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Successful White Hair Removal with Combined Coloring and Intense Pulsed Light (IPL): A Randomized Clinical Trial

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Abstract

Objective: The purpose of this study was to introduce adjunct therapy to intense pulsed light (IPL) and to assess it in terms of safety, expense, feasibility, and efficacy. ***Background data:*** Currently there is no satisfactory, efficient method for long-term white hair removal. ***Methods:*** We conducted a randomized clinical trial of hirsute patients with excessive white hair on the chin and cheeks. In addition to IPL, the patients were randomly assigned to have their white hair colored with either black eyeliner or black hair dye as an adjunct to IPL aided for of six sessions (with a 4-week interval between sessions). The primary efficacy outcome, which was defined as the outcome after six sessions of therapy, was scored as poor ($<30\%$), fair (30–60%) or good ($>60\%$) response to white hair removal in predefined areas. The secondary outcome was recurrence 6 months after the final therapy session. ***Results:*** In the eyeliner group ($n=31$), 15 (48.4%) individuals showed a fair response, and 16 (51.6%) individuals showed a good response. In the color-dye group ($n=31$), 1 (3.2%), 17 (54.8%) and 13 (41.9%) participants scored poor, fair, and good, respectively. There were no differences in clinician judgment of the treatment success between the eyeliner and color-dye groups after the six therapy sessions ($p=0.895$). Thirty-one patients had 6 months of visits (11 in the hair dye and 20 in the eyeliner group). Three participants in the color-dye group and five participants in the eyeliner group failed to show improvement 6 months after the laser surgery. There was no distinguishable pattern of failure between the two study groups ($p=1$). ***Conclusion:*** This study supports that hair coloring is an efficient and feasible technique that can be combined with IPL to eliminate white facial hair.

Introduction

Hirsutism is described as excessive hair growth over androgen-dependent areas in women.[1] This could be accompanied by anxiety, depression, and low self-esteem; hence, hirsutism can create a heavy psychosocial burden.[2–4] Studies have reported that idiopathic hirsutism is a common form of the disease, and polycystic ovarian syndrome (PCOS) has also been shown to cause hirsutism.[5,6] Hirsutism affects a considerable percentage of women throughout the world, and expectations and questions about hair removal vary from case to another. In addition, 5–10% of women of child-bearing age may be affected, and average reports from Iran are even higher.[6] Hirsutism is more prevalent in Asian than in Western communities (mostly in Mediterranean compared to Indian and Mongolian areas within Asia).[7–9] Indeed, a survey among female medical students in Tehran, Iran, showed that the incidence was as high as 22.8%.[7] In addition, a research study from Yazd, Iran, reported that 10.8% of Iranian female high school girls aged 15–19 years were hirsute.[10] Furthermore, Hashemipoor et al. published a paper about the prevalence of PCOS among 1,000 Iranian high school girls aged 14–18 years,[11] which showed that clinical PCOS was present in 30 (3%) girls, and hirsutism was present in 60 (6%) girls.

In Iran, increasing numbers of hirsute women, primarily those 16–35 years old, have been referred to dermatologists during the last two decades. It has been postulated that this increase may be secondary to the 8-year Iran–Iraq war and changing life styles (mostly influenced by the machinery world). Indeed, stress has been shown to be an important causative factor of hirsutism.[12]

Over the past 20 years, there has been a trend toward moving away from older treatments of hirsutism (e.g., plucking, waxing, depilatories, bleaching, shaving, electrolysis) to

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more advanced modalities (e.g., laser and intense pulsed light [IPL]).[13] These advanced techniques provide clearer, shinier, and smoother results with less pain, infection, and scarring. In addition, these new techniques require less time than the older methods. Each of the methods mentioned previously have advantages and disadvantages.

