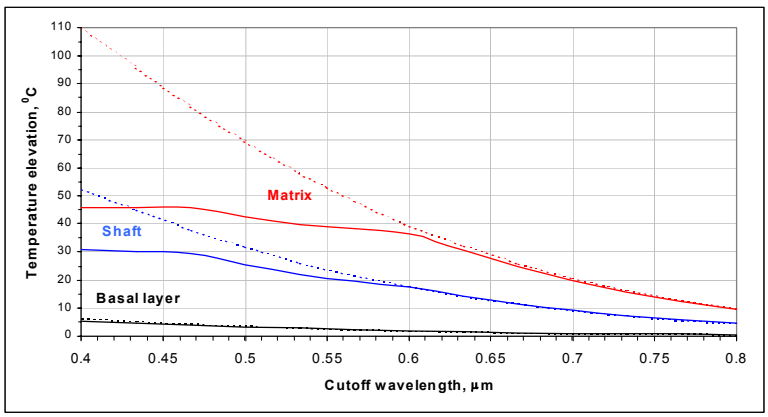
Figure 2. Temperature rise for a melanin-rich target heated by light with a unit fluence (1 J/cm^2) received from different lasers (694 nm - ruby laser, 755 nm - alexandrite laser, 800 nm - diode laser and 1064 nm – neodimium laser) or from a lamp with varying cut-off wavelength λ_s. Color temperature of the lamp plasma is 6000 K.

The thermal effect on a target in the tissue is characterized by the temperature rise of a target with the same melanin content (in our case, the absorption coefficient α of the melanin-containing target is approximately 10 cm^{-1} at 700 nm) produced by the adiabatic absorption of 1 J/cm^2 of the light energy. As shown in Figure 2, the thermal effect of the lamp with λ_s= 480 nm is equal to the ruby laser (694 nm), λ_s= 570 nm is equal to the alexandrite laser (755 nm), λ_s= 620 nm is equal to the diode laser (800 nm), and λ_s= 920nm is equal to the neodimium laser (1064 nm). Therefore, from the melanin absorption criterion, the lamp has a thermal efficiency similar to most lasers used for photoepilation. One important difference between the lamp and the laser is a higher divergence of the lamp beam in comparison to the laser beam. Because of the high divergence and presence of the short-wavelength components prone to strong scattering in the skin, the penetration depth of the lamp beam is less than that of a laser beam with the same thermal effect on a melanin-rich target. This disadvantage of the lamp can be partially compensated by increasing dimensions of the lamp beam. Thence, by carefully optimizing parameters of the lamp beam, such as the cut-off wavelength and the beam size, performance of a lamp-based photoepilation system can be increased to match a more expensive laser-based system.

Effect of the Short Wavelength Spectrum Cut-off

Choice of the short wavelength cut-off of the lamp spectrum is governed by the same principles as selection of laser wavelength in case of a laser-based system. Shorter wavelengths are better suited for moderately pigmented skin and hair. Longer wavelengths are more suitable for highly pigmented skin and hair. Figure 3 shows the temperature rise in the epidermis, the hair shaft (1-mm depth), and the hair matrix (3-mm depth) as a function of the cut-off wavelength λ_s. Simulations have been performed for skin types II and VI. The concentration of melanin in the epidermis of skin type VI is 15 times higher than in the epidermis of skin type II. For the hair shaft and the hair matrix, a melanin content typical for dark brown hair has been assumed. The pulsewidth was shorter than the thermal relaxation time of either the epidermis, the hair shaft, or the hair matrix. Equal fluence was assumed for all λ_s's.

As shown in Figure 3, the temperature elevation is increasing with shorter λ_s's for the epidermis and the hair shaft. For the hair matrix, it starts to saturate for the cut-off wavelength of about 600 nm, due to blood absorption. Compressing skin eliminates this effect and makes it possible to use shorter λ_s's, which are more effective thermally. For skin type II, the contrast ratio of the temperature elevations at the hair shaft/matrix and at the basal layer is higher than 10 for all cut-off wavelengths.



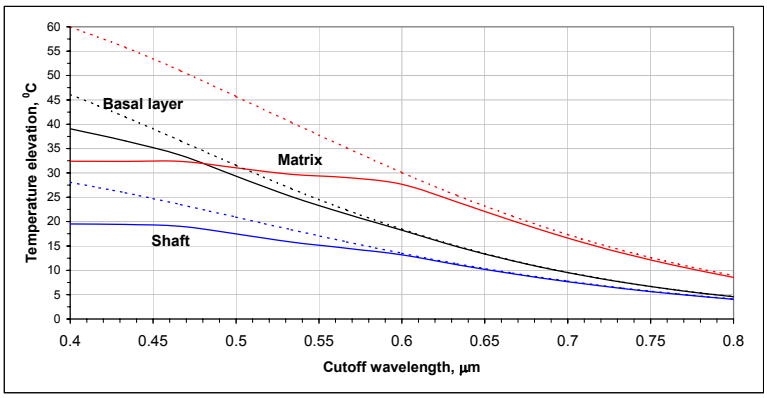


Figure 3b

Figure 3. Temperature elevations in the basal layer (black curves), the hair shaft (1 mm depth, blue curves), and the hair matrix (3 mm depth, red curves) as a function of the cut-off wavelength λ_s for skin type II (Figure 3a) and type VI (Figure 3b) for normal (solid curves) and compressed (dotted curves) skin.

