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Photoepilation with high power LED - holonyak: evaluation of efficacy, satisfaction and incidence of side-effects

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ABSTRACT

Background: Devices that use light, especially lasers, have become popular and are commonly used in aesthetics and hair removal. Laser-assisted photo epilation was originally described in 1996 and the proposed mechanism is based on the destruction of the follicular unit. Diode laser has been demonstrated to be an effective method for hair removal, however, the safety of patients with different skin types and colours is questionable due to thermal damage as the main side-effect. In this sense, the technological innovation of Photoepilation using high power LED equipment with high head cooling efficiency represents a great advance for the area. In this work, we evaluated the results of photoepilation using high-power LED in 117 patients with phototypes 01 to 06. **Methods**: A High potency LED equipment (Holoniak® – Adoxy Equipments – Brazil) was used. The LED allows the therapist to customize illumination parameters according to the sensitivity of the patients. All 117 participants were submitted to an initial sensitivity test to the LED irradiation, in order to determine adequate parameters to each participant. Sensitivity test was performed in both stationary and scanning modes. In scanning mode the test started with the following parameters – temperature of the at 10oC, fluence of 5 J/Cm2 and frequency 2 – 3 Hz. In stationary mode the sensitivity test started with temperature of the probe at 10 oC, fluence of 10 J/Cm2 and frequency of 0.8 Hz. No phototype restrictions were applied. To analyze the satisfaction of results, we created an arbitrary scale ranging from 1 to 4, where Grade 1 was considered unsatisfactory, Grade 2 - little satisfactory, Grade 3 - satisfactory and Grade 4 - very satisfactory. We also analyzed the number of sessions needed to achieve the hair removal result for each skin phototype. **Results:** Analyzing the percentage of satisfaction after LED photoepilation, satisfaction grade 3 and 4 represent approximately 95% of the participants. Surprisingly, there was no statistical correlation between the increase in skin phototype and the number of sessions needed to achieve the complete photoepilation effect. Unlike laser technology, which usually requires a high number of sessions for higher phototypes. No correlation with age was also reported. **Conclusion:** We can conclude that high power LED technology with effective tip cooling was able to achieve highly efficient results for 95.7% of treated patients, without the need to increase the number of sessions for phototypes 4 to 6.

Keywords: LED; Photoepilation; Hair removal; Light-emitting diode.

BACKGROUND

Devices that use light, including lasers and LEDs, have become popular and are commonly used in aesthetics. With the aging of the population associated with technological progress, the growing demand for non-invasive aesthetic treatments has led patients and professionals in the dermato-aesthetic area to look for novelties, especially with regard to photoepilation.

Photoepilation is generic term currently employed to denominate a common method using different light sources such as pulses of laser or intense pulsed light (IPL)[(1)] and more recently LEDs Lopes-Martins et al[(2)] to remove unwanted body hair. A hairless body is a modern tendency of both women and men in the present days.

The first Laser-assisted photoepilation was described in 1996 and the proposed mechanism is based on the destruction of the follicular unit[(3)]. During photoepilation light is intensively and selectively absorbed by the melanin in the growing hair follicle (HF), but frequently by the skin as well, depending on the phototype and skin characteristics, resulting in a local temperature increase. The ability to remove hair without damaging the surrounding skin is based on selective photothermolysis[(4,5)], however tissue damage may occur under some circumstances. This temperature increase depends on the parameters of the light source (wavelength, pulse duration, energy density) and on the hair Folicule properties[(6)].

Diode laser has been demonstrated to be an effective method for hair removal, however, the safety of patients with different skin types and colours is questionable due to thermal damage as the main side-effect. Essentially, laser-induced hair removal depends on the effects of light interaction with the chromophore which can be found in the hair but also in skin in different amounts. Melanin contents are frequently related to photoepilation side-effects[(7)].

During the past decade, laser hair removal has become an accepted and popular practice, with satisfactory results achieving hair reduction[(8)]. The scientific literature has numerous articles that discuss the safety and effectiveness of Photoepilation, however, the vast majority of these studies were carried out with populations with little mixed race. Practioners rarely analyses the ethnic background of the patients what may result in several side-effects mostly caused by excessive temperature increases. Obviously, the ethnic origin of the patients matters a lot in the occurrence of these effects, especially in countries with high racial miscegenation such as Brazil.

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Few Studies performed in countries with higher miscegenation and diverse coloured skin participants reports high incidence of adverse effects resulting from the use of high-powered lasers in photoepilation, including folliculitis, skin eruptions, prolonged erythema, ecchymosis, paradoxical hyperkeratosis, post-inflammatory discoloration, and even burns or a burning sensation on the skin[9,10].

