Received: 21 December 2021 | Revised: 18 February 2022 | Accepted: 16 March 2022

DOI: 10.1111/jocd.14926

JCD Journal of Cosmetic Dermatology WILEY

ORIGINAL ARTICLE

Safety and efficacy for hair removal in dark skin types III and IV with a high-powered, combined wavelength (810, 940 and 1060 nm) diode laser: A single-site pilot study

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Abstract

Background: Previous studies have demonstrated the superior efficacy of a high-power diode laser (4800 W) with a wavelength of 810 nm over others with less power and the same wavelength, while also being safe and comfortable for the patient. However, the use of this laser is limited on dark skin.

Objectives: This study aims to compare the efficacy, safety, and comfort of a 4800 W diode laser (810 nm) with that of the new Blend diode laser (810 nm, 940 nm, and 1064 nm). Furthermore, the study aims to demonstrate that the Blend diode laser delivers better results on darker skin.

Materials and methods: A 810 nm diode laser was compared with the Blend diode laser (810, 940 and 1064 nm) (Primelase, Cocoon Medical). A side-by-side comparative study was carried out over three sessions involving fourteen participants with skin types III and IV, with evaluation of the results 6 months after treatment. The study was performed at the Tennessee Clinical Research Center, Nashville, Tennessee, USA. This evaluation was based on efficacy, safety, comfort, and participant satisfaction.

Results: Blend diode laser treatments were performed with fluences 40% (SE = 0.04%) higher than those of the 810 nm. Besides mild-to-moderate transient discomfort during the procedure, the Blend diode laser also produced an increased pricking sensation that was 1.8 points higher on a 10-point scale ($p < 0.05$), due to the higher fluence used. Hair reduction was 12% higher with the Blend diode laser, with a confidence level of 70%. Moreover, participants were more satisfied with the results of the Blend diode laser than with the diode laser (50% very satisfied vs. 36%, respectively). No long-term adverse effects were observed.

Conclusions: The new Blend diode laser has been shown to be more effective and satisfactory than 810 nm diode laser on dark skin types III and IV, while also being safe and comfortable for participants.

KEYWORDS
blend wavelength, dark skin types, diode Laser hair removal, high efficacy, short pulse duration

1 | INTRODUCTION

Laser hair removal is an established technique for the reduction in unwanted hair. The technique is based on the principle of selective photothermolysis. This process is based on the absorption of light (optical energy) by the melanin of the hair which is then converted to heat, damaging the hair follicle. There are three wavelengths in commercial use (755, 810 and 1064 nm), which correspond to the three types of lasers on the market: 755 nm alexandrite lasers, 810 nm diode lasers, and 1064 nm Nd:YAG lasers.[1]

Several previous studies have demonstrated the efficacy of a high-power diode laser (810 nm) for removing hair more efficiently and equally as safely as other diode lasers with less power and the same wavelength. High-power diode lasers increase the efficacy for fine-hair removal as shorter pulses can be used, while also being more comfortable for the patient.[2,3]

However, the 810 nm diode laser is of limited use on dark skin due to the absorption of light by the melanin in the skin. The absorption coefficient changes according to the skin type due to the different concentrations of melanin in the epidermis. As skin type classification increases, the melanin concentration in the skin is higher and therefore the absorption of the laser radiation that causes heating of the skin increases. In order to avoid burns, it is necessary to use lower fluences, which means that the result is not as optimal as on fair skin.[4]

Laser devices incorporating higher wavelengths have been developed to improve hair removal on dark skin, such as the 1064 nm Nd: YAG laser. They not only provide deeper light penetration for targeting deeply located follicles but also allow for higher fluences to be used since absorption by melanin decreases when wavelength is increased and therefore the skin is heated less. This makes the treatment safer for dark skin where abundant epidermal melanin may lead to excessive heating and burns.[4–6]

A previous pilot study showed that a novel Blend diode laser that combines three wavelengths (810, 940 and 1064 nm) was found to be safe and effective for dark skin, minimizing the risks of laser hair removal on these types of skin.[2]

2 | OBJECTIVE

The main objective of this study is to compare the efficacy, safety, and comfort of hair removal treatments in skin types III and IV using the diode laser (810 nm) with those performed using the new Blend diode laser (810, 940 and 1064 nm). For this purpose, a single-center study is carried out, where subjects are randomly epilated in both armpits with the two applicators mentioned.

