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CASE SERIES

Real-World Evidence on The Use of a Novel Skin Pigmentation Balancing Kit in Melasma Management in Filipino Patients with Asian Skin Types

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ABSTRACT: A topical skin pigmentation-balancing (SPB) kit containing kojic acid and glycolic acid has previously been evaluated in individuals with Fitzpatrick skin phototypes II–III. This case series aimed to assess the efficacy and safety of the SPB kit in women of Asian origin with melasma and Fitzpatrick skin phototype IV. Ten patients were treated individually over a period ranging from 2 to 24 months. Clinical assessments were performed at baseline and at the final visit using a melanin index derived from a melanometer and the modified Melasma Area and Severity Index (mMASI). Additional evaluations included dermoscopic assessment, QuantifiCare medical imaging system analysis, and Physician's Global Assessment scores to further explore their utility in skin pigmentation studies. Mean melanin index and mMASI scores decreased in all patients, with consistent improvement observed across all secondary outcome measures. Patients reported satisfaction with the treatment, and no treatment-related adverse events were observed. This is the first case series evaluating the SPB kit in patients with Fitzpatrick skin phototype IV, demonstrating its efficacy and tolerability.

Keywords: Asian skin phototypes, Dermoscopy, Glycolic acid, Kojic acid

INTRODUCTION

Asian skin types typically fall within Fitzpatrick phototypes III (light brown) to V (dark brown) [1,2]. Differences in Asian skin compared with lower or higher phototypes are largely attributed to variations in melanosome characteristics, including single, larger, more discrete units (typical of higher phototypes) and clustered units that degrade more rapidly (typical of lower phototypes) [2,3]. Following ultraviolet (UV) exposure, melanogenesis results in an approximate increase in melanin content of 1% in phototypes I–II, 4% in phototypes III–IV, and 12% in phototypes V–VI [4]. In some individuals, this process may contribute to melasma, which can lead to psychological distress, frustration, and embarrassment, thereby negatively affecting emotional well-being, interpersonal relationships, and social functioning [5].

Management of melasma generally aims to inhibit melanocyte proliferation and/or melanin synthesis, disrupt melanosome-associated pigment granules, and promote melanin removal [6]. Among various treatment modalities, topical therapy remains a mainstay of management, particularly due to its accessibility. In this context, a

topically applied skin pigmentation-balancing (SPB) kit has been developed for the management of melasma. The SPB kit consists of a cleanser and day and night creams and is applied as a daily regimen. The cleanser, which contains scrubbing beads, is used morning and night, followed by application of either the day or night cream. The formulation contains ingredients known to reduce melasma-associated pigmentation and promote cellular renewal [7–13]. These include kojic acid, a metabolite of Aspergillus oryzae that inhibits tyrosinase activity and induces keratinocyte interleukin-6 expression, thereby reducing melanogenesis [11,12], and glycolic acid, an alpha hydroxy acid that enhances epidermal turnover and accelerates desquamation of pigmented keratinocytes [13]. The combination of these ingredients has been reported to demonstrate efficacy comparable to a glycolic acid and hydroquinone regimen in the treatment of melasma [12]. The SPB kit has also previously been evaluated in individuals with Fitzpatrick skin phototypes II–III, demonstrating significant reductions in dark spot area, pigmentation intensity, and colour contrast after 28–90 days of use, with good tolerability [7–9].

This case series reports the effects and tolerability of the SPB kit in women with predominantly Fitzpatrick skin phototype IV from the Philippines. Treatment with the SPB kit was individualised for each patient.

METHODOLOGY

Participants

Ten women with melasma were included in this case series. All patients had a clinical diagnosis of melasma of any aetiology, confirmed by a consultant dermatologist at the De La Salle Medical and Health Sciences Institute, Dasmariñas City, Philippines. Baseline medical histories were obtained prior to treatment initiation. There were no restrictions regarding disease duration or prior treatments. Participants first attended the clinic between 15 April and 5 May 2022. Written informed consent was obtained from all patients for inclusion and publication of anonymised clinical data in this case series.

Treatment Protocol

The SPB kit (Pigment Solution Program™, Relife Menarini S.r.l., Florence, Italy), consisting of a cleanser, a day cream, and a night cream, was provided to each patient. The cleanser, containing 1.5% scrubbing beads, was used twice daily. The day cream applied each morning after cleansing contains 0.3% kojic acid, vitamins A and E, and Aquaxyl™ (a combination of glucose and xylitol). Following evening cleansing, the night cream was applied; it contains 0.3% kojic acid, 5.7% glycolic acid, and biodegradable scrubbing beads. The cleanser was applied to the entire face, whereas the day and night creams were gently massaged only onto hyperpigmented areas.

Patients used a minimum of two SPB kits, with additional kits provided according to individual clinical need. A two-week washout period was required for patients using other SPB products. However, treatments for other medical conditions were allowed to continue. These included isotretinoin or metronidazole for rosacea and 577-nm laser therapy for facial erythema and telangiectasia. Patients were instructed to apply broad-spectrum sunscreen daily (sun protection factor ≥30), as ultraviolet exposure is a known contributing factor in melasma pathogenesis [14]. Patients were followed up after completion of the SPB kit regimen for the duration of their clinical care, which varied between individuals.