Patients who undergo laser hair reduction procedures may expect skin irritation, erythema, edema, postoperative hypersensitivity and possible burns manifested by blisters and scabs. Atta-Motte and Zaleska[7] reported that the occurrence of burns depended on ethnicity and on the number of treatments. Increases in skin temperature seems to be one of the most important factors responsible for burns and burn-related lesions. In this context, prevention of temperature increases in skin can be an effective strategy to prevent photoepilation-induced side effects. We recently demonstrated in a Pilot Study[2] that the photoepilation technique using LED (Holonyak® – Adoxy Equipamentos, Brazil) with a cooled applicator did not show significant increases in the temperature of the participants' coloured skin. Furthermore, no adverse effects such as pain, burns or hypersensitivity were reported 24 hours after treatment. The possibility to fully customize photoepilation with LED light points to the direction of decreasing the occurrence of side-effects. In this pilot study we employed infrared thermography in order to analyse skin temperatures before and after LED Photoepilation.

Photoepilation using high power LED (Holonyak®) is capable of emitting light in a wavelength range of 780 to 850nm, in which the light reaches the dermis with less effect on water and on hemoglobin, but preferentially melanin in the hair follicle, causing it to overheat and resulting in its destruction. The presence of a specific spectrum to perform selective photothermolysis is necessary in order to reach the cells responsible for hair growth[11].

The high-power LED technology is innovative because it emits light in a specific spectral range, providing greater patient comfort. Until then, the great discomfort during the treatment was among the main complaints of those who do definitive epilation. Photoepilation using high power LED (Holonyak®) also uses an associated technology called “Extreme Cooling”, which cools the surface of the patient's skin, reaching temperatures of up to -15ºC. This brings more comfort during the session, without harming the treatment. However, our first study was a pilot study with a small limited number of participants. Here we report the results of 117 participants with different phototypes that undergone LED photoepilation.

METHODS

Participants

The study was designed and conducted in accordance with the Declaration of Helsinki, and principles of Good Clinical Practice (GCP). All subjects were completely informed about the procedure and its side effects and written informed consent to participate in the study was obtained from the subjects at baseline. This is a pilot study performed to evaluate possible temperature increases. The LED-based technology for hair removal (Holoniak®) is approved for commercial use by the National Health Surveillance Agency of Brazil (ANVISA) and by the National Metrology Institute (INMETRO) for safety.

One hundred and seventeen male and female participants (18 - 60 years old) underwent monthly LED-induced hair removal sessions. They were instructed to avoid any cosmetic product for at least 24 hours before LED irradiation and to shave their legs 24 to 48 hours before irradiation.

Participants were accommodated on a hospital stretcher for a period of 15 minutes for acclimatization to environmental conditions. Room temperature and relative humidity were recorded and entered into the thermographic camera software for automatic corrections and calibrations. Before and after application of LED irradiation, images were recorded in a designated area with non-reflective surfaces.

Inclusion criteria

Body Mass Index (BMI = Weight / Height²) up to 29.9 kg / m²; having regular menstrual cycles (between 26 and 30 days) and having used the same oral contraceptive in the last 3 months, stable weight for at least 3 months (variation less than 2.0 kg); sedentary and without the use of cosmetics that act on the local circulation.

Participants were asked to refrain from using any cosmetic product with retinoids, Dimethylaminoethanol (DMAE), alpha hydroxy acid (AHA) or beta hydroxy acid (BHA) for 1 month prior to the start of the study.

Exclusion criteria

The following factors were considered exclusion criteria: a) leg pathology or injury; b) Possible or confirmed pregnancy; c) Metallic prosthesis close to the irradiation site; d) Any recent surgery in the LED application area; e) Use of medication such as NSAIDs, corticosteroids or antibiotics during the study period; f) history of photosensitivity; g) porphyria or any other hematological disease;

Satisfaction Score

In order to better evaluate the patient´s satisfaction, we created an arbitrary numeric score as follows: 1 – Not Satisfactory effect; 2 – Less than satisfactory; 3 – Satisfactory; 4 – Very satisfactory; The satisfaction score was used to apply the non-parametric statistic tests.

LED Photoepilation

A High potency LED equipment (Holoniak® – Adoxy Equipments – Sorocaba – SP) was used. The LED allows the therapist to customize illumination parameters according to the sensitivity of the patients. Technical characteristics are described below in table 01.

All participants were submitted to an initial sensitivity test to the LED irradiation, in order to determine adequate parameters to each participant. Sensitivity test was performed in both stationary and scanning modes.