3 | MATERIALS AND METHODS

The study was performed at the Tennessee Clinical Research Center, Nashville, Tennessee, USA. This single-center study had a small sample size of 14 women, between the ages of 18 and 40 years (with a mean age of 29 years (SE = 1.9 years)), with skin types III and IV according to the Fitzpatrick classification and had not previously been treated in that area. The inclusion criteria were adult females between 18 and 40 years with skin types III and IV, these subjects should be willing to comply with the study procedure and schedule, also subjects should agree to remain unshaven of a minimum of 3 days before each visit. The exclusion criteria were pregnancy, lactation, children under 18, photosensitive medication or photosensitive diseases, skin diseases, and lesions or tattoos present in the area being treated.

Participants were treated with the 4800 W Primelase device (Cocoon medical), using the 810 nm diode laser and the new Blend diode laser (810, 940 and 1060 nm) applicators with a 20 × 9 spot size (FDA-approved). Subjects were randomized to receive a treatment with 810 nm versus the new Blend to the right and left side, according to randomization provided by the sponsor (Cocoon Medical) and followed in chronological order. Therefore, two cases were studied on each subject to reduce the bias of the sample. They underwent three sessions with the Primelase platform on both armpits every eight weeks. One armpit was treated with the 810 nm applicator and the other with the new Blend applicator using fluences of between 13 and 21 J/cm^2 and pulse widths of between 4 and 12 ms. The frequency used for all treatments was 1 Hz. Epidermal cooling was performed in each and every session using an integrated cold sapphire in contact with the skin that provided a continuous contact cooling. All treatments were carried out by a single technician and the exact parameters were selected using the treatment tables recommended by the manufacturer, in accordance with the skin and hair type of each treated subject.

A side-by-side comparative study of the three sessions was carried out at 6 months after the last treatment session. This evaluation was based on hair removal efficacy, safety, comfort, and participant satisfaction. The pain experienced by the participants due to pricking and heating of the skin during the treatment was evaluated subjectively on a visual analog scale (VAS) of 0–10 (0 = no pain, 1–4 = mild pain, 5–7 = moderate pain, 8–10 = intense pain).[7] A safety assessment was performed during each treatment and the follow-up visits, with erythema, edema, dryness, peeling, crusting, blistering/burning, hyperpigmentation, and hypopigmentation being assessed by the researcher, and stinging, tingling, and itching, (bruising, pigmentation, or burns) being rated on a scale of 0–4 (0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe). Efficacy was evaluated by two independent researchers through hair counting using "before" and "after" high-resolution digital photographs. Hair reduction was assessed in an area of 3 × 3 cm^2 using the percentage of hair lost 6 months after the treatment with respect to baseline. The participants' satisfaction (how good the subject feels with the result of the treatment) and comfort (how good the subject feels during the treatment) were measured on a subjective scale of 1–5 (1 = very unsatisfied/ very uncomfortable, 2 = unsatisfied/uncomfortable, 3 = no difference/ no opinion, 4 = satisfied/comfortable, 5 = very satisfied/ very comfortable).

The Excel statistical package was used to perform a student t-test for paired data with two tails. A comparison of the laser fluences used with each laser in the three was also made to assess the sensation of pain experienced by the participants. The differences between the two lasers in terms of hair reduction, comfort, and satisfaction were analyzed. Hair reduction differences have been expressed as a percentage difference between the Blend and 810 nm applicators and calculated by subtracting the average percentage of hair lost by the participants using the Blend and 810 nm and dividing it by the value for the 810 nm. Comfort and satisfaction differences between the Blend and the 810 nm have been evaluated according to on the differences in number of points on a 10-point scale for pain and on a 5-point scale for comfort and satisfaction.

4 | RESULTS

A total of 14 participants, with skin types III and IV, were treated in this study. A comparative study was made in the axillary area. Baseline hairs (first visit) and hairs present at 6 months (3×3 cm^2 area), pain during treatment (score from 0 to 10), participant satisfaction and comfort 6 months after treatment session (score from 1 to 5), as well as adverse effects just after treatment (score from 0 to 4) were taken into account.

Figure 1 shows the mean fluence value used and the pain reported by the participants in every session. Fluence values were increased gradually by around 2 J/cm^2 at each visit for both the 810 nm and the new Blend applicator. Compared with 810 nm, the Blend applicator used on average 40% (SE = 0.04%) more fluence in each session.

