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Original article

Evaluation of Clinical Outcomes After 808-nm Diode Laser Hair Removal: A Prospective Study in Benghazi, Libya

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ABSTRACT

Laser hair removal has emerged as an extensively adopted intervention, yet long-term data in Fitzpatrick skin types IV-VI are relatively limited. This prospective observational study evaluated the outcomes of 808 nm diode laser therapy in fifty patients (46 females, 4 males) presenting with familial or racial hirsutism at a private clinic in Benghazi, Libya, between September 2019 and December 2022. Participants underwent monthly sessions using standardized parameters of fluence (10-50 J/cm²), spot size (15×35 mm), pulse duration (17 ms), and pulse rate (1-10 Hz). Over the 12-month treatment period, hair regrowth time increased significantly from a mean of 8 days after the first session to 33.7 days after the twelfth, reflecting progressive follicular suppression. Patient satisfaction rose regularly, with 80% reporting satisfaction or satisfaction by the sixth session, and visual assessments confirmed that 60% achieved both hair thinning and weakening, while 40% achieved thinning alone. Adverse effects were minimal, limited to transient erythema in a small proportion of patients, with no burns or permanent pigmentary changes observed. The most commonly treated areas included the bikini, axilla, and face, reflecting typical cosmetic priorities in this population. These findings indicate that the 808 nm diode laser provides effective, durable hair reduction with a favorable safety profile in Fitzpatrick IV-VI skin types, supporting its role as a reliable modality for managing familial and racial hirsutism. The high levels of patient satisfaction, progressive extension of hair-free intervals, and absence of significant complications underscore the clinical utility of this technology, while the long-term follow-up adds valuable evidence to the limited literature on laser hair removal in darker skin phototypes.

Introduction

Increasing aesthetic demands have made the achievement of long-term reduction of unwanted hair a hard task to achieve, leading laser hair removal to be considered an essential procedure for this task. However, careful assessment of the long-term effects must be kept in mind [1]. Laser hair removal (LHR) is based on selective photothermolysis, using specific wavelengths to target melanin in the hair follicle while saving the surrounding tissues. Although effective in lighter skin tones, treatment in Fitzpatrick types III to V is complicated by higher epidermal melanin [2]. This phenomenon, in turn, boosts the risk of clinical complications including thermal burns, erythema, and hyperpigmentation if procedural correct guidelines are not precisely controlled. In addition, these challenges underscore the critical importance of accurate optimization and have necessitated careful evaluations of laser systems to precisely assess their relative efficacy and safety [3,2].

LHR has gained widespread popularity, yet notable gaps persist in establishing safe and effective treatment protocols across diverse populations. Evidence emphasizes the need for further research on resistant body areas, such as the full bikini in women and full back in men, as well as on outcomes across different ages and skin types. Patient education also remains underexplored, despite its importance in reducing complications and ensuring adherence to treatment regimens, which typically require six to eight sessions spaced 6-8 weeks apart. Thus, underscoring the need for ongoing research, structured training, and evidence-based protocols to optimize both efficacy and patient safety [4].

For many years, diode laser therapy has become increasingly popular. Yet, significant deficiencies remain in the formulation of safe and effective treatment protocols for various populations. Accordingly, evidence underscores the necessity for additional research on resistant body regions, specifically the complete bikini area in women and the entire back in males, as well as on outcomes across various ages and skin types [5]. In summary, a few clinical studies were done to evaluate the effectiveness of diode laser therapy for hair removal, cosmetic demands, and the safety of this procedure when applied for dark skin patient. But small sample size and ignoring long-term assessment of the side effects raise concerns about these studies and highlight the need for prospective studies [6,7].

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Considering these findings, this study aims to assess the effectiveness of Diode laser therapy in hair reduction and to evaluate patient satisfaction with minimal side effects, low discomfort levels, and a high safety profile in Libyan patients with skin type IV-VI In Libyan patients.

Methods

Study design and setting

This prospective observational study was carried out at a private dermatology clinic (Nefertiti clinic) in Benghazi, Libya, between September 2019 and December 2022. All participants provided verbal informed consent.

Sampling Technique

This is a non-probability sampling technique.

Participants

A total of 50 patients were enrolled in the study.

