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Aspects of Diode Laser (805 nm) Hair Removal Safety in a Mixed-Race Group of Patients

Izabela Załęska[1], Magdalena Atta-Motte[2*]

[1]The Section of Professional Cosmetology, The Faculty of Motor Rehabilitation, the University of Physical Education in Krakow, Poland
[2]5th Avenue Medical Clinic, London, UK

***Correspondence to**
Magdalena Atta-Motte,
5th Avenue Medical Clinic,
London, UK.
Tel: +4407932857109
Email:
magda.atta.motte@consultant.com

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Abstract

Introduction: Laser hair removal (LHR) has become one of the most popular treatments in aesthetics. Side effects are an inevitable part of laser therapy, therefore managing them is crucial for every laser practitioner to ensure patients' safety along with achieving the best results. The available references describe the effectiveness of the diode LHR for all skin types according to the Fitzpatrick scale, but the question of patient safety and minimization of side effects and postoperative complications in mixed-race patients remains unanswered. This study aims to illustrate aspects of specific side effects in patients of mixed ethnicity and the impact of those effects on the results of the treatment.

Methods: The study was conducted in Poland and the United Kingdom on 216 patients of various ethnic backgrounds. This study analyses the frequency of side effects in a mixed-race group of 32 participants, taking into account their skin type according to the Fitzpatrick scale. The patients received a course of 6 treatments using diode laser 805 nm. An objective and a subjective method were used to analyse treatment results and side effects, with adverse effects documented, if observed. Treatment settings were adjusted to skin reaction during the patch test.

Results: Objective analysis was different from the subjective analysis of the treatment's effectiveness. No adverse effects were observed. Side effects such as hyperpigmentation, skin irritation, skin burns, and skin hypersensitivity were found.

Conclusion: 805 nm diode laser is effective and efficient at hair removal in mixed-race patients. It is a safe treatment in terms of skin reaction as only short-term side effects were observed in the treated area and no adverse effects were noted. To achieve the best results and to avoid adverse effects it is necessary to adjust treatment settings according to the individual patient's skin reaction.

Keywords: Side effects; Epilation; Diode laser; Ethnicity; Hair removal.

Introduction

Patients who decide to undergo a permanent hair removal course of treatments put the effectiveness of the method and a fast and long-lasting result as their priority.[1] For the practitioner, patient safety should be as important as the results of the treatment. During the initial consultation, it is necessary to inform the patients about the possible occurrence of side effects as part of the therapy and educate them on all skin care routines that might cause or minimize those side effects.[2,3]

Patients may expect redness, skin irritation, erythema, postoperative hypersensitivity and possible burns manifested by blisters and scabs. It is also possible to experience pigmentary changes such as hyperpigmentation. Less frequently described cases are scarring, purpura, folliculitis, cyanobacteria, pruritus or urticaria.[3-6]

The available literature describes the effectiveness of the diode laser as a method for all skin types according to the Fitzpatrick scale hair removal, but the question of patient safety and minimization of side effects and postoperative complications in mixed-race patients remains unanswered.[1-3,7-14]

In diode laser, the hair removal principle of selective photothermolysis applies where the chromophore is melanin in the hair shaft itself and the bulge. However, the same chromophore can be found as skin pigment. Some parts of the body, such as underarms or the pubic area, are more pigmented.

It is difficult to achieve the best results in laser hair removal (LHR) in the pubic area – one of the most popular treatments – and the procedure itself is quite embarrassing for the patient. On top of that, darker-skinned patients are much more sensitive in this area, which makes the treatment even more challenging. That is why the authors focused on this part of the body for further analysis.

The literature reports on such adverse effects and

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complications resulting from the use of an Alexandrite laser as: paradoxical hyperkeratosis and discoloration and post-inflammatory discoloration, de-novo growth of hair outside the area treated by laser, potentiation of co-existing vellus hair in the treatment area, induction or aggravation of acne, rosacea-like rash, premature greyness of hair, tunnelling of hair under the skin, prolonged diffuse redness and enema of the face, focal hypopigmentation of the lip, angular cheilitis, purpura and inflammatory and pigmentary changes of pre-existing nevi.[15-23] Research on cooling sapphire handpiece Alexandrite reports no severe side effects.[19] The literature also provides information about side effects using Ng-Yage Q switched and ruby lasers.[4,15] It is said the majority of diode laser patients experience no long-term side effects.[20]