The 810 nm produced an average pinprick sensation of 3.8 (SE = 0.4) compared with the Blend scoring 5.6 (SE = 0.4) on a ten-point scale; therefore, the pinprick sensation caused by the new Blend applicator was shown to be by 1.8 points higher compared with the 810 nm applicator ($p < 0.05$). The 810 nm applicator produced an average heat sensation of 2.1 (SE = 0.4) compared with 4 for the Blend (SE = 0.5), so the new Blend applicator produced a heat sensation that was 1.9 points higher more than that of 810 nm ($p < 0.05$). With these p-values, this can be considered a statistically significant result.

The researcher reported erythema and edema immediately after treatment with both applicators and the participants in both treatment methods reported stinging, tingling, and burning sensations immediately after each treatment. On the whole, side effects were reported to be minimal in all cases and disappeared in less than 48 h. No long-term adverse effects were reported.

Figure 2 shows examples of photographs of the hairs in the axillary regions of two participants one with skin type III and the other with skin type IV with the hairs present before and 6 months after treatment.

Figure 3 shows the hair removal evaluation according to the percentage of hair lost after treatment with the two applicators comparing all participants and the different skin types.

Six months after treatment an average of 47% (SE = 5.1%) of hair was removed with the 810 nm applicator, while 53% (SE = 5.3%) was removed with the Blend applicator. Therefore, 12% more hair was removed using the new Blend applicator compared with the 810 nm applicator with a 70% of statistical confidence level.

Moreover, differences between both skin types can be seen by assessing the results for reduction percentage. For skin type III, 52% (SE = 4.8%) of hair was effectively removed with the standard 810 nm applicator, compared with 54% (SE = 6.7%) of hair with the Blend, meaning that 4% more hair was removed, with a 40% confidence level. On the other hand, for skin type IV, with the 810 nm applicator only 31% (SE = 13.7%) of hair was removed as opposed to 51% (SE = 4.9%) of hair that was lost with the Blend applicator, thus 65% more hair was removed with the Blend with an 85% confidence level.

Figure 4 shows the mean value of the comfort and satisfaction scores given by the participants 6 months after the treatments.

Six months after the treatments, participants considered the 810 nm applicator more comfortable than the Blend applicator by 0.6 points on a 5-point scale ($p < 0.05$).

With regard to participant satisfaction, a very similar value was obtained for both applicators. Interestingly, 50% of the participants were very satisfied with the result achieved with the Blend applicator, compared with 36% that were very satisfied with the 810 nm applicator.

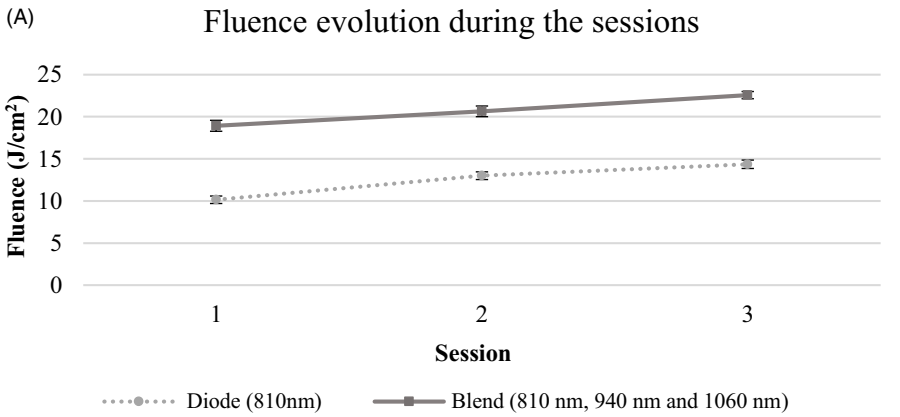
5 | DISCUSSION

This side-by-side study aims to show the improvement in hair removal efficacy, safety, and satisfaction offered by the new Blend diode laser applicator, which combines 810, 940 and 1060 nm, over the standard 810 nm diode laser.

High-power 810 nm diode laser hair removal technology is already considered to be one of the most prominent options available on the market. However, the approach of using combined wavelengths represents a paradigm shift for the treatment of dark skin.[2] Consequently, the focus of this study has been to evaluate the application of diode laser hair removal techniques using multi-wavelength diodes. This study compared therapeutic efficacy, subject satisfaction, and safety. Two cases were studied on each subject to reduce the bias of the sample.