Inclusion criteria

- Age 18-40 years
- Clinical diagnosis of familial or racial hirsutism
- Fitzpatrick skin types IV-VI
- Willingness to complete 12 months of treatment

Exclusion criteria

- Suspected or confirmed hormonal abnormalities (elevated androgens, PCOS, adrenal disorders)
- Pregnancy or lactation
- Active skin infection or inflammation in the treatment area
- History of keloid formation
- Use of photosensitizing medications
- Previous laser hair removal within 6 months

Hormonal evaluation (testosterone, DHEAS, LH, FSH) was performed in all patients to exclude endocrine causes of hirsutism.

Treatment protocol

All treatments were performed by a single operator using an 808nm diode laser device (DILAS Module). Treatment parameters were:

- Wavelength: 808nm
- Spot size: 15×35mm
- Pulse duration: 17ms (short pulse)
- Pulse rate: 1-10 Hz
- Fluence: 10-50 J/cm² (gradually increased based on patient tolerance)
- Treatment interval: Monthly for 12 months

The treatment area was shaved 24 hours before each session. A thin layer of clear gel was applied to facilitate laser contact. The handpiece was applied with slight pressure, and adjacent areas were treated with minor overlap.

Outcome measures

Primary outcomes

- Hair regrowth time (days between treatment sessions)
- Patient satisfaction (assessed at each session using a 3-point scale: unsatisfied, satisfied, fully satisfied)

Secondary outcomes

- Visual analogue scale (VAS): Hair quality assessed as hair thicker or hair thinner and weak
- Side effects: erythema, burns, hypopigmentation and hyperpigmentation.

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Statistical analysis
Data were analyzed using SPSS version 25.0. Continuous variables were expressed as mean and standard deviation, and categorical variables as frequencies and percentages. The Friedman test was used to compare hair regrowth time across sessions. Fisher's exact test was used for categorical variables. A p-value <0.05 was considered statistically significant.

Recruitment procedures
Appropriate participants were identified through outpatient dermatology. Interested individuals underwent a preliminary screening visit, during which eligibility was assessed by a board-certified dermatologist. Comprehensive medical and dermatologic histories were obtained, and physical examinations were conducted to confirm suitability for laser hair removal.
Eligible candidates received detailed verbal and written information regarding the study objectives, procedures, potential risks, and benefits. Informed consent was obtained in accordance with institutional and international ethical standards. For participants with limited literacy, the consent process was fully discussed and explained, ensuring comprehension and voluntary participation.
To safeguard participant privacy, all personal identifiers were removed from study records, and data were coded using unique alphanumeric identifiers. Recruitment continued until the predetermined sample size was achieved, accounting for anticipated attrition and ensuring adequate statistical power for primary and secondary analyses.

Sample size determination and power calculation
The sample size was calculated to ensure sufficient statistical power to detect a clinically meaningful reduction in hair density, the primary efficacy endpoint. The calculation was based on prior studies of diode laser hair removal, anticipated effect sizes, and variability in hair count reduction.
Assuming a mean baseline hair count of 40 hairs per defined region of interest (ROI) and an expected mean reduction of 65% at six months post-treatment, with a standard deviation of 15%, the following parameters were used:

- Type I error rate (α): 0.05 (two-sided)
- Type II error rate (β): 0.20 (power = 80%)
- Non-inferiority margin: 10% absolute difference in hair reduction rate, based on clinical relevance and prior literature.

The sample size formula for paired continuous outcomes was applied, accounting for within-subject correlation due to repeated measures. To accommodate potential loss to follow-up (estimated at 15%), the final target enrollment was set at 60 participants. This sample size provides robust power to detect the anticipated treatment effect and supports planned subgroup and sensitivity analyses. Despite the targeted sample size of 60 participants, only 50 were recruited during the study period and included in the final analysis. However, even after sample size was reduced, the study preserved enough statistical power. The measured effect magnitude and variability resulted in an achievable power of around 75-78%, approaching the initially anticipated power of 80%. Therefore, a sample size of 50 participants was considered sufficient to assess the wanted outcomes.

Treatment protocol, device specifications and calibration
All laser hair removal procedures were performed using a medical-grade diode laser system (DILAS Module), selected for its established efficacy and safety profile in diverse skin phototypes. The device operates at a wavelength of 808 nm, optimized for selective photothermolysis of melanin within hair follicles.