The researchers' experience shows that the ethnic background of patients is rarely analysed by the therapist which might result in unexpected, severe side effects. Unfortunately, practitioners performing these treatments focus only on using the basic minimum information – like the Fitzpatrick skin phototype, colour and hair structure.[24-26] Those are not the only factors which affect the safety of the treatment or treatment parameter settings. When treating mixed-race patients, it is essential to consider their ethnicity and a detailed ethnic history.[27]

The scientific literature presents numerous reports on the effectiveness of LHR but is limited to different parts of the body and no reports on mixed-race participants have been found.[6,8,10,11,13-28]

Objective

The authors of this study have noticed that mixed-race patients' skin reacts differently than similar skin types according to the Fitzpatrick scale of non-mixed-race patients and so far no related research was found. The objective of the study was to investigate the occurrence and types of side and adverse effects after performing diode laser 805 nm hair removal in a group of mixed-race participants with phototypes III-V and to assess its impact on the results of the treatment measured as a percentage of hair reduction in the treated area.

Methods

The research was carried out in Poland and the United Kingdom from April 2015 to April 2017.

235 people took part in the study, of which 216 – after the initial consultation – were qualified for the course of 6 treatments (n = 216 / f = 174 (1 transgender), m = 42).

Exclusion criteria included:

- any previous laser or IPL treatments in the study area,
- cancer,
- use of hormonal drugs,
- photosensitizing drugs,
- antibiotic therapy,
- use of cosmetics containing retinol, vitamins A, E, C, fruit acids,
- intake of herbs which can be photosensitizing,
- suntan,
- chemical or mechanic depilatory, or hair bleaching during prior 6 weeks,
- irritated skin,
- dermatosis of various etiology,
- reticularis,
- photodermatitis,
- epilepsy,
- pregnancy and breastfeeding,
- isotretinoin use within the past year,
- history of photosensitivity,
- history of hypertrophic scars and keloids,
- age below 20 or above 40 years old.

A course of 6 treatments was completed by 206 participants (f = 168, m = 39). One person was excluded from the analysis due to a 100% success of the therapy after three treatments. Nine participants discontinued the therapy due to the occurrence of side effects.

During initial consultations, according to the study protocol and to ensure patients' safety, investigators assessed skin types using the Fitzpatrick Scale Quiz.

The Fitzpatrick scale is defined as a classification for human skin colour as a way to estimate the response of different types of skin to light exposure. The Fitzpatrick scale is a recognized tool for dermatological research into human skin pigmentation.

Type I always burns, never tans (pale white; blond or red hair; blue eyes; freckles).

Type II usually burns, tans minimally (white; fair; blond or red hair; blue, green, or hazel eyes).

Type III sometimes burns mildly, tans uniformly (cream white; fair with any hair or eye colour.)

Type IV burns minimally, always tans well (moderate brown).

Type V very rarely burns, tans very easily (dark brown).

Type VI never burns, never tans (intensely pigmented dark brown to darkest brown).

To define ethnicity, in addition to the medical questionnaire ethnic background questions were asked following the Census 2001 scheme acknowledged in the United Kingdom.

Several ethnic background types were distinguished in the examined group:

- White: participants with white skin,
- Black: participants with black skin,
- Asian: participants who come from Asia,
- Mixed-race
  - White and Black African: participants whose ancestors were white and black who originally came from Africa.
  - White and Black: participants whose ancestors had white and black skin which came from non-African countries.
  - White and Asian: participants whose ancestors had white skin and Asian skin, who came from

Asian countries.

This study was focused on a sub-group of mixed-race participants n = 32 (f = 24, m = 8) (Figure 1) of various nationalities (Figure 2) and skin types (Figure 3) chosen from the main group, who indicated their ethnicity as mixed-race.

Diode laser with the wavelength of 805 nm, minimum peak power 2100 W and a pulse duration between 15 and 400 ms, ET sapphire cooling assisted handle 9 × 9 mm large, and pulse energy density between 10 and 100 J/cm^2 used for all treatments.

This research protocol adhered to patch tests treatment settings such as fluence (J/cm^2) and pulse duration (ms) as per manufactures guidelines for different Skin Type, Hair Colour, Hair Texture (Table 1) and modified according to individual skin reactions.

Patch test settings were starting points for treatments. To achieve the best results and to ensure patients safety (and taking into account their ethical history) during each treatment, fluence and pulse width were adjusted to the individual participants' skin reaction.

Initial settings and final settings of pulse duration (ms) and fluence (J/cm^2) were documented for this study.