Both laser conditions produced significant hair reduction after treatment, with greater hair reduction being seen with the use of the Blend applicator, especially on the darker skin types.

Firstly, the pricking and heat sensations reported by the participants with Blend applicator were shown to be higher than with the 810 nm in all sessions. This is in accordance with the six-month survey results showing a higher comfort score for the 810 nm diode. This can be explained by the fact that with the Blend applicator the fluence can be increased as a consequence of the use of longer wavelengths (810, 940 and 1060 nm) which are absorbed less by the skin as compared with pure 810 nm. Besides the greater fluence, longer



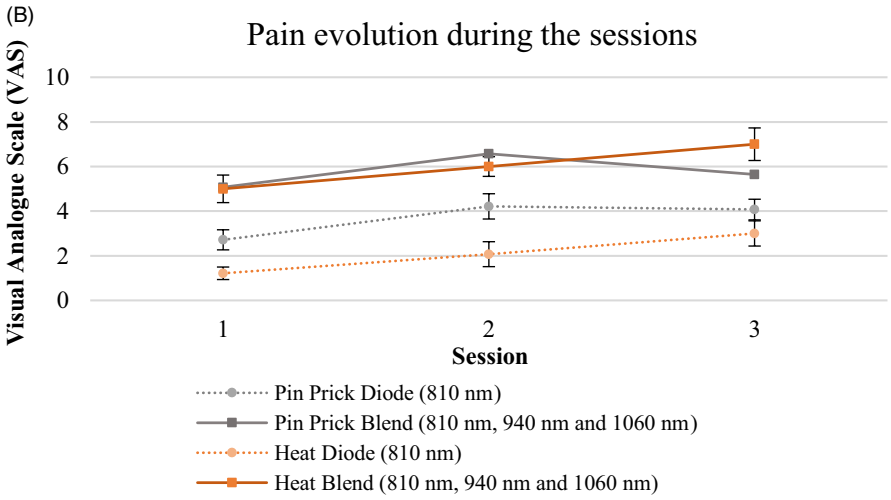


FIGURE 1 Evolution of the average fluence used during the three sessions (A). Evolution of the average pricking and heat sensations during the three sessions (B), (n = 14). The error bars are presented as the standard error for each measurement

wavelengths penetrate deeper into the skin further, and therefore a higher temperature is reached in the hair follicle, and a greater thermal effect is induced. Pain is closely related to the thermal damage of the hair follicle, which is expected to be greater with the Blend.

It is notable that a decrease in both pricking and heat sensations was seen between the second and the third sessions with the Blend applicator. This result is also possibly due to the greater hair removal efficacy of this applicator. The use of higher fluence more greatly diminishes the density of hair in the area and, therefore, although a higher fluence is used, less sensation of pricking and heat were reported by the participants with the passing of the sessions.

Regarding the quantitative efficacy results for hair removal, the new Blend laser applicator was shown to be more effective than the 810 nm applicator. The Blend applicator removed 12% more hair than the 810 nm (but with a low confidence level of 70% due to the small sample size of this study). The difference was found to be greater for participants with the darker skin type IV, where an improvement of 65% was achieved (with an 85% confidence level). The satisfaction survey also revealed that participants treated with the Blend reported greater satisfaction. The superior efficacy of hair reduction is a consequence of the use of higher fluences and deeper skin penetration. Through the use of higher wavelengths that are less absorbed by the melanin in the skin, better results are achieved without increasing skin side effects. A previous in silico model generated by the co-authors of this article[6] had predicted an improvement in efficacy when using longer wavelengths with skin types higher on the Fitzpatrick scale. The model allowed the maximum operating conditions for each wavelength and skin type to be determined. Shorter wavelengths have difficulties providing epidermal protection for darker skin due to the higher absorption by melanin. Longer wavelengths have a lower melanin absorption and thus allow higher fluences to be used. The model clearly showed that the higher the fluence, the greater the thermal damage caused to the hair structure. Moreover, it was shown that long wavelengths suffer less scattering in the dermis and this increases the penetration depth of the laser into the dermis.