One major drawback to lasers is their inability to adequately remove white, blond, and gray hair. During laser treatment, melanin in hair shafts conducts the energy to hair follicle stem cells within the papilla and bulge region of the outer sheath. This leads to heat destruction of the hair.[14] The darker and thicker the hair, the more efficient the thermolysis. Melanin content of bright hair (pheomelanin) differs from that of dark hair (eumelanin); hence, energy absorption and thermoconduction are impaired in lighter colored hair. Exogenous chromophores, such as liposomes (encapsulated melanin),[15] photosensitizers (aminolevulinic acid),[16] and carbon particles (carbon suspension) have been proposed to augment white, gray, and bright blond hair elimination. Moreover, the hair-free interval may be enhanced by combination therapy with metformin,[17] elfornithine cream (13.9%),[13] or fennel extracts.[18] The overall success rate, however, was not great, and the cost of the treatment was very high. In addition, there have not been sufficient long-term and large-scale human studies to test these methods. The present study was designed to test the effectiveness of a new method of enhancing bright hair photothermolysis-aided (IPL) elimination and assess the safety, expense, feasibility, and efficacy in terms of permanent or long-term white hair removal.

Methods

Study design and eligibility criteria

We conducted a randomized, single-blinded (assessor, biostatistician), active-controlled, parallel- assigned trial to determine the safety and efficacy of hair coloring to treat unwanted facial (buccal and chin area) hair in hirsute females. This study was accepted by the ethics committee of the Iranian Medical Laser Association and followed the guidelines of the Declaration of Helsinki.

The present study enrolled patients with excessive white facial hair and skin type I-III (Fitzpatrick classification) who sought laser hair removal. Patients were excluded if they were <16 years of age; uncooperative because of psychological or mental problems; had associated photo-aggravated skin diseases or a medical illness (e.g., systemic lupus erythematosus [SLE], treatment area with active cutaneous infections, herpes labialis and staphylococcal infections), keloid or history suggestive of tendency to keloid formation, superficial cuts and injury in the treatment area; or had been on photosensitizer medication during the last month (e.g., minocycline, isotretinoin, or chloroquine and its derivatives). We also excluded patients with unrealistic expectations and patients who had tanned during the previous 2 weeks. Special attention was given to cases with psoriasis, vitiligo at risk for Koebner phenomenon, and previous herpes infection. In cases of previous herpes infection, a course of acyclovir was recommended, and the patients were informed about the risk and benefits of the cosmetic surgery, considering the probability of severe *in situ* activation of herpes.[19] A written informed consent was obtained from the patients.

Randomization and blindness

The participants were assigned to have their white hair colored with either black eyeliner or black hair color. Hence case and control groups were both treated actively. We designed the study with such assignment, because there was no effective treatment with satisfactory long-term outcome and low side effects. Therefore, subjects treated with methods such as epilation, which can cause a considerable amount of discomfort, scar formation, and infection rate were not included as the control group. Randomization was performed with a computer-generated list and permuted blocks with four intervals and a ratio of 1:1. Sequential numbers were sent via closed envelopes to the chief clinician in charge of supervising and performing the study. Assessments were made by experienced office members. Both the assessors and biostatisticians were blinded to the randomization.

Study protocol

After informed consent and final enrollment, the long hairs were cut (final length of 1–5 mm). White hairs were carefully colored with either dark hair color (dye), 2 days prior to each therapy session using fine microbrushes, or black eyeliner on the same day of the therapy. Soon after the eyeliner or dye was applied, the area was cured with an icepack held for 10 min at the site. Also, the perifollicular area was protected with a thin layer of Zinc oxide cream 20%; thereafter the area underwent laser therapy. Photothermolysis was accomplished by an IPL delivery system. The setup parameter (frequency, fluence, pulse width, and delay time) were adjusted based upon each patient's skin type and treatment order. The device we used had a wavelength of 530–1200 nm, a pulse width of 5 ms, a 20-ms delay time, and a fluence of 40 J/cm^2. To lessen patient postsurgical inconvenience and side effects, ice packs were held on the site for 10 min before and after IPL therapy. Cooling during phototherapy was managed via an internal cooling system of the IPL device. We designed six sessions with 4-week intervals. Surgical sites were assessed for probable serious side effects, including severe irritation, bulla, burn, and folliculitis, between subsequent remedial visits. After the final session, all patients had 3- and 6-month follow-ups to control inflammatory changes (postinflammatory hyperpigmentation and hypopigmentation), hypertrichosis, and paradoxical hair growth at the border of irradiated area.[20,21] The patients were instructed not to take other medication, including over the counter (OTC) medications, and to avoid tanning and other alternatives, such as waxing, during the study.[19]