Thus, selective damage of the hair follicle without damage to the epidermis can be achieved with the broad-spectrum light from the lamp. For skin type VI, the temperature elevation of the basal layer is higher than the temperature elevation of the hair shaft and close to that of the hair matrix. As a result, producing thermal damage of the hair follicle without damage to the epidermis requires a very effective protection of epidermis by selective pre-cooling and parallel cooling, as well as using a longer cut-off wavelength.

Effect of Spotsize

The spotsize is more critical for the lamp beam than for the laser beam. Figure 4 shows the thermal effect on the melanin-containing target in the tissue for a lamp beam of varying size. Polychromatic Monte Carlo modeling was done for the following conditions: beam size 16 mm x 46 mm, λ_s of 525 nm, beam coupled into the skin through a sapphire waveguide (Figures 4a,c); and beam size 8 mm x 34 mm, λ_s of 695 nm coupled into the skin through a quartz waveguide (Figures 4b,d). Skin type II has been assumed.

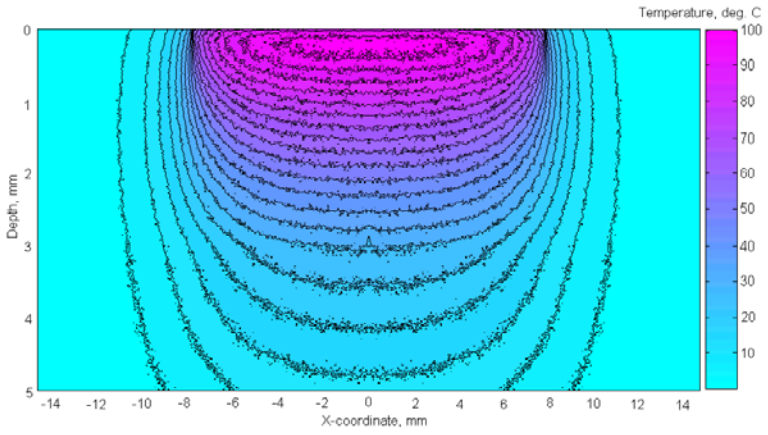


Figure 4a

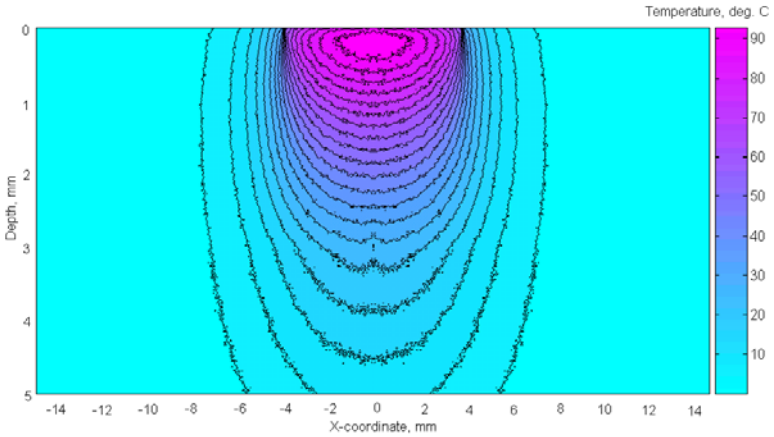


Figure 4b

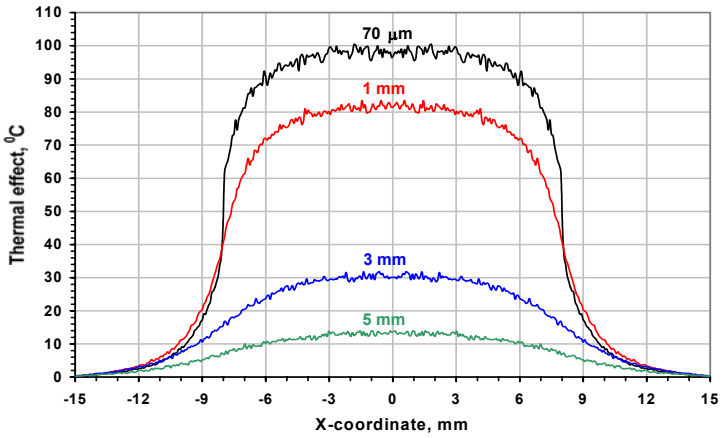


Figure 4c

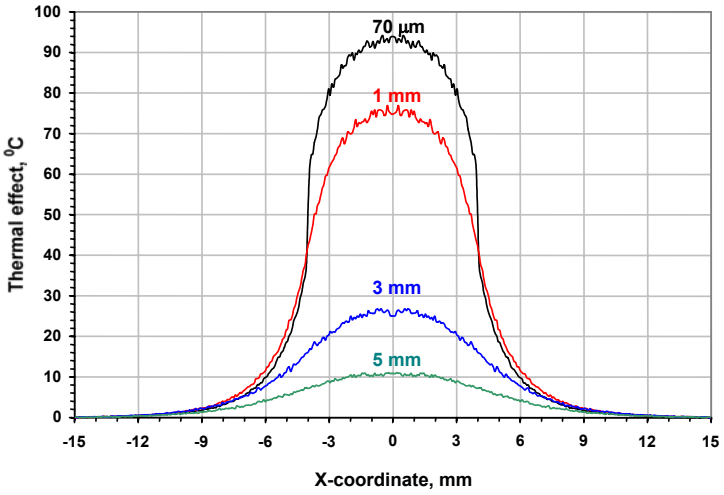


Figure 4d

Figure 4. The thermal effect on the melanin-containing target in the skin for 16 mm- and 8 mm-wide lamp beams with equal fluences on the skin surface. Figures 4a (16-mm beam) and 4b (8-mm beam) show 2D distribution of the thermal effect on the melanin-containing target in the vertical cross section of the skin.