Device Specifications

- Wavelength: 808 nm (diode laser)
- Spot size: 15*35 mm
- Fluence range: 10-100 J/cm²
- Pulse duration: 5-400 ms (The device was set as a short pulse, 17ms.)
- Pulse rate: (1 Hz-10Hz)

Treatment protocol, procedural steps, and operator qualifications
Pre-Treatment Preparation
Participants were instructed to avoid sun exposure, tanning agents, and hair removal methods (e.g., waxing, plucking, depilatory creams) in the target area for at least four weeks before the first treatment and throughout the study period. Shaving was permitted up to 24-48 hours before each session to ensure hair shafts were present but not protruding above the skin surface.

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Patient advised using a body scrub before each session to unravel hair [9]. On the day of treatment, the target area was cleansed with a mild, non-alcoholic antiseptic solution. A thin layer of water-based ultrasound gel was applied to enhance optical coupling and facilitate smooth gliding of the laser handpiece.

Laser Application

All procedures were performed by board-certified dermatologists with documented competency in laser safety and operation. Operator training included completion of a formal laser safety course, hands-on device training, and annual competency assessments.

The laser handpiece was applied perpendicular to the skin surface, ensuring full contact and even pressure. Treatment parameters (fluence, pulse duration, repetition rate) were selected based on skin phototype, hair color, and anatomical site. The handpiece was moved in a continuous, overlapping pattern to ensure complete coverage of the treatment area, with a 10-20% overlap between adjacent pulses. During each session, real-time monitoring of skin response (e.g., erythema, perifollicular edema) was performed to identify the clinical endpoint and adjust parameters as needed.

Post-treatment care

Participants received standardized post treatment instructions, including avoidance of sun exposure and use of broad-spectrum sunscreen (SPF >30). And use appropriate moisturizers on the areas where treated [9]. All adverse events and participants' reported symptoms were documented at each visit and managed according to established clinical guidelines.

Primary outcome definition and measurement methods

Primary Outcome

The primary efficacy outcome was the Subjective reduction in hairiness, which was determined by a subjective overall impression of the hair reduction.

Secondary Outcomes and Safety Assessments

Time to assess hair regrowth: Defined as the interval (in weeks) from the final treatment session to the first participant-reported observation of visible hair regrowth within the treated area.

Patient satisfaction: Assessed using a validated 100 mm visual analogue scale (VAS), with anchors at 0 (no improvement) and 100 (complete satisfaction), administered at each follow-up visit.

Reduction in frequency of hair removal: Self-reported change in the frequency of shaving or other hair removal methods in the treated area, compared to baseline.

Safety Assessments

Side effects: All immediate and delayed adverse events were systematically recorded at each visit, categorized by severity (mild, moderate, severe), duration, and relationship to the intervention.

Pain assessment: Participants rated procedural discomfort using a 10-point VAS (0 = no pain, 10 = worst imaginable pain) immediately following each session.

Pigmentary changes: Incidence and severity of post-inflammatory hyperpigmentation, hypopigmentation.

Treatment and Follow-up Timeline

Treatment phase

Participants were first scheduled to complete a standardized course of twelve-monthly laser treatment sessions. However, some patients commonly achieved satisfactory outcomes earlier. For this reason, some of the participants discontinued after 8, 9, 10, or 11 sessions. This variability in treatment duration reflects the individualized attainment of optimal therapeutic results, with follow-up assessments anchored to the point of patient-reported satisfaction rather than a rigid protocol.

Follow-up assessment: post-treatment evaluation was conducted after the final session, according to the patient's satisfactory results obtained. At each visit, efficacy and safety assessments were performed as per protocol. Participants received reminders via phone and SMS before each appointment.

Retention Strategies

To maximize participant retention and minimize loss to follow-up, the following strategies were employed: Comprehensive education regarding the importance of follow-up for both personal benefit and study integrity. Flexible scheduling options, including evening and weekend appointments.

Regular communication and engagement by the research team, including interim check-ins between visits. Collection of multiple contact methods and secondary contacts to facilitate re-engagement in case of missed appointments.