Assessment

Skin examinations were performed at baseline and at the end of the treatment period, with duration varying according to individual patient needs. Treatment response in melasma was evaluated using both objective and subjective assessment methods [15–17].

a. Melanometer assessment (Quanta Systems, Milan, Italy)

Objective assessment was performed using a melanometer-based skin analysis system. The Melanin Index (MI) was measured at the most hyperpigmented areas of the melasma lesions (malar and zygomatic regions, as close as possible to the Redka–Galadari point). Three readings were obtained per site and the mean value was recorded.

b. Modified Melasma Area and Severity Index (mMASI)

Clinical severity was assessed using the mMASI score, calculated using a weighted formula incorporating the extent of involvement and pigmentation intensity across four facial regions (forehead, right malar, left malar, and chin) [15,16].

c. Dermoscopic assessment (DermLite, San Juan Capistrano, CA, USA)

Dermoscopy with polarized light was performed on melasma-affected areas. Grading was based on the presence of pseudoreticular brown pigmentation and dark brown blotches or clods at baseline and after treatment. Changes were assessed relative to baseline (score of 0), ranging from 0 (no improvement) to 5 (complete disappearance of all dermoscopic features), corresponding to estimated percentage improvements of 0 = 0%, 1 = 20%, 2 = 40%, 3 = 60%, 4 = 80%, 5 = 100%.

d. Physician's Global Assessment (PGA)

Overall clinical improvement was assessed using dermoscopic findings and clinical photographs. The PGA scale was defined as: 0 = completely clear; 1 = almost clear with minimal residual hyperpigmentation; and 2 = significant residual hyperpigmentation [17].

e. *QuantifiCare medical imaging system (LiveViz® Mini, QuantifiCare, Biot, France)*

This system was used to capture standardized 3D clinical images. Melasma improvement was graded based on percentage change from baseline (score of 0), determined by the appearance of black dots within a defined triangular region (base at the infraorbital area and apex at the lower malar region). Improvement was scored from 0 (no improvement) to 5 (complete disappearance of black dots), corresponding to estimated percentage changes of 0 = 0%, 1 = 20%, 2 = 40%, 3 = 60%, 4 = 80%, 5 = 100%.

f. Patient Satisfaction

Patient-reported outcomes included treatment satisfaction (slightly satisfied to very satisfied), willingness to continue treatment (yes/no), and occurrence of adverse events (yes/no).

RESULTS

Patient Characteristics

Figure 1 summarizes patient clinical characteristics, prior treatment history, and duration of SPB kit use for each case. The majority of patients had Fitzpatrick skin phototype IV and presented with varying subtypes of melasma. As treatment was individualised, the duration of SPB kit use varied widely, ranging from 2 to 24 months. While some patients used the SPB kit as monotherapy, others received concurrent treatments, including low-dose oral isotretinoin for rosacea and monthly 577-nm laser therapy for facial erythema and telangiectasia (**Tables 1** and **2**).

Primary Outcomes

Overall, improvement in melasma was consistently observed across all cases based on the assessed outcome measures (**Table 1**). However, the magnitude of improvement varied among patients and did not appear to be consistently associated with treatment duration or concomitant therapies.

Changes from baseline in MI and mMASI scores are shown in **Figure 2**. For MI, reductions were observed on both facial sides following treatment with the SPB kit in all patients, with generally comparable improvement between the right and left regions. Among patients who received adjunctive 577-nm laser therapy, the greatest reduction in MI was observed in Case 4 after 3 months of combined SPB kit and laser treatment. In contrast, Case 5, who also received the same combination therapy for 3 months, demonstrated the smallest reduction in MI. Among patients who did not receive concomitant therapies, Case 1, treated with the SPB kit for 2 months, demonstrated a greater reduction in MI compared with Case 10, who underwent 24 months of treatment.

Reductions in mMASI scores were also observed in all patients. The greatest reduction in mMASI was seen in Case 1 after 2 months of SPB kit monotherapy, whereas the smallest reduction was observed in Case 7 after 6 months of treatment without adjunctive therapy.