Figures 4c (16 mm beam) and 4d (8 mm beam) show the thermal effect on the melanin-containing target as a function of lateral coordinate at the depth of the epidermis (70 μm, black curve), the bulge (1mm, red curve) and the bulb (3mm, blue curve and 5mm, green curve).

As can be seen from Figure 4, the larger lamp beam produces a higher thermal effect. In addition, the temperature profile produced by the 16-mm beam in the 1- to 5-mm depth is closer to a flat-top curve, while the result for 8-mm beam is closer to a Gaussian beam. For uniform treatment of multiple deep targets, such as hair follicles, without overlapping, it is highly desirable to have a flat-top temperature profile. Our simulations have demonstrated that the beam profile can be maintained flat for depths of more than 3 mm when the initial beam is wider than 15 mm.

Percentage of light reflected from the skin in the broad wavelength spectrum of the lamp varies from 10-20% for dark skin to 40-60% for fair skin. Returning this substantial energy into the skin greatly increases the efficacy of the treatment. This phenomenon is known as photon recycling. Apparently, gain of the light energy due to the photon recycling is higher for light skin types than for dark ones. This is an attractive feature of this technique, because darker skin types require milder regiments of irradiation, as discussed above. Thus, photon recycling "self-adjusts" to the type of skin. The gain of light energy due to the photon recycling depends strongly on the beam size. For a 16-mm beam and fair skin, photon recycling can achieve a gain of 1.5 to 2 times. Special handpiece design is required to realize this gain. For smaller beam sizes, the gain factor of photon recycling is always lower than for large beam sizes.

Effect of Pulsewidth

Pulsewidth requirements for lamp-based photoepilation are the same as for laser-based systems. However, the high divergence of the beam and the broad spectrum of light increase the risk of overheating the epidermis. Thus, the correct choice of pulsewidth becomes a critical design consideration. For better protection of the epidermis, the pulsewidth should be longer than the thermal relaxation time of the epidermis (10 to 20 ms). For additional advantages of parallel cooling, the pulsewidth should be significantly longer than 50 ms. The thermal relaxation time of the hair matrix is in the range between 0.3 and 10 ms. Therefore, an optimal pulsewidth for thermal damage of the hair matrix and arresting hair growth should be close to 10 ms, where it is still safe for the epidermis and does not require significant fluence to damage the hair matrix. The thermal relaxation time of the terminal hair follicle is in the range of 20 to 100 ms depending on hair size. For thermal destruction of the entire follicle, including stem cells, the pulsewidth can be comparable or longer than the thermal relaxation time of the hair follicle. As a result, an optimal pulsewidth for permanent photoepilation can be between 20 and 1000 ms. Longer pulse requires higher fluence, which for large spot size demands very high total energy output. When the total energy is limited, the optimum pulsewidth for permanent photoepilation lies in the range of 20 to 100 ms.

In Vitro Study

The goal of this study was to evaluate the thermal damage of different target structures of the hair follicle over a wide range of fluences and pulse widths (Table 1) for optimized spot size and spectrum.

Materials and Methods

Post-mortem scalp skin of one donor with light skin and dark brown hair (d= 68±12 m) was used for the experiments. The sample was procured 8 hours post mortem, frozen, and stored at -80°C. The hairs of the post-mortem scalp sample were shaved before exposure. From this sample, 6-mm punch biopsies were obtained. The biopsies were placed into human, hairless, post-mortem back skin of 3x3 cm^2 size and 1.5-cm thickness that was serving as a frame. In order to obtain good fit, an opening was prepared in the hairless back skin using a 5-mm skin punch. The entire sample was placed on a temperature-controlled plate (37°C).

The exposures were performed with an experimental Palomar flashlamp system with the emission spectrum shown in Figure 1. The light was delivered through a sapphire waveguide with passive cooling and an aperture of 16 x 46 mm^2. The range of fluences tested was from 6 J/cm^2 through 25 J/cm^2 and the pulsewidths ranged from 6 ms to 100 ms. All tested parameters are listed in Table 1. Additional exposures (marked in Table 1 with *) in the fluence range between 4 J/cm^2 and 6 J/cm^2 were performed on tissue of a different donor with similar hair pigmentation and diameter. For comparison, the samples from the same donor were irradiated with a LightSheer prototype (Coherent, Inc.) at 30 J/cm^2 and 40 J/cm^2 at pulsewidths of 30, 100, and 200 ms. The samples were evaluated for thermal damage of the hair shaft and the hair follicle at the infundibulum, bulge, and bulb level. A new grading system was used to categorize different levels of thermal damage at different structures of the tissue.

Histochemical technique: The samples were processed in transversal frozen sections of 15- m thickness, and a histochemical evaluation of lactate dehydrogenase (LDH) activity was performed as described by Balogh and co-workers (NBTC stain). Representative micrographs were taken at a level close to the bulge and bulb. The following grading system was used to categorize the degree of thermal damage in different structures of the tissue.

Grading system: In order to categorize the extent of thermal damage at different structures, of the hair follicle a new 7-level grading system was used. Since only transversal sections were evaluated, epidermal damage could not be assessed. The samples were graded blindly by one of the investigators (DM) and categorized according to the grading system. The accuracy of the 7-level relative grading system is estimated to be about ± 1 level.