Primary and secondary end points

The primary efficacy outcome (defined as the outcome after six therapy sessions scored from poor to good response) was based on clinician discretion. The secondary outcomes were patient self- assessed satisfaction scored from poor to desirable, recurrence after 3 and 6 months from final therapy session, and major side effects during and after remedial visits.

Assessment

Age, initial white hair count, and skin type (Fitzpatrick classification) were entered into medical records. Afterwards,

each participant underwent a thorough clinical examination and further clinical testing, including abdominal ultrasonography, complete blood count (CBC), fasting blood sugar (FBS), serum prolactin, free testosterone, thyroid stimulating hormone (TSH), free T4, luteinizing hormone (LH), follicle-stimulating hormone (FSH), and dehydroepiandrosterone sulfate (DHEAS) based on physician discretion.[19] Hair count, which was carefully measured through the use of magnified digital images by two experienced office members in a blinded manner, was performed before and after the therapy and at the 3- and 6-month follow-up appointments. In cases of disagreement between the two observers, the average count was recorded. Patients judged their improvement and scored their satisfaction as 1, 2, and 3 for poor, good, and desirable outcomes, respectively. After the six therapy sessions were completed, white hairs were counted for each patient and recorded in her medical file. Success was rated by clinician as poor for $<30\%$ reduction, fair for 30–60% reduction and good for $>60\%$ reduction from baseline counts. Patients were recalled for 3- and 6-month post-laser-therapy visits to assess the failure rate ($>20\%$ increase in white hair counts since the last laser therapy session).

Statistical analysis

We estimated that 62 patients would be required to achieve 80% power to detect 0.7 standardized difference between two groups in the rate of primary end point (with Altman's nomogram). Continuous data were expressed as mean ($\pm$standard deviation). Comparison of quantitative data performed with Pearson's χ^2 test and reported with Fisher's exact test where appropriate. Significant differences were expressed as odds ratios with 95% confidence intervals (CIs). Correlation coefficients of ordinal and continuous variables were assessed by Spearman's ρ and Pearson statistics, respectively. In addition, Cochran Q test was used to evaluate the confounding effects of qualitative variables. Homogeneity of odds ratio was measured by Breslow-Day statistic. Because some of ordinal logistic regression assumptions were not met, a generalized linear model was formulated with an ordinal response. We reported the β coefficient, Exp (b) and model effect of each predictor with CI 95%. A final model was chosen by the set of predictors that built the best model, and the last category was designated as a reference. First, all predictors were entered as factors, as they were judged to be important predictors. For clinician score, all variables remained in the final equation because the model Omnibus test was significant [likelihood ratio $X^2(8)=15.98$, $p=0.043$], although no strong model was reached for patient self satisfaction [likelihood ratio $X^2(8)=10.35$, $p=0.329$]. Statistically significance was defined as $p<0.05$ (two-tailed).

Results

Study population

Patient recruitment was accomplished by referral to one private laser clinic in Babol (northern Iran), Mazandaran province during 2008–2009. We assessed 125 hirsute females and we enrolled 62 into the final randomization. The most common reason for ineligibility was tanning, which was followed by unrealistic expectations. All 62 patients completed the six therapy sessions and appeared at the 3-month follow-up, but only 31 patients returned for the 6-month follow-up. A detailed description is displayed in Fig. 1.