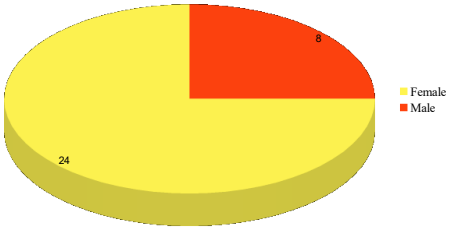

Figure 1. Group of Mix Race Participants.

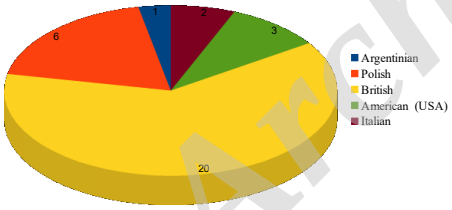

Figure 2. Nationality of Mix Race Participants.

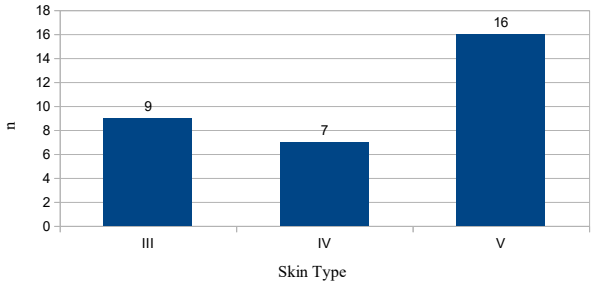

Figure 3. Fitzpatrick's Skin Types in Group of Mix Race Participants.

Table 1. Initial Patch Tests Settings for Different Skin Types, Hair Color and Hair Structure According to the Manufacturer's Guidelines

Skin Type	Hair Colour	Hair Texture	Fluence (J/cm^2)	Pulse Duration (ms)
III	Blond/red	Fine	30	15
		Medium	28	15
		Coarse	28	30
	Light brown	Fine	30	15
		Medium	28	15
		Coarse	28	30
	Dark brown	Fine	28	15
		Medium	26	15
		Coarse	26	30
	Black	Fine	26	15
		Medium	24	15
		Coarse	24	30
IV	Blond/red	Not observed	N/A	N/A
	Light brown	Fine	6	30
		Medium	5-6	30
		Coarse	9	100
	Dark brown	Fine	5-6	30
		Medium	5	30
		Coarse	8-9	100
	Black	Fine	5	30
		Medium	8-9	100
		Coarse	8	100
V	Blond/red	Not observed	N/A	N/A
	Light brown	Not observed	N/A	N/A
	Dark brown	Fine	7	100
		Medium	6-7	100
		Coarse	6-7	400
	Black	Fine	6-7	100
		Medium	6	100
		Coarse	6	400

During the initial consultation, practitioners had explained a realistic expected outcome of the course of 6 treatments. Participants were familiarized with the definition of permanent hair reduction issued by the FDA and the possible result of the treatment as a long-term, stable reduction in the number of hairs regrowing after the course of treatments. Participants were aware that hair reduction would last for four to twelve months and permanent hair reduction doesn't mean the elimination of all hairs in the treatment area. The reference point for an excellent result was defined to be an 80% hair loss. Participants were aware of side effects and adverse effects possibilities. Before carrying out the treatment, the patient's skin was shaved and cleaned, and during the course of 6 treatments the patients were not using any other methods of hair removal, as per the therapist`s pre and post instructions.

All respondents had 6 treatments planned with intervals

of 6 weeks, in accordance with the pubic area hair growth cycle. The duration of the telogen phase in this public area is three months, 30% of hairs are in the anagen phase of growth; therefore, authors adjusted the study protocol to the manufacturer's guidance.

Subjective and objective percentage assessment of hair reduction was indicated.

In the objective method, reliable evaluation of hair reduction was introduced by taking photographs with zoom ×20 of a 1 cm^2 area, 4 cm lower from the middle distance between iliac spines. The number of hairs was counted and the assessment of percentage reduction was introduced before the first treatment and 6 weeks after the last one was carried out.

Simultaneously, 6 weeks after completing the treatment cycle the patients were asked to share their opinion on hair loss percentage and to estimate the percentage of hair loss in the treated area.

Before and after each treatment, in cooperation with participants the side effects were defined as:

- skin hyperpigmentation,
- skin redness,
- skin irritation,
- skin hypersensitivity,
- skin burns

and adverse effects defined as:

- discomfort,
- damage to the natural skin texture,
- scarring,
- excessive swelling,
- blisters,
- bruising

all of which were documented when observed.