Hair shaft damage: evaluation within infundibulum level

0- no evidence for any alteration related to exposure
1-borderline, occasional alterations (beginning cavity formation)
2-minor, alterations of coarse hair shafts (cavity formation, no browning)
3-coarse and medium hair shafts altered, cavity formation, occasional browning may occur
4-browning of hair shafts present
5-browning of most medium and coarse hair shafts
most of hair shafts demonstrate browning or ablation, only vellus hairs remain unaltered

Infundibulum damage: evaluation within supra sebaceous gland level

0-no evidence for any alterations related to exposure

1-borderline, occasional alterations (some specific decrease of NBTC stain at outer root sheath (ORS))
2-minor, occasional alterations (loss of NBTC stain; partially within ORS)
3-most hair follicles (HF) demonstrate parts of the ORS with decreased NBTC stain, occasionaly complete loss
4-most HF with complete or quasi complete damage or loss of NBTC stain at ORS
5-loss of NBTC within complete ORS of most HF with medium to coarse hair shaft (HS)
6-most of the HF have complete loss of NBTC stain within ORS, some loss of NBTC stain in perifollicular tissue, only vellus hair follicles not altered

Bulge damage: evaluation at the bulge level, all damage evaluation for single hairs

0-no evidence of any light specific alteration
1-borderline, occasional alterations (some specific decrease of NBTC stain at ORS)
2-minor, occasional alterations (loss of NBTC stain partially within ORS)
3-many HF with loss of NBTC stain of less than 1/3 of ORS, almost no ORS more than 1/3 staining loss
4-many HF with loss of NBTC stain of more than 1/3 of ORS, some staining loss in stem cell area
5-most follicles of medium and coarse hairs have partial or complete loss of NBTC stain in stem cell area
6-most of the HF with medium to coarse hair nearly complete or complete loss of NBTC stain in stem cell area, partial loss of NBTC stain of perifollicular tissue

Results

Table 1 Results of *in vitro* study

Sample #	Device	F	τ	I	Damage			
		[J/cm2]	[ms]	[W/cm2]	Hair shaft	infundib.	bulge	bulb
1*	Palomar lamp	4	10	400	0	0	0	0
2*	Palomar lamp	5	10	500	0	0	0	1
3*	Palomar lamp	6	10	600	0	0	0	2
4	Palomar lamp	7	95	74	0	0	0	0
5	Palomar lamp	7	30	233	0	3	0	2
6	Palomar lamp	7	6	1170	2	3	1	3
7	Palomar lamp	11	6	1830	4	3	0	3
8	Palomar lamp	15	50	300	0	5	1	3
9	Palomar lamp	15	50	300	0	5	4	5
10	Palomar lamp	15	15	1000	4	5	4	4
12	Palomar lamp	15	15	1000	3	5	4	3
11	Palomar lamp	15	7	2140	3	3	4	4
13	Palomar lamp	15	50	300	0	4	3	2
14	Palomar lamp*	15	15	1000	3	5	3	3
15	Palomar lamp*	15	50	300	0	4	2	4
16	Palomar lamp	25	50	500	1	4	2	4
17	Palomar lamp	25	10	2270	6	6	6	4
18	LightSheer	30	30	1000	5	6	6	6
19	LightSheer	40	30	1330	6	NA	6	6
20	LightSheer	40	100	400	4	6	6	6
21	LightSheer	40	200	200	3	6	6	6
22	Control	0			0	0	0	0

* with additional filter (λ_s=620 nm)

Bulb damage: evaluation of the damage within bulb level (only anagen hair follicles considered)

0 - no evidence for any light specific alteration
1 - borderline, occasional decrease of NBTC stain within the bulb
2 - decrease of stain of some hair bulb
3 - significant decrease of stain of many bulbs
4 - major damage to most hair bulbs
5 - almost all bulbs completely damaged
6 - loss of stain of surrounding fat

It has been found that the threshold fluence for histologically evident bulb damage was about 5 J/cm^2 for a pulsewidth of 10 ms (Figures 5a and 5b). Thermal damage of the papilla could be demonstrated for these parameters. With increasing fluence the outer root sheath and the perifollicular sheath were also thermally damaged (Figure 5c). The extent of thermal damage was related to the fluence and the pigmentation of each hair follicle.