Baseline characteristics

The mean age was 34.62 ($\pm$8.19) years, and ranged between 21 and 49 years. One patient (1.6%) had skin type I, 37(59.7%) had type II, and 24(38.7%) had type III. Eight individuals were diagnosed with PCOS and two had thyroid dysfunction. Baseline counts clarified that 20 patients (32.3%) had <10 white hairs and 42 patients (67.3) had ≥ 10 white hairs.

Primary and secondary end points

In the eyeliner group, the clinician assessed 15 (48.4%) and 16 (51.6%) individuals with fair and good responses, respectively (Table 1). In the color-dye group, one (3.2%), 17 (54.8%), and 13 (41.9%) participants were scored as poor, fair, and good, respectively. There were no differences between the treatment success in the eyeliner and color-dye groups ($p=0.895$). In the eyeliner group, 18 (58.1%) and 12 (38.7%) judged treatment outcomes as good and desirable, respectively. One (3.2%), 18(58.1%), and 11(35.5%) females in color-dye group stated poor, good, and desirable satisfaction, respectively (Table 2). A comparison of two hair-coloring methods did not reveal any significant difference in patient satisfaction ($p=0.746$). The younger individuals had lower levels of clinical outcome scores (Kendall's τ-b $p=0.044$, $r=0.247$). Further analyses clarifying clinical outcomes (clinician judgment) were not affected by skin type ($p=0.939$), initial white hair count ($p=0.06$), concomitant PCOS ($p=0.186$), or thyroid hormonal disturbances ($p=0.150$). In addition, we did not notice any significant relationships between participant contentment and skin type ($p=0.692$), age ($p=0.194$), initial white hair count ($p=0.051$), concomitant PCOS ($p=0.251$), or thyroid hormonal disturbances ($p=0.275$). There was a tendency for older hirsute females to have a better response than younger females (40–50 years vs. 20–40 years, $p=0.023$, odds ratio: 3.33, CI 95%: 1.16–11.52). This correlation remained significant even after adjustment for the presence of PCOS (Cochran's $p=0.031$). We also observed a significant positive relationship between clinician and patient scores ($r=0.771$, $p<0.001$). Minor expected side effects were ignored because of inaccurate recordings. One patient in the color-dye group burned severely and developed hyperpigmentation. Treatment included burn management, which continued for depigmentation of the affected skin, and the problem resolved completely within 7 months. Three months later, 62 participants returned, and all had minimal hair growth ($<20\%$ from final therapy session). After 6 months, only 31 patients (11 in the hair dye and 20 in eyeliner group) returned: 3 in the hair-dye group and 5 in the eyeliner group failed to show improvement in the 6-month recall (Figs. 2–5). Moreover, one patient in the eyeliner group returned with hypertrichosis. There was no distinguishable pattern of failure between the two study groups ($p=1$). Failure was not affected by thyroid dysfunction ($p=0.243$), age ($p=0.406$) or skin category ($p=0.687$). We did, however, observe a significant contribution of the presence of PCOS to the final failure rate ($p<0.001$, odds ratio: 4, CI 95%: 1.16–11.52). Other variables did not significantly predict the 6-month follow-up outcomes. The extra cost of