In scanning mode, the test started with the following parameters – temperature of the at 10ºC, fluence of 5 J/Cm^2 and frequency 2 – 3 Hz. Applications were performed by the same physiotherapist in a constant scanning speed of 5 cm/s. Participants were instructed to report the moment they began to feel the LED trigger. Fluency was adjusted so as not to cause discomfort to the participant, considering that we can observe different sensitivities to the technique. To this end, fluency was gradually increased to the tolerable limit, without too much discomfort for the participant. Immediately after application, the participant assessed the degree of pain or discomfort, using the visual analogue pain scale.

In stationary mode the sensitivity test started with temperature of the probe at 10 ºC, fluence of 10 J/Cm^2 and frequency of 0.8 Hz. No phototype restrictions were applied. Fluency was gradually increased to the tolerable limit, without too much discomfort for the participant. Immediately after application, the participant assessed the degree of pain or discomfort, using the visual analogue pain scale.

Statistical Analysis

In order to choose the best statistical test to be used, we carried out tests of normality of the samples, including phototype, age and number of sessions.

Phototype, age and number of sessions – Since p-value<α we reject the H0. It is assumed that the data is not normally distributed. In the other words, the difference between the data sample and the normal distribution is big enough to be statistically significant.

Given that the above variables do not have a normal distribution; the chosen correlation test was Spearman's rank correlation coefficient.

LED Parameters

The table 01 shows de LED irradiadion parameters used in this study.

Table 1. LED Parameters

Light Source	NIR LED
Wavelength Band	780 – 850 nm
Peak Power	1200 W
Output Power	840 W
Operation modes	Scanning or Single shot
Pulse width	5 – 750 ms adjustable
Fluence	5 – 100 J/Cm^2 adjustable
Spot Size	17 X 22 mm
Spot Cooling	10 to -15ºC

RESULTS

Satisfaction Score

The results of the patients' satisfaction score, for evaluation purposes, were initially divided by phototype, bearing in mind that this seems to be one of the most important points reported in the literature, for obtaining results and also for the incidence of intercurrences.

Figure 01 shows the percentage of patients with Phototype 01 to 06 and the satisfaction score obtained for Photoepilation. As we can see, in all phototypes, score 03 and 04 represent more than 90% of the patients evaluations.

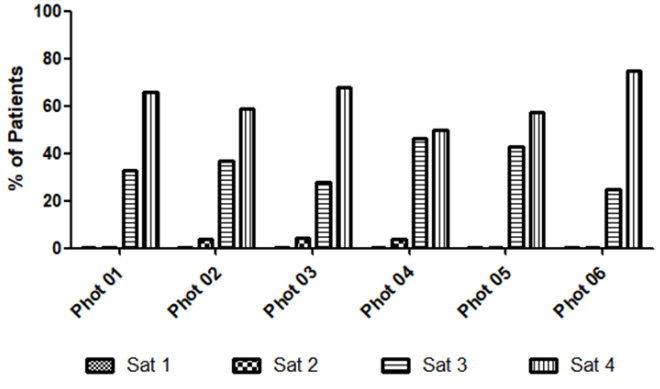

Figure 1. Satisfaction score for LED Photoepilation with Holonyak.

Correlation of Number of Sessions and Satisfaction

The statistical tests of spearman correlation revealed that there is a significant but very small

negative relationship between the number of sessions and result satisfaction as we can observe in Table 02.

Table 2: Statistical results of non-parametric Spearman correlation on number of photoepilation sessions and patient´s satisfaction

Parameter	Value
Spearman's rank correlation coefficient (r_s)	-0.1963
P-value	0.03392
Covariance	-178.9073
Sample size (n)	117
Statistic	-2.1467

Correlation of Number of Sessions and Skin Phototype

The statistical tests of spearman correlation revealed that there is no significant difference between the number of sessions and the skin phototype as we can observe in Table 03.

Table 3. Statistical results of non-parametric Spearman correlation on number of photoepilation sessions and skin phototype.

Parameter	Value
Spearman's rank correlation coefficient (r_s)	0.1332
P-value	0.1521
Covariance	132.4246
Sample size (n)	117
Statistic	1.4417

Correlation of Number of Sessions and Age

The statistical tests of spearman correlation revealed that there is a non-significant difference between the number of sessions and the age of the participants, as we can observe in Table 04.

Table 04: Statistical results of non-parametric Spearman correlation on number of photoepilation sessions and age of the participants.