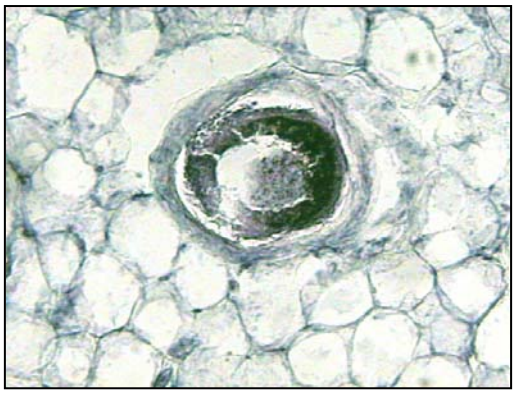


Figure 5a

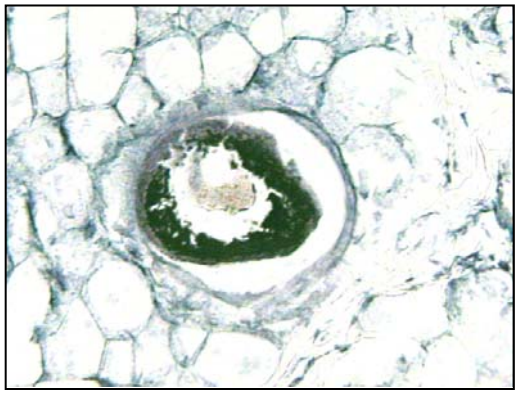


Figure 5b

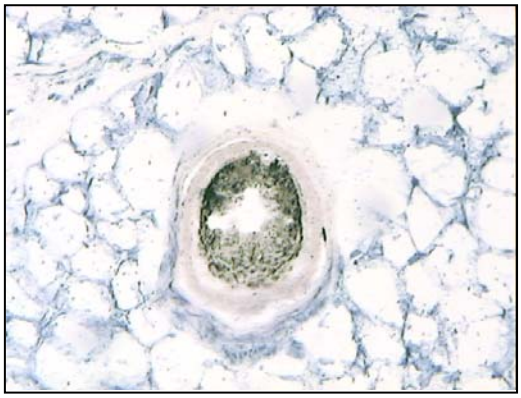


Figure 5c

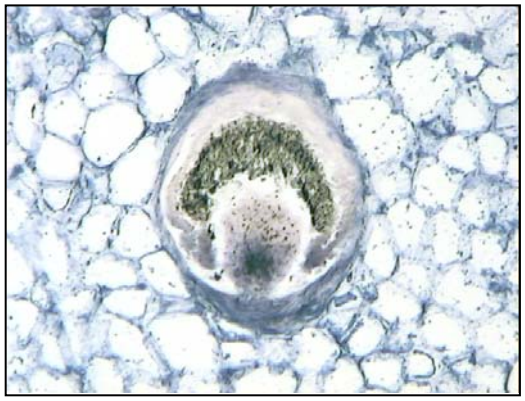


Figure 5d

Figure 5. Hair bulb with papilla after exposure with 4 J/cm^2, 10 ms (a); 6 J/ cm^2, 10 ms (b); 15 J/ cm^2, 15 ms (c); and 15 J/ cm^2, 50 ms (d).

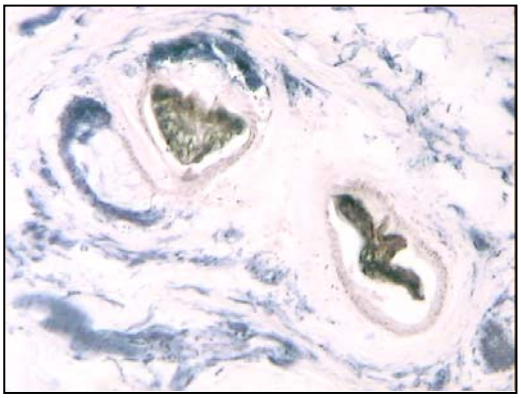


Figure 6a

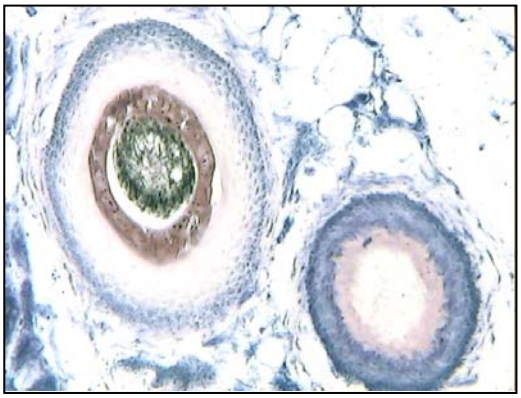


Figure 6b

Figure 6. Thermal damage of sample #10 (15 J/cm^2, 15 ms) at infundibulum and bulge levels. (a): almost complete and complete loss of LDH stain of the ORS at the infundibulum. The hair shafts demonstrates structural alterations and discrete browning for this particular hair shaft. (b): ORS close to bulge level. Partial loss of LDH stain for ORS with fading of stain in stem cell area.

In general, the extent of the thermal damage of the ORS was more pronounced at the infundibulum than at the bulge level for all samples. For a given fluence, the extent of the bulb damage decreased with increasing pulsewidth. Hair follicles of coarse dark pigmented hair shafts presented more thermal damage than follicles containing fine light pigmented hairs. The threshold for bulb damage was lower than for hair shaft alterations within the papillary dermis. The extent of hair shaft alterations strongly decreased with increasing pulsewidths for a given fluence.

In Vivo Study of Side Effects and Pain

Materials and Methods

A prototype Palomar EsteLux system has been used in the study. The system was equipped with a 16 mm x 46 mm handpiece. The "working" spectrum of the lamp is shown in Fig.1. The range of fluences has been chosen based on the results of the *in vitro* study (See previous section). Specifically, the lowest fluence (4 J/cm^2) was close to the observed threshold of the histologicaly evident bulb damage, while the highest one (12 J/cm^2) suggested an on-set of permanency. Table 2 summarizes the parameters used.

Each setting has been assigned a single test spot. Single pulse has been administered to each test spot. Evaluation procedures included assessment of the skin type, pre- and post-treatment photography, assessment of pain level by the subject, assessment of post-treatment side effects, and determination of the pre- and post-treatment pigmentation and erythema indices. Subjects have been asked to characterize their sensations at the test spots during treatment using a zero to ten scale. The scale was defined as follows: Level zero - no sensory input; levels 1 through 4 - sensations below pain level; levels 5 through 7 - tolerable pain; levels 8 through 10 - unbearable pain. Pigmentation index and erythema index have been determined using measurements of the diffuse reflectance of

skin at three selected wavelengths (560 nm, 650 nm, and 710 nm). The measurements have been performed with a specially designed portable reflectometer, which also incorporated automatic computation of the indices from the measured quantities. The pigmentation index linearly correlates with the melanin content of skin, whereas the erythema index directly correlates with the blood content of the skin.