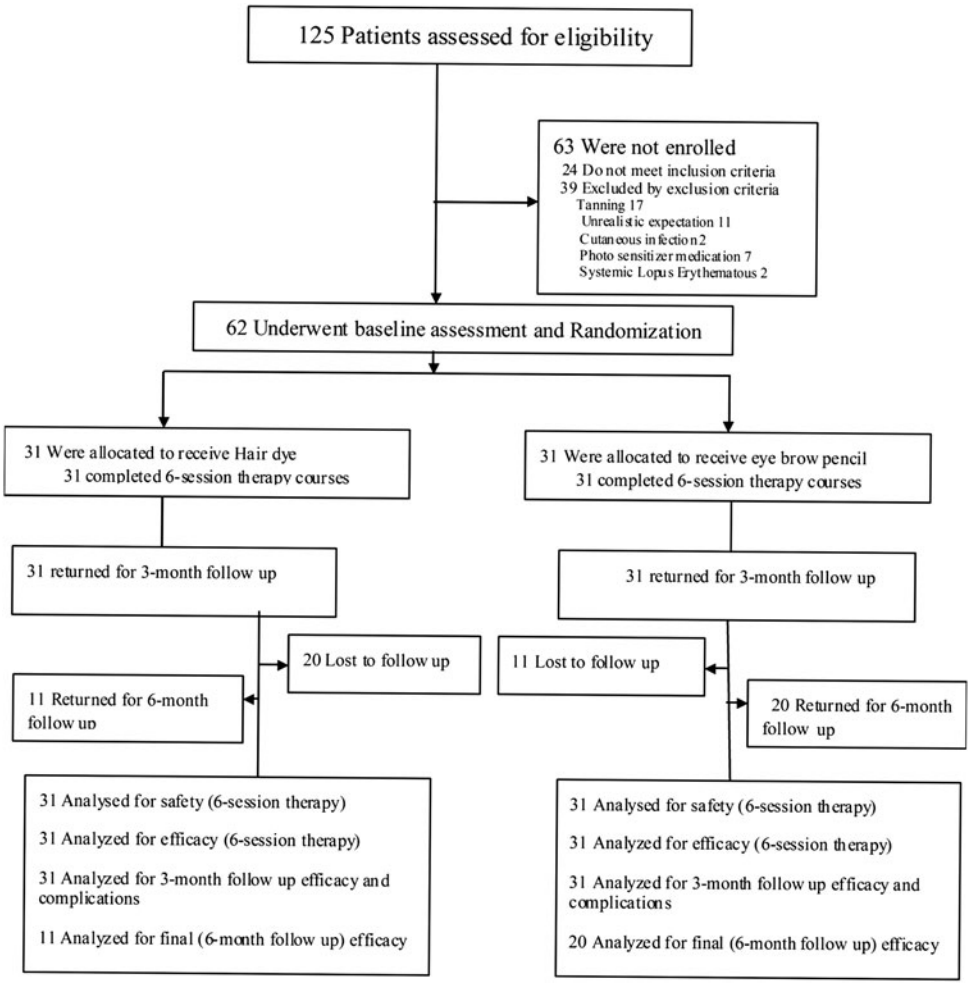

FIG. 1. Enrollment and randomization flow chart.

the coloring procedure was calculated as an average $5 for the whole study duration.

Discussion

The present study assessed an innovative method to eliminate excessive facial white hair in Iranian hirsute females. We used a combination of hair coloring, with either eyeliner or hair dye color, and IPL technology. Patients and clinicians were generally satisfied with the results (only one [1.6%] participant judged the results as poor). Based on a generalized linear model, both clinician and patient assessments were not related to baseline white hair counts, underlying hormonal disturbance, age groups, or skin types ($p > 0.05$). In addition, the patient and clinician satisfaction statuses were positively correlated ($r = 0.771$, $p < 0.001$). Among the eight patients with PCOS in this study, five had a good response and three had a fair response after the six therapy sessions ($p > 0.05$, power 0.22). Six patients out of 8 (75%) with PCOS, at 6-month follows-ups, displayed failure ($p < 0.001$, odds ratio: 4). Interestingly, further simultaneous adjustment for study group interventions showed remarkable correlations between the presence of PCOS and the 6-month failure rate (Cochran's $p < 0.001$). High levels of circulating androgens were probably responsible for the higher failure rate. Androgens are the main sex hormones accounting for hair growth regulation, and studies suggested that they act by lengthening the anagen phase.[22] Different skin types (I–III) did not differ in the degree of response to photolysis in our study (Kendall's τ-b $p = 0.447$, power 0.05). Surprisingly, no authentic classification exists for Iranian race, Caucasians, or Asians. Skin and hair contrast in Iranian population (darker hair, darker skin) is comparable to that of white European Caucasians (brighter hair, brighter skin). Although a wide range of combination exists in various parts of the country, brighter hair and skin are more common in northern part of Iran, whereas darker hair and skin are common in the southern part of Iran. A significant reduction ($\sim 60\%$) was seen after six sessions, but there was not a marked difference between the two interventions (risk difference 10%, power 0.12). Approximately 54 patients (88%) were satisfied, and at the 6-month follow-ups they had maintained $>80\%$ of laser hair elimination. The final result did not differ in either study group (risk difference 2%, power 0.05). Our remarkable result is even comparable to the previous success rate of IPL systems application on black hair (50–80%).[23–26]