The greater efficacy of the Blend diode laser device on skin types that are high on the Fitzpatrick scale suggests that these types of patients could also achieve hair reduction results similar to those of lighter skin types. The fact that the 4800 W Blend is more efficient on darker skin types implies a great advantage, since, with the majority of diode lasers on the market, dark skin types are difficult to treat, and the treatment is often painful and less effective.

Importantly, no complications or adverse effects were observed, and side effects were either transient and minimal or, in some cases, mild. This shows that using the Blend diode allows safe hair removal

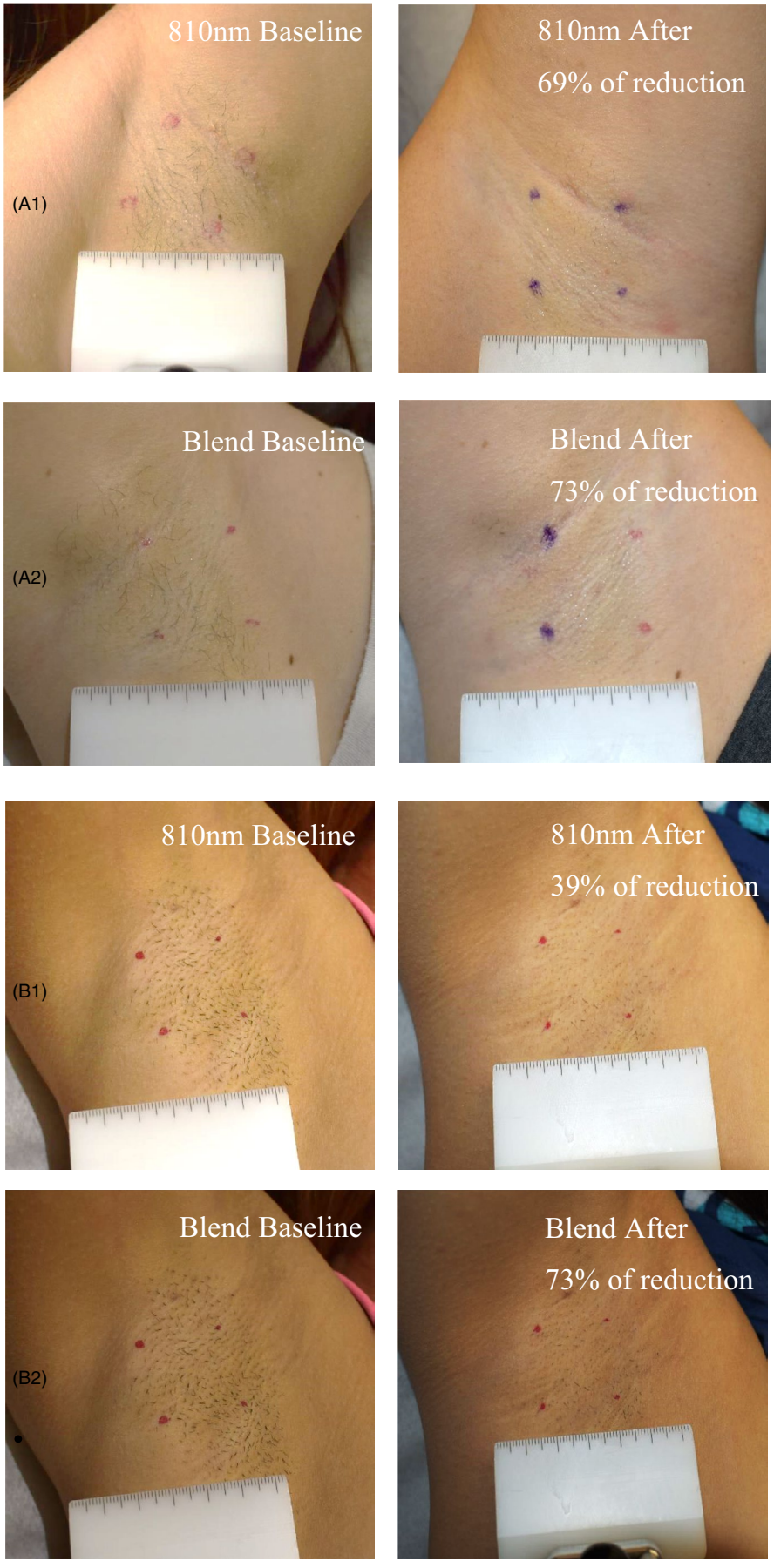


FIGURE 2 Axillary of two participants before treatment and 6 months after treatment for Diode and Blend applicators. The photos are of participant 2 with skin type III (A1 and A2) and participant 12 with skin type IV (B1 and B2)