Table 2. Palomar EsteLux Parameters used in the study

Settings #	Fluence, J/cm^2	Pulsewidth, ms	Power density, W/cm^2
1	4	10	400
2	5	10	500
3	6	10	600
4	8	20	400
5	10	20	500
6	12	60	200
7	12	40	300
8	12	20	600

Results

Table 3. Side Effects

Subject #	Skin type	Pigmentation index ±SD	Pronounced side effects
1	I	18±4	None
2	II	37±1	None
3	III-IV	50±1	None
4	V-VI	82±10	Settings 5, 7, 8
5	V-VI	54±1	Setting 8
6	VI	130±8	All settings

Table 3 summarizes results of the study for the observed pronounced side effects (blistering). Pigmentation index given in the Table 3 is an average of several test spots before the tests. Pronounced side effects were defined as side effects persistent more than one day after the test.

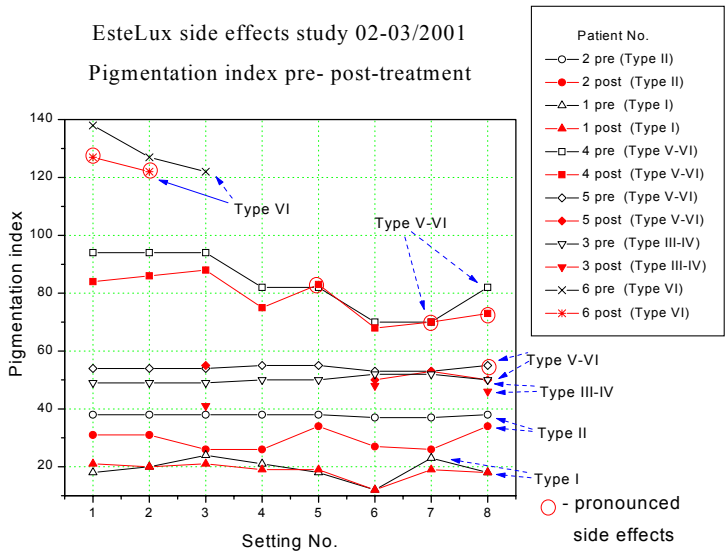


Figure 7. Pigmentation index as a function of the treatment spot (setting).

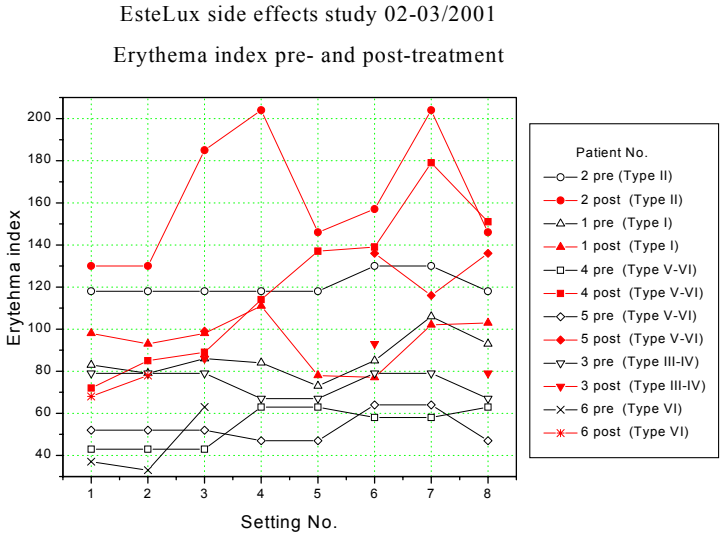


Figure 8. Erythema index as a function of the treatment spot (setting).

Figures 7 and 8 show results in more detail, as a function of the test spot (setting). The sensory assessment data are summarized in Figure 9.

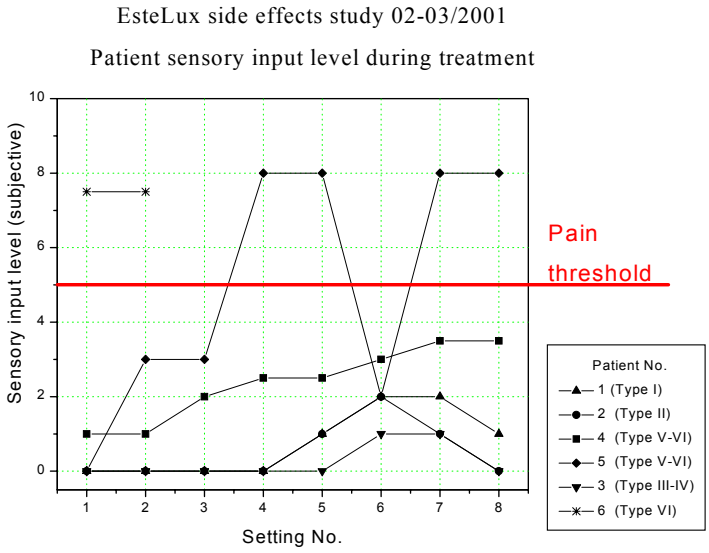


Figure 9. Sensory input level assessed by subjects as a function of the treatment spot (setting).

The Following Preliminary Conclusions Can Be Drawn from the Results of the Study:

- Pigmentation index correlates well with skin type and with the observed side effects, and can be used as a predictor.

- Palomar EsteLux can be safely and painlessly used with all tested parameters when the pigmentation index of the skin is below 50.
- For pigmentation index between 50 and 100, the high-fluence treatment regimens (setting 4 through 8) can cause pain and/or lead to pronounced side effects.
- For pigmentation index higher than 100, all tested settings can cause pain and lead to pronounced side effects.
- There are no substantial changes in the pigmentation index immediately after the test.
- Erythema index correlates neither with the skin type nor with the side effects, but increases substantially immediately after the treatment.