Interestingly, older women (>40 years) responded better to therapy (odds ratio 3.33). This study revealed that higher-order outcomes were achieved in older groups ($r = 0.247$). Tyrosinase converts thyrosine to melanin with an intermediate compound, dopaquinone. Older individuals have increased activity of tyrosinase, which may be responsible for the better response in older patients;[27] however, Liew et al. claimed that there was no age-related response pattern.[28]

Table 1. Predictors' Contribution to Clinician Satisfaction Level

		Clinician assessment scores (n)			Generalized Linear Model[a]			
					Model effect	Parameter estimates		
Predictors		*Poor*	*Fair*	*Good*	p *value*	*B*	p *value*	*Exp(B),CI 95%*
Skin type (Fitzpatrick classification)	*I*	0	0	1	0.939	22.15	1	4.18
	II	0	21	17		−0.22	0.724	0.79,0.22-2.82
	*III***	1	12	10		-	-	1
Age	*21-30*	0	5	2	**0.023****	−3.02	**0.01**	0.48,0.00-0.48
	31-40	0	22	14		−1.37	**0.041**	0.25,0.06-0.94
	*41-50****	1	6	12		-	-	1
Intervention group	*Eye liner*	0	16	15	0.895	0.085	0.895	1.08,0.30-3.87
	*Hair dye****	1	17	13				
Polycystic ovary syndrome	*No*	1	30	23	0.186	−1.326	0.186	0.26,0.03-1.89
	*Yes****	0	3	5				
Other hormonal disturbance	*No*	1	30	28	0.150	2.83	0.150	16.97,0.35-803.91
	*Yes****	0	2	0				
Initial white hair count	*<10*	0	9	11	0.06	1.45	0.06	4.28,0.94-19.44
	*>10****	1	24	17				

[a]Omnibus test: likelihood ratio $X^2(8) = 15.98$.
$p = 0.043$ ** statistically significant *** last category in each variable assigned as reference category.

One patient in the hair-dye group (3%) suffered from moderate to severe burns, and one in eyeliner group (3%) experienced hypertrichosis. Leukotrichia, paradoxical hair growth in the periphery of beamed area (previously hair-free) and hypertrichosis of cured skin area have been reported as side effects of IPL.[20] Hypertrichosis may be observed more often in patients with a combination of darker skin and hair with underlying hormonal disturbances. A recent review article reported that the prevalence of hypertrichosis may be as high as 10% of cases treated with laser devices.[29] Radmanesh (Iran, 2009) showed that 51/991(5%) cases treated with IPL developed hypertrichosis,[30] whereas a study by Alajlan (Canada, 2005) showed that only 3/489(0.6%) cases had increased hair after laser hair removal.[21] Different skin types and diverse hair colors may attribute to these contrasting findings.