Parameter	Value
Spearman's rank correlation coefficient (r_s)	0.09439
P-value	0.3114
Covariance	98.6121
Sample size (n)	117
Statistic	1.0167

Side Effects

The occurrence of side effects was considered low and fully acceptable. No serious side-effects were observed in any of the participants. Only 03 recurrent side effects were reported as follows: Skin whitening of the irradiated skin – 18 out of 117 participants; remaining fine hair – 9 out of 117 participants; improvement of folliculitis – 12 out of 117 participants;

Table 05: Occurrence of side-effects after LED photoepilation

Observed effects	Occurrence	%
Skin whitening	18/117	15.4
Remaining fine hair	9/117	7.7
Improvement in folliculitis	12/117	10.2

DISCUSSION

This is the first large observational study, with 117 participants that undergone photoepilation with a high power LED equipment. Here we report the satisfaction of the participants using an arbitrary score. All phototypes, from 01 to 06 were contemplated in the study. As noted, photoepilation performed with the parameters described in the present study was able to generate efficient results and participant satisfaction at a satisfactory or very satisfactory level. Taken together, scores 3 and 4, in all phototypes, exceeded more than 90% of the participants, that is, about 95% of all participants in all phototypes assigned a score of 3 or 4 to the results of photoepilation (Figure 01).

The significant number of 117 participants allowed a consistent statistical methodology. Considering that the data obtained do not follow a normal distribution, we used non-parametric tests to evaluate the results. Spearman's correlation revealed surprising data as a significance for negative correlation between the number of sessions and satisfaction. This means that the smaller the number of sessions necessary to obtain the desired result, the more satisfied the participant will be (Table 02).

Another relevant point, which perhaps we can consider as the most important finding of the study, was precisely the lack of correlation between the phototype and the number of sessions required for photoepilation. These results clearly demonstrate that even higher phototypes, which normally demand a greater number of sessions, were not changed in this case. Photoepilation performed with high-power LED (Holoniak™) was not influenced by phototype, that is,

from phototype 01 to 06, the number of sessions necessary to obtain a high degree of satisfaction was similar, without statistically significant differences (Table 03). In addition, we studied the degree of correlation between the number of sessions required as a function of the participant's age. Again, there were no significant differences or correlation between these variables. This means that the treatment used was not dependent on the patient's age (Table 04).

During photoepilation, light is selectively absorbed by melanin in the growing hair follicle, resulting in an increase in local temperature and resulting in hair removal without damaging the surrounding skin, at least theoretically. However, the temperature increase depends on the physical parameters of the light and on the skin properties. Most of the clinical trials have been performed in Caucasian populations where safety is already proved. On the other hand, the safety of patients with different skin types and genetic characteristics has become also important, not only skin colour.

Practioners rarely analyses the ethnic background of the patients what may result in several side-effects mostly caused by excessive temperature increases. Besides, melasma and paradoxical hypertrichosis (PH) may also occur. Snast et al.[12] in a systematic review of 9733 patients showed that PH prevalence was 3% in face and neck, but the study was not able to demonstrate associations to skin type or gender. On the other hand, Atta-Motte and Zaleska[7] reported that the occurrence of burns depended on ethnicity and on the number of treatments and prevalence of side-effects including burns, erythema and folliculitis can be as high as 50%. In our study, no important side-effects were observed. The only reported side-effects were skin whitening (15.4%), some remaining fine or white hairs (7.7) and one interesting effect reported was the reduction of local folliculitis (Table 05). In a previous pilot study[2] we had already shown that photoepilation using high power LED (Holonyak™) did not cause pain, burns or any discomfort after application to coloured skin (phototypes 4 to 6), even 24 hours after application. However, the study carried out was only a pilot study with few participants. In the present study, now with 117 participants, no serious adverse effects were observed, confirming previous findings.

These data are of great importance, considering that this is the first study of its kind, using an LED photoepilation platform in Brazil, a particularly mixed-race country.

CONCLUSION

The present study proves the efficiency and user satisfaction of the technology that uses high-power LED for photoepilation. In addition, it demonstrates that the observed effect was not influenced by skin phototype, not causing the need to increase the number of sessions or reduce efficiency. No serious adverse effects were observed, not even in high phototypes (04 to 06). Therefore, we consider that the high-power LED technology used in this study can be considered more suitable for use in countries with high miscegenation or racial diversity.

Authors Contribution: Patricia Sardinha Leonardo, Rodrigo Alvaro B. Lopes-Martins – team leaders of the study; Felícia Cadenas de Paiva Bueno, João Pedro Ribeiro Afonso, Danny Cristina Caixeta Gomes and Mayara Oguri, – Protocol and tests execution. Ricardo Henrique Marques – Critical Reading of the manuscript and Statistical Analysis;

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Conflict of interest: Felícia Cadenas de Paiva Bueno and Mayara Oguri physiotherapists on the technical staff of Adoxy Inc. The other authors declare no conflict of interests for this study.

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