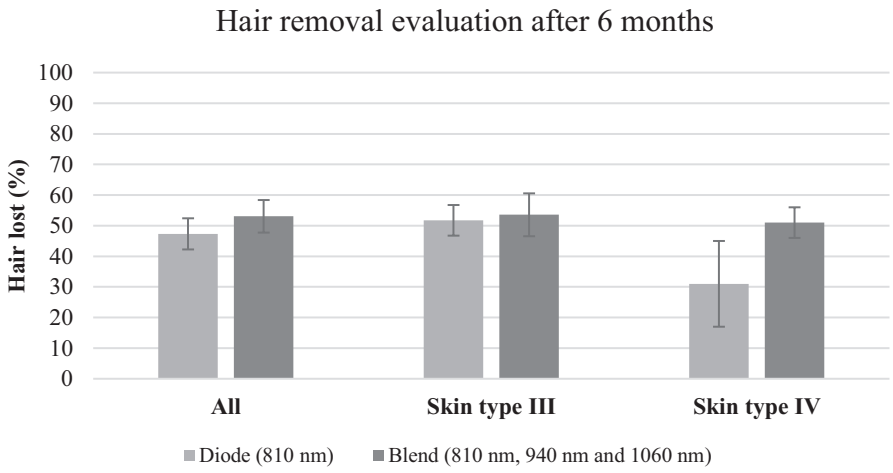


FIGURE 3 Hair removal evaluation of the treatments (n = 14). Expressed as the percentage of hair lost at 6 months after treatment compared to baseline. The error bars are presented as the standard error for each measurement

FIGURE 4 Comfort and satisfaction of the participants with Diode and Blend 6 months after treatment (n = 14). Level of comfort/satisfaction: 1–5 (1 = very unsatisfied/very uncomfortable, 2 = unsatisfied/uncomfortable, 3 = no difference/ no opinion, 4 = satisfied/ comfortable, 5 = very satisfied/ very comfortable). The error bars are presented as the standard error for each measurement

treatments to be performed, without them being significantly affected by the use of higher fluences.

These results are consistent with those presented in the study by Fajardo et al. where the primelase device with the Blend applicator showed 55% more reduction than the 810 nm laser. It was also seen that the sensation of pain throughout the sessions was similar in the two devices, although in the 810 nm device it was still less.[2]

It has been also reported that the use of multiple wavelengths offers improved efficacy with dark skin types.[8] The use of the so-called blend laser reduces skin heating, improves safety, and offers deep penetration of the hair follicle with minimum risk of epidermal damage as the absorption curve for melanin decreases as the wavelength increases.[9]

Finally, future clinical research will aim to increase the number of participants in the sample in order to obtain more representative results that reinforce the efficacy of both applicators for hair removal, and add participants of skin type V to further assess the efficacy and safety of the new Blend on dark skin types.

6 | CONCLUSIONS

The 810 nm and Blend (810, 940 and 1060 nm) high-power diode laser applicators of the Primelase Excellence platform have provided effective, safe, and comfortable hair removal treatments.

Finally, the use of combined wavelengths offered by the Blend applicator has been shown to be more effective than the 810 nm wavelength for hair removal on darker skin types IV. The use of higher wavelengths allows the hair to be heated at deeper levels, thus achieving better results without jeopardizing the safety of the treatments.

ACKNOWLEDGEMENT

None.

CONFLICT OF INTEREST

Tennessee Clinical Research Center was compensated for clinical research executed on behalf of Cocoon Medical, Barcelona. Cocoon Medical is a company developing products related to the research being reported in this manuscript. The authors associated with this publication are employees of the Site and/or the Sponsor. This publication strictly adheres to the objectivity and ethics of an independent research.

ETHICAL APPROVAL

IRB oversight of this study was obtained through Advarra Institutional Review Board.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Gold MH, Biron J, Wilson A, et al. Safety and efficacy for hair removal in dark skin types III and IV with a high-powered, combined wavelength (810, 940 and 1060 nm) diode laser: A single-site pilot study. *J Cosmet Dermatol*. 2022;00:1–7. doi:10.1111/jocd.14926