Suboptimal energy may be delivered with IPL systems. Studies have postulated that such inefficient energy transmission may thermally damage the melanocytes without further follicular destruction, which means that the resultant depigmented hair shaft has the potential to continue to grow.[14]

In addition to the melanin content of melanosomes, the different stages of the hair cycle are a key determinant of hair follicle susceptibility to thermolysis. Suboptimal energy delivery could shift the cycle to late anagen rather than miniaturization of the hair shaft.[14] Willey et al. proposed cold packs over irradiated area as a solution to this problem.[14] Moreover, dye penetration depth varies in different stages of the hair cycle. As a hair follicle passes from the anagen to the telogen phase, a gap between hair shaft and outer root sheath (ORS) is formed, allowing for deeper penetration of dye during catagen and telogen phases. This may be another explanation for the different levels of response among treated participants.[31] Based on previous study, for the eyeliner dye group, immediate laser therapy after application of dye

Table 2. Predictors' Contribution to Patient Satisfaction Level

		Participants assessment scores (n)			Generalized Linear Model[a]
					Model effect
Predictors		*Poor*	*Fair*	*Good*	p *value*
Skin type (Fitzpatrick classification)	*I*	0	0	1	0.692
	II	0	23	13	
	III	1	13	9	
Age category	*21-30*	0	5	2	0.194
	31-40	0	22	13	
	41-50	1	9	8	
Intervention group	*Eye liner*	0	18	12	0. 746
	Hair dye	1	18	11	
Polycystic ovary syndrome	*No*	1	32	20	0.251
	Yes	0	4	3	
Other hormonal disturbance	*No*	1	34	23	0.275
	Yes	0	2	0	
Initial white hair count	*<10*	0	9	10	0.051
	>10	1	27	13	

[a]Omnibus test: likelihood ratio $X^2(8) = 10.35$, $p = 0.329$.

FIG. 2. First session, before laser surgery.

was planned to achieve best results based on the time-dependent manner of dye penetration and the higher intensity of the penetrated dye just after the dying procedure.[31] The present study did not conduct a histological or biochemical survey. In addition, there were several other limitations of our study including the lack of a specific dermatological quality-of-life questionnaire, a small sample size, and a relatively large number of participants lost prior to the 6-month follow-up. Low achieved powers in our study indicate that larger sample size may be needed to display significant differences by skin types, study groups, the presence of PCOS, or thyroid dysfunction, to predict the rate of hair reduction. A 1-year follow up program may better reveal conclusive and authentic results. Considering the disappointing results from our pilot study investigating the efficacy of IPL to eliminate white hairs, we did not design the control group as IPL therapy without coloring intervention (i.e., because of medical ethics). Both mentioned methods were hypothesized to be efficient based upon a similar mechanism (i.e., exogenous chromophore). Future laboratory studies of energy absorbance properties of the products used in this research would be noteworthy.

FIG. 3. Third session after two therapy sessions.

FIG. 4. Sixth session after five therapy sessions.

Studies have proposed that vascular endothelial growth factor (VEGF) derives its angiogenesis effect via nitric oxide (NO) modulatory pathways.[32] There may be a benefit of upregulation of VEGF angiogenesis via augmented NO pathways by means of NO donors such as topical arginine or nitroglycerin. Further research with a larger sample size and more precise histopathological and bimolecular studies (particularly negotiating NO pathways in hair growth) may be warranted for better recognition of hair growth pattern. Indeed, these studies would probably help the clinician activate dormant follicles, which otherwise could not be affected by the laser, and achieve a greater effect on hair growth phases.

Conclusion

Over the past 20 years, there has been a striking increase in the demand for cosmetic procedures, even among men. Based on our result, hair coloring techniques can safely and affordably be used in combination with IPL to enhance the elimination of white hair. Because of diverse sensitivity and

FIG. 5. Post 6-month follow-up outcome after the completion of six therapy sessions.

special growth characteristics, special consideration should be given to each body area, or even different dermatomes of facial skin; however the method described in this study may be practically implemented when undesirable white hair (e.g., aging, hirsutism) is a concern.

Author Disclosure Statement

No conflicting financial interests exist.

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