Preliminary Evaluation of Efficacy

The primary objective was to investigate the clinical efficacy of the Palomar EsteLux system as a device for temporary hair growth reduction. The secondary objective was to obtain preliminary results with regard to long-term hair removal effects.

Materials and Methods

The device used for this evaluation was the Palomar EsteLux prototype with a Lux Y handpiece. The tested fluence settings ranged from 4 J/cm^2 to 12 J/cm^2 with two sets of pulsewidths (10 ms and 20 ms). Five volunteers have been treated over a time period of up to six months. The areas tested were the back, the neck, and the lower legs. Effects of multiple treatments with the device for two particular settings were tested on the back of one male subject with pronounced hair growth on the back (skin type II, dark brown hairs). Test site 2 was irradiated with 6 J/cm^2, 10 ms, and test site 3 was irradiated with 12 J/cm^2, 20ms. We also compared these two test sites with a symmetric site treated with another flash lamp device (SpaTouch, Radiancy Inc.) for one particular setting (setting 7J/cm^2, 20 ms). This device had a spot size of 22 x 54 mm^2, and the beam was delivered through air to the skin. For all test sites the subject was treated three times with same settings at a treatment interval of one month.

Results

We found that the threshold for a clinically significant reduction in the growth rate was lower than the threshold we had found in the previous *in-vitro* study. Even at the lowest fluence tested (4 J/cm^2), we observed for some body sites (lower legs) a clinically apparent, although temporary, hair reduction in comparison to non-treated areas. Similarly good cosmetic effect was observed one month after treatment of the neck with 5 J/cm^2, 10 ms (Figure 10). However, we have not seen any reduction of hair growth for this particular subject at 4 J/cm^2 for the anterior neck.

Results of multiple treatments of one subject are demonstrated in Figure 11. The marked test sites on the back of the subject before treatment are shown in Figure 11a. This subject had pronounced hair growth in a dense and homogeneous distribution over the entire back. One month after the first treatment, all three test sites were clearly distinguishable from the non-treated area (Figure 11b). A patchy appearance of test site 1 (SpaTouch) can also been seen. This pattern suggests that the treatment was performed in an inappropriate manner (partially omitted areas). However, during the treatment we carefully tried to avoid unexposed areas within the test sites. The observation that the area of the maximal efficacy of the SpaTouch system is smaller than the width of the handpiece

suggests that the patchy appearance has been caused by an optical phenomenon. Figure 11c shows the same subject three months after the third treatment. Figure 11d shows the same subject four months

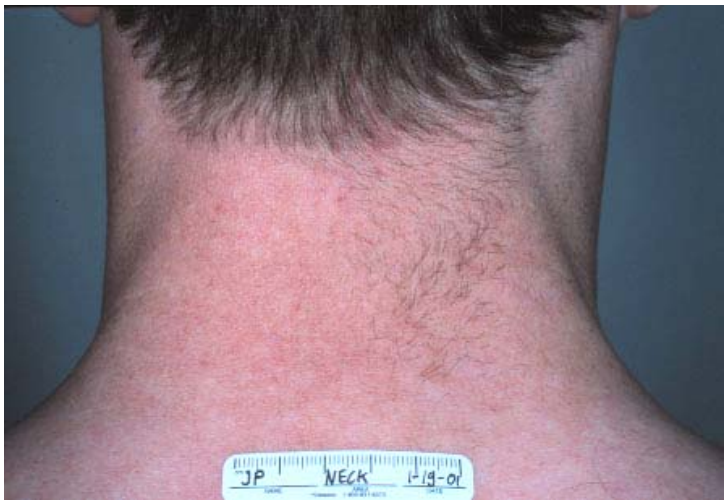


Figure 10. One month after treatment of left neck with EsteLux (5 J/cm^2,10 ms)

after the third treatment. A clinically apparent reduction of hair regrowth still can be observed for all three test sites, with test site 3 demonstrating the strongest reduction. High resolution digital images were obtained from test site 2 (Figure 12b), site 3 (Figure 12c), and the area in between that served as a control (Figure 12a). With a standardized image processing procedure, changes in pigmentation and hair shaft diameter can be easier assessed (Figure 13). For test site 2 (Figure 13b), a reduction of hair diameter and density relative to the untreated control site (Figure 13a) is evident. However, no obvious decrease in hair density was observed. For test site 3 (12 J/cm^2, 20 ms), we observed a decrease in hair shaft diameter and pigmentation (Figure 13c). In addition, the hair density decreased in comparison to the untreated control site. Considering a relatively homogeneous hair density within the test site 3 and at the adjacent untreated control area, we can conclude that the reduction of the hair density has been caused by the treatments. This indicates that the Palomar EsteLux system can deliver long-lasting hair reduction with the settings of 12 J/cm^2 and 20 ms pulsewidth.