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Safety Monitoring and Adverse Event Reporting

A comprehensive safety monitoring plan was implemented, encompassing the following elements: Adverse event (AE) collection: All AEs, regardless of severity or causality, were recorded at each visit and followed until resolution or stabilization.

Results

The majority of patients were young adults, with 68% falling between 21–30 years, while only 8% were ≤20 years and 24% were aged 31–40. The mean age was 27.7 years (SD = 5.8), with a median of 27 years, indicating a relatively homogeneous age group (Table 1).

Table 1. Distribution of patients according to age.

Age /year	No	%
≤20	4	8
21 - 30	34	68
31 - 40	12	24
Total	50	100

Mean age =27.7, Std. Deviation =5.8, Median= 27, Minimum age= 18, Maximum = 40

The gender distribution of patients is illustrated in Figure 2, showing the relative proportions of male and female participants. This provides context for interpreting treatment outcomes across genders.

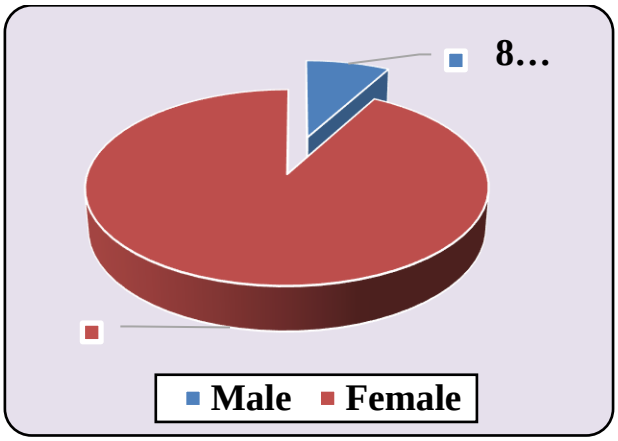

Figure 2. Distribution of patients according to gender.

Figure 3 demonstrates the distribution of patients according to skin type, which is clinically relevant given the influence of skin type on laser treatment response and side effect profiles.

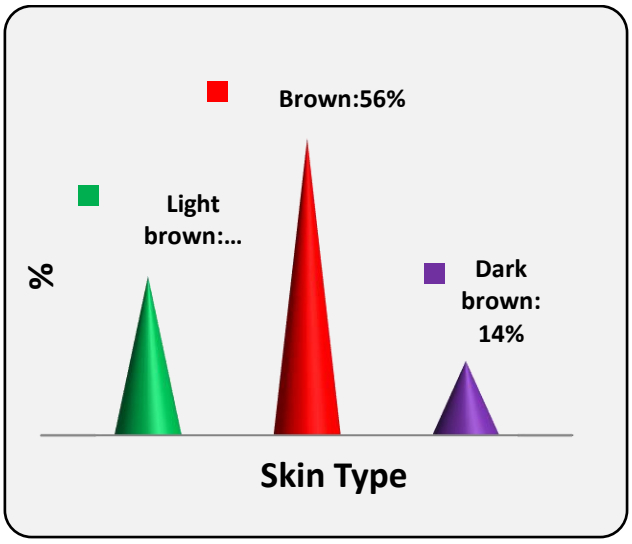

Figure 3. Distribution of patients according to skin type

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The most common treatment sites were the bikini area (28%) and axilla (20%), followed by the face (14%) and legs (15%). Less frequent sites included upper lips (12%), chest (4%), arms (4%), and beard (2%), reflecting patient preferences for diode laser application (Table 2).

Table 2. Distribution of patients according to area of diode laser treatment application.

Area	No.	%
Face	7	14
Upper lips	6	12
Beard	1	2
Axilla	10	20
Chest	2	4
Bikini	14	28
Legs	8	15
Arms	2	4
Total	50	100

Across sessions, side effects were minimal. Redness was the most frequent, occurring in up to 10% of patients, while post-inflammatory pigmentation appeared only in later sessions (up to 9.1%). No burns or hypopigmentation were reported. The majority of patients remained free of adverse effects throughout treatment (Table 3).