Treatment settings such as fluence and pulse duration were documented.

The STATISTICA 12 PL tool, licensed by the Jagiellonian University of Krakow, Poland, was used for statistics. The Wilcoxon signed-rank test used for comparison of exposure parameters of first and sixth treatment and the hair loss percentage in the subjective and objective assessment according to the study methodology in the area of 1 cm^2. Spearman's rank correlation coefficient was used for the results of exposure and selected parameters of laser radiation analysis. Multivariate modelling by multiple regression was also applied. In the obtained study model, the dependent variable was the hair loss percentage according to the study methodology in the area of 1 cm^2, and the independent variables were the parameters of the first and sixth treatments and changes in the observed area of 1 cm^2 between first and sixth treatment. The results were statistically significant when the significance level was less than or equal to 0.05. Lack of statistical significance was marked with the abbreviation NS (statistically nonsignificant).

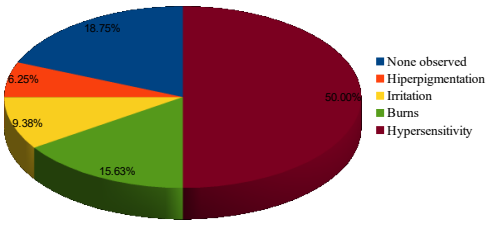

Figure 4. Side Effects Occurrence in Group of Mix Race Participants.

Results

It was noted that side effects such as hyperpigmentation (n = 2), skin irritation (n = 3), skin burns (n = 5), skin hypersensitivity (n = 16) were observed in 81.25% of mixed-race participants (Figure 4).

None of the adverse effects such as discomfort, damage to the natural skin texture, scarring, excessive swelling, blisters, bruising were observed.

It was observed that occurrence of side effects correlates to the skin type ($P < 0.01$) according to the Fitzpatrick scale (Figure 5).

The treatment effectiveness was statistically different ($P < 0.001$) in the objective and subjective assessment (Figure 6).

In this study pulse duration (ms) and fluence (J/cm^2) were adjusted to the participants' skin reaction during a patch test to ensure best results and to minimize the risk of side effects; therefore, initial settings of pulse duration were increased (Figure 7).

During multivariate analysis, multivariate regression was used in which the hair loss percentage determined

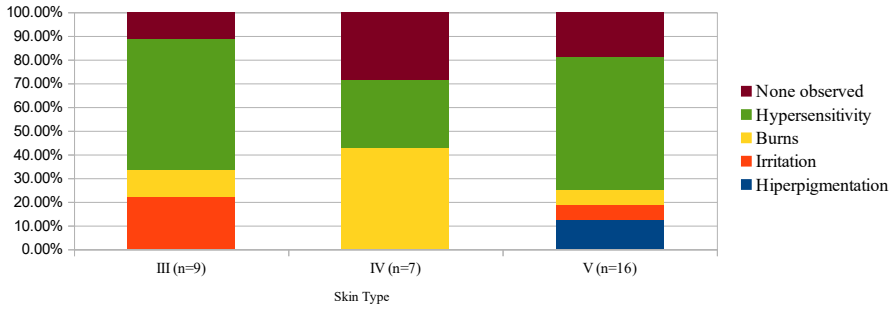

Figure 5. Side effects Occurrence According to the Skin Type in Group of Mix Race Participants.

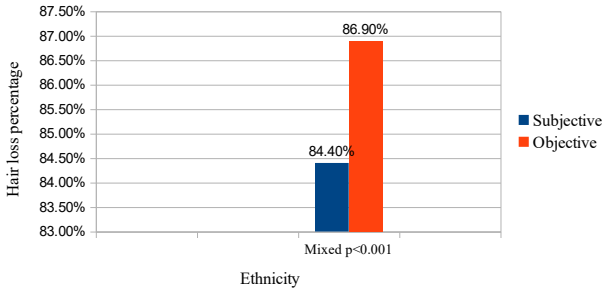

Figure 6. Subjective and Objective Assessment of Hair Loss Percentage.