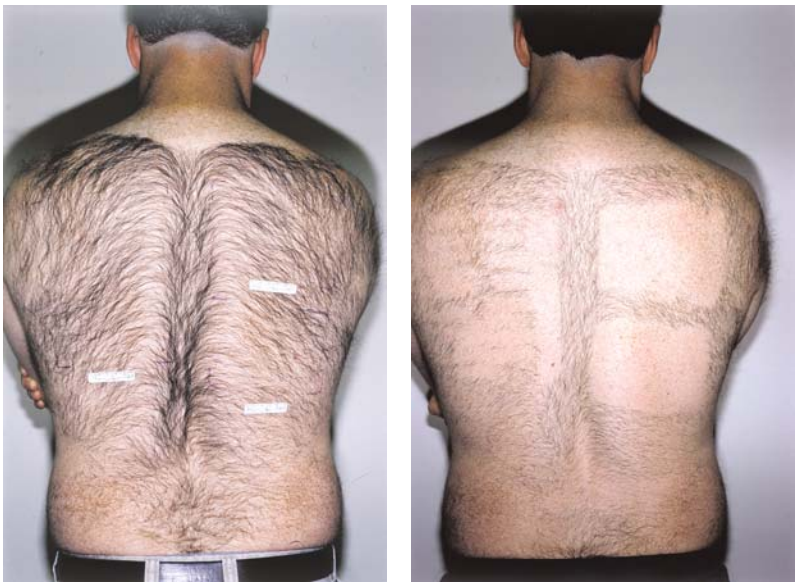


Figure 11a

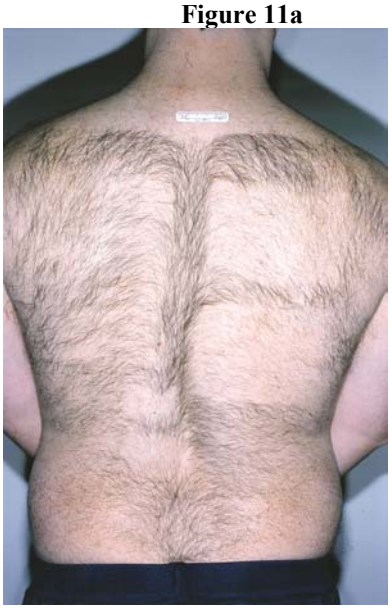


Figure 11b

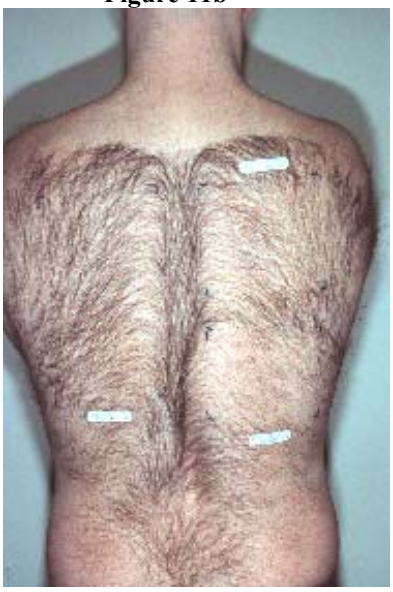


Figure 11c

Figure 11d

Figure 11. (a) Before treatment with marked test sites; (b) One month after one treatment. Test site 1 (left side), test site 2 (upper right), test site 3 (lower right), see text for parameters; (c) Three months after three treatments; (d) Four months after three treatments.

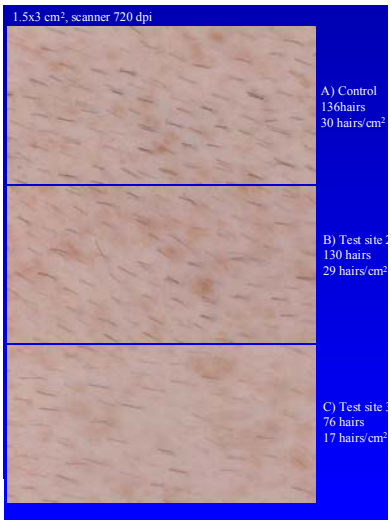


Figure 12. Digital pictures of control (a) and test sites 2 (b) and 3 (c).

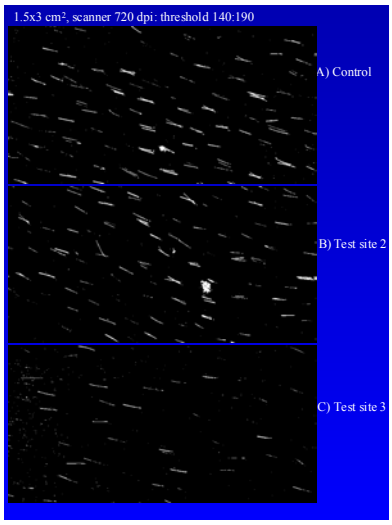


Figure 13. Same as Figure 12, after standardized digital image processing.

Conclusions

Efficiency of energy delivery from a flash (arc) lamp to the hair follicle increases when the spotsize is larger than 15 mm in its minimal dimension.

- Short cut-off wavelength should be chosen in the range from 500 nm for fair skin (thermal effect close to ruby laser) to 650 nm for dark skin (thermal effect close to diode laser).
- Optimal pulsewidth of a low-fluence system for growth delay is close to 10 ms, and for permanent photoepilation is in the range between 20 and 100 ms.
- For dark brown hair, threshold of hair matrix damage is in the range between 4 J/cm^2 and 6 J/cm^2. Threshold of entire follicle damage in the bulge area is 10 J/cm^2 to 15 J/cm^2.
- Fluence / pulsewidth combination of 12 J/cm^2 / 20 ms with a 525-nm short cut-off wavelength is safe and not painful for skin types I-IV. Fluence / pulsewidth combination of 12 J/ J/cm^2 / 60 ms is safe for skin type V, with an acceptable pain level.
- One subject with a high hair growth rate, skin type II, dark brown hair demonstrated significant hair growth delay after treatment with 6 J/cm^2 and 10 ms pulsewidth. For 12 J/cm^2 / 20 ms setting, long lasting reduction of hair re-growth has been observed.