Table 3. Distribution of patients according to side effects

Number of Session (No.of patients)	Side effect				
	No	Redness	Burn	Post-inflammatory pigmentation	Hypo pigmentation
	No./%	No./%	No./%	No./%	No./%
1st Session (50)	50/100	0	0	0	0
2nd Session (50)	47/94	3/6	0	0	0
3ed Session (50)	49/98	1/2	0	0	0
4th Session (50)	49/98	1/2	0	0	0
5th Session (50)	47/94	3/6	0	0	0
6th Session (50)	48/96	1/2	0	1/2	0
7th Session (50)	49/98	1/2	0	0	0
8th Session (50)	46/92	4/8	0	0	0
9th Session (41)	36/87	4/9.8	0	1/2.4	0
10th Session (30)	25/83.3	3/10	0	2/6.7	0
11th Session (25)	23/92	0	0	2/8	0
12th Session (22)	20/90.9	0	0	2/9.1	0

Satisfaction increased progressively with successive sessions. Initially, all patients were unsatisfied (2nd session), but by the 6th session, 80% reported satisfaction or satisfaction. By the 9th–12th sessions, nearly all patients were satisfied, with satisfaction reaching 68% (Table 4). This trend highlights the cumulative benefit of repeated treatment.

Table 4. Distribution of patients according to the degree of satisfaction.

Number of Sessions	Unsatisfied		Satisfied		Full satisfied	
	No.	%	No.	%	No.	%
2nd Session (50)	50	100	0	0	0	0
3rd Session (50)	44	88	6	12	0	0
4th Session (50)	28	56	21	42	1	2
5th Session (50)	15	30	31	62	4	8
6th Session (50)	10	20	33	66	7	14
7th Session (50)	2	4	36	72	12	24
8th Session (50)	1	2	28	56	21	42
9th Session (41)	0	0	22	53.7	19	46.3
10th Session (30)	0	0	15	50	15	50
11th Session (25)	0	0	8	32	17	68
12th Session (22)	0	0	7	31.8	15	68.2

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Hair regrowth time increased significantly across sessions. The mean regrowth interval extended from 8 days after the 1st session to 33.7 days after the 12th session. Statistical analysis confirmed significant differences beginning from the 2nd session onward ($p < 0.01$), indicating sustained efficacy of diode laser treatment (Table 5).

Table 5. Distribution of patients according to time of hair regrowth.

Number of Sessions	Time of hair regrowth /day		
	Mean ± St. Deviation	Range	p value
1st Session (50)	8±1.7	5 - 10	0.544
2nd Session (50)	8.3±2.5	5 - 15	0.006
3ed Session (50)	9.9±3.1	5 - 18	0.004
4th Session (50)	12.1±4.4	7 - 20	0.001
5th Session (50)	15.3±4.7	7 - 28	0.010
6th Session (50)	18.4±6.5	7 - 30	0.010
7th Session (50)	22.14±6.7	7 - 35	0.006
8th Session (50)	25.94±7.9	10 - 45	0.010
9th Session (41)	26.84±6.9	15 - 45	0.575
10th Session (30)	28±6.7	20 - 45	0.434
11th Session (25)	30.7±5.7	25 - 45	0.126
12th Session (22)	33.7±6.4	25 - 45	0.091

Discussion

The demographic analysis of this study cohort (n=50) shows that most patients were young adults, with 68% (34/50) falling within the 21-30 age bracket. Patients aged 31-40 accounted for 24% (12/50), while only 8% (4/50) were 20 years old or younger. This age distribution is consistent with the typical population seeking aesthetic or therapeutic interventions for hirsutism.

Safety and efficacy in high Fitzpatrick skin types

There are many concerns about laser hair removal for dark skin types has presented significant clinical challenges. For example, the primary difficulty with the mechanism of action, which targets melanin, in darker skin, the high concentration of epidermal melanin competes with the hair follicle for energy absorption. This proximity increases the risk of thermal injury to the surrounding tissue [3]. However, the results of this study demonstrate that the 808nm diode laser system is a highly effective and safe modality for hair reduction in dark-skinned Libyan patients when administered across a multi-session protocol. Moreover, long-term monitoring 12 months post-treatment revealed a 0% incidence of permanent pigmentary changes, with no cases of persistent hypopigmentation or hyperpigmentation observed. While transient hyperpigmentation may occur, it remains temporary and typically resolves within a few months.
Correlation Between Treatment Frequency and Hair Regrowth. A notable finding in this research is the direct correlation between the number of treatment sessions and the latency of hair regrowth. We observed a progressive, statistically significant increase in mean regrowth time ($p < 0.05$ through the 8th session), extending from 8 ± 1.7 days following the initial session to 33.7 ± 6.4 days by the 12th session. This shift highlights the cumulative damage inflicted upon the follicular apparatus, effectively transitioning hair from a rapid regrowth phase to a prolonged dormant state.