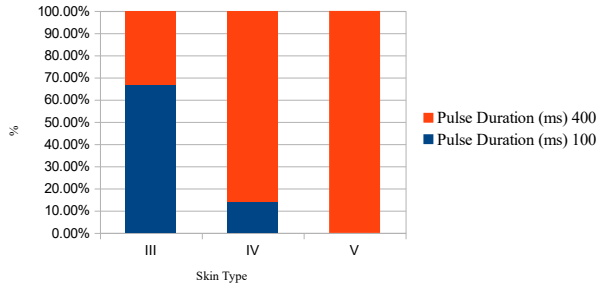

Figure 7. Initial Settings for Pulse Duration (ms) in Various Skin Types.

the dependent variable after 6 treatments according to methodology in the area of 1 cm^2, and the independent variables were the treatment parameters settings of the first and sixth treatment and changes influence (J/cm^2) between treatments first and sixth as shown in Table 2. Pulse duration increase (ms) has no impact on the effectiveness of the treatment.

For a model carried out in a group of mixed-race participants only fluence (J/cm^2) had a statistically significant inversely proportional effect on the therapy results. Although pulse duration (ms) was included in the regression model, its impact on the outcome of the therapy was statistically insignificant (Table 3).

Discussion

This study reports unique aspects of diode laser 805 nm hair removal safety in a mixed-race group of patients and no similar study is found among available references.

Available references report that hair removal using diode laser is safe and effective in all skin types according to Fitzpatrick scale, as shown in studies of Cameron et al,[1] Pavlović et al[11] and Fayne et al[2]; however no study was made in accordance to mixed race patients. In this study, investigators achieved excellent results in pubic area in a group of mixed race patients in objective 86, 90% and subjective 84, 40% assessments.

Adverse events such as burns and blisters reported as most frequent by Tremaine and Avram.[12] using diode laser in hair removal as most reported technology caused by operator or improper settings. This study reports no adverse effects such as blisters, and 15.63% burns as side effects in the group of mixed race participants among other side effects such as hyperpigmentation 6.25%, hypersensitivity 50% and skin irritation 9.38%.

To minimize the occurrence of side effects in this study treatment settings were adjusted to an individual response of participants and pulse duration varied between 100 and 400 ms. Investigators suggest that on top of Fitzpatrick scale, LES scale as indicated by Lancer[27] should be used among mixed race patients of various ethnicities.

Conclusion

Diode laser 805 nm hair removal is safe and effective for mixed-race participants. However, to minimize the occurrence of side effects, it is necessary to adjust

Table 2. Correlation Between Treatment Settings and the Effectiveness of the Teatment in the Group of Mixed-Race Participants

Ethnicity	Effectiveness	Pulse Furation (ms) 1st Treatment	Fluence (J/cm^2) 1st Treatment	Fluence (J/cm^2) 6th Treatment	Delta J/cm^2
Mixed raced	Objective	r=0.283	r = 0.4293	r = 0.3848	r = 0.2884
		N = 32	N = 32	N = 32	N = 32
		P=0.0117	*P*=0.014	*P*=0.030	*P*=0.100
	Subjective	r=0.1446	r = 0.3123	r = 0.2456	r = 0.2504
		N = 32	N = 32	N = 32	N = 32
		P=0.430	*P*=0.082	*P*=0.175	*P*=0.167

r, correlation ratio; N, number of participants; *P*, statistical significance.

Table 3. Regression Summary for Dependent Variable: Hair Loss Percentage After 6 Treatments According to Methodology in the Area of 1 cm^2

N=32	b*	Standard Error of b*	b	Standard Error of b	t (29)	*P* Value
Intercept			112.466	11.537	9.748	0.0000
Fluence (J/cm^2) 1st treatment	-1.042	0.395	-1.115	0.422	-2.640	0.0132
Pulse duration (ms) 1st treatment	-0.670	0.394	-0.0298	0.018	-1.698	0.1001

R=0.50801394, R^2=0.25807816, Adjusted R^2=0.20691114, F (2,29) =5.0438, *P*<0.01319, Standard Error of estimate: 4.9812.
Include condition: Ethnicity=Mixed Raced.
In the dependent variable regression b* includes standardised regression ratios. The value of b* ratios lets us compare the relative input of each independent variable to a dependent variable prediction.

treatment settings – such as pulse duration and fluence – according to the individual skin reaction taking into account the patient's ethical history.

Besides excellent results (above 80%) of hair reduction observed in the treated area in subjective and objective assessments, a high percentage of side effects were observed but no adverse effects were noted. Side effects occurring in the group of mixed-race patients correlated to their skin type.

It is worth to note that the study was conducted among participants of various ethnicities who live in Poland or United Kingdom, which can be a factor minimising the risk of heat or sun exposure related side effects.

Ethical Considerations

All procedures in this study and involving human participants were performed following the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study has been registered in the ISRCTN registry (identifier: ISRCTN10288390).

Conflict of Interests

The authors declare no conflict of interest.

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