Clinical management and patient satisfaction

From a clinical management perspective, the longitudinal tracking of patient satisfaction provides essential data for practitioner-patient counselling [1]. Initially, the data reflected a 100% dissatisfaction rate at the second session, likely due to patients' unrealistic expectations for immediate results. On the other hand, as cumulative energy reached therapeutic thresholds and regrowth intervals widened, satisfaction scores shifted dramatically. By the 12th session, no patients remained unsatisfied, with 68.2% reporting they were fully satisfied. These findings underscore the necessity of the importance of patient education to manage expectations regarding the long-term nature of the treatment plan, which typically requires more than eight sessions to achieve anticipated clinical success. Our results align with previous studies in the field, further validating this treatment protocol [6,7].
Anatomical Variations in Treatment Response. Finally, this study indicates that anatomical location and the size of the treated area significantly influence treatment duration and outcomes. Larger or more hormonally sensitive areas, such as the bikini and chest, appeared to require a higher number of sessions for effective

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clearance compared to other regions. While the 808nm wavelength is well-absorbed by follicular melanin, its safety profile in dark skin is bolstered using appropriate pulse durations (17ms). In the end, practitioners must remain aware of transient side effects to ensure the continued safety and comfort of the patient throughout the treatment course.

While this study provides valuable clinical evidence for treating darker skin phenotypes, several limitations must be mentioned:

- Sample Size and Gender Imbalance: The study cohort consisted of only 50 patients. Furthermore, the population was heavily skewed toward females (46 females vs. 4 males), which may limit the generalizability of these results to male patients, whose hair density and hormonal influences on regrowth differ significantly.
- Sampling technique: Participants are selected based on their accessibility to the researcher.
- Subjective Assessment Metrics: The primary measures of efficacy were based on a subjective overall impression of hair reduction and a visual analogue scale. The lack of objective, quantitative data, such as manual hair counts per square centimeter or high-resolution photographic analysis, introduces a risk of observer bias.
- Data Attrition in Later Sessions: There was a notable decrease in the number of participants as the study progressed. While 50 patients participated through the 8th session, only 22 patients completed the full 12-session course. This attrition may create a "survivor bias," where the final satisfaction rates (68.2% Full satisfied) reflect only those who were seeing enough progress to continue treatment. The decision to evaluate patient satisfaction after around eight sessions, instead of waiting until the twelfth session to assess, was guided by the clinical intentions of recording outcomes as soon as possible when patients typically report noticeable benefits. Hence this judgmental expert decision reflects recognized practice patterns and authentic patient experiences, ensuring that the obtained data aligns with therapeutically significant achievements rather than an inconsistent completion criterion.
- Anatomical Heterogeneity: The study grouped various body areas, ranging from the face to the legs. Given that hair growth cycles and terminal hair depths vary significantly by anatomical location, the combined analysis may mask specific variances in treatment response between different regions.

Conclusion

This study supports that the 808nm diode laser system is a highly effective and safe option for hair reduction in Fitzpatrick skin types IV-VI. In conclusion, the research highlights a direct, statistically significant correlation between the number of treatment sessions and the remission of hair regrowth, which extended from approximately 8 days to nearly 34 days by the 12th session. Overall, for clinical practice, the evolution of patient satisfaction, while initial dissatisfaction is high, indicates the importance of patient education and long-term follow-up. By the 12th session, every patient in the study reported being either Satisfied or fully satisfied, with a complete absence of permanent pigmentary complications. These results suggest that the 808nm diode laser provides a reliable long-term solution for unwanted hair for dark-skinned patients. Also, remind clinicians to manage patients' expectations regarding the necessity of a multi-session regimen (typically 8-12 sessions) to achieve optimal clinical outcomes.

Conflict of interest. Nil

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