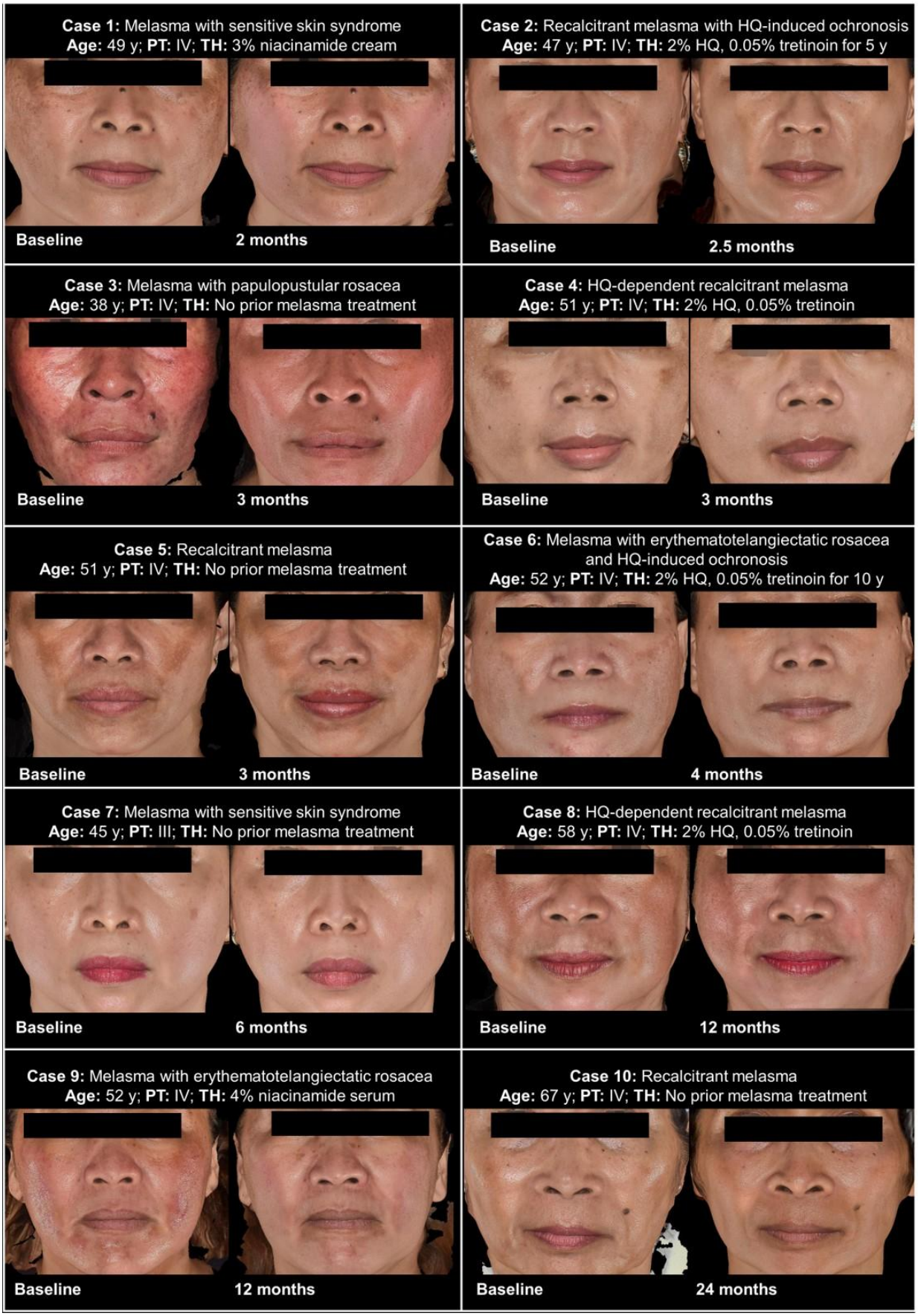

Figure 1. Patient characteristics, previous treatment history, and clinical appearance before and after use of the SPB kit. Abbreviations: HQ, hydroquinone; PT, skin phototype; TH, previous melasma treatment history.

Table 1. Melasma improvement based on Melanin Index and modified Melasma Area and Severity Index (mMASI) scores.

Case	Duration of SPB kit Use (months)	Melanin Index (Melanometre)				Modified Melasma Area and Severity Index		Concomitant Treatments During SPB kit Use
		Right Side		Left Side				
		Baseline	Post-treatment	Baseline	Post-treatment	Baseline	Post-treatment	
1	2	57.6	48.6	56.4	47.5	8.1	7.5	None
2	2.5	66.4	56.4	63.4	54.8	3.6	2.4	Monthly 577 nm laser[a]
3	3	57.6	40.4	56.4	42.4	6.0	5.4	Low-dose oral isotretinoin[b]; metronidazole cream 0.75%[b]
4	3	57.6	20.1	56.4	19.8	5.4	4.8	Monthly 577 nm laser[a]
5	3	70.4	64.8	64.8	62.8	10.1	1.8	Monthly 577 nm laser[a]
6	4	68.4	2.0	55.4	3.0	4.8	4.2	Low-dose oral isotretinoin[b]
7	6	42.0	34.6	40.6	34.0	0.9	0.3	None
8	12	65.6	48.8	66.4	46.4	9.9	4.5	Monthly 577 nm laser[a]
9	12	66.4	54.2	64.8	53.2	8.2	5.9	None
10	24	58.4	52.8	56.6	52.4	2.4	1.8	None

[a] QuadroStar Pro Yellow (Asclepion, Jena, Germany), used for treatment of facial erythema and telangiectasia.
[b]Treatment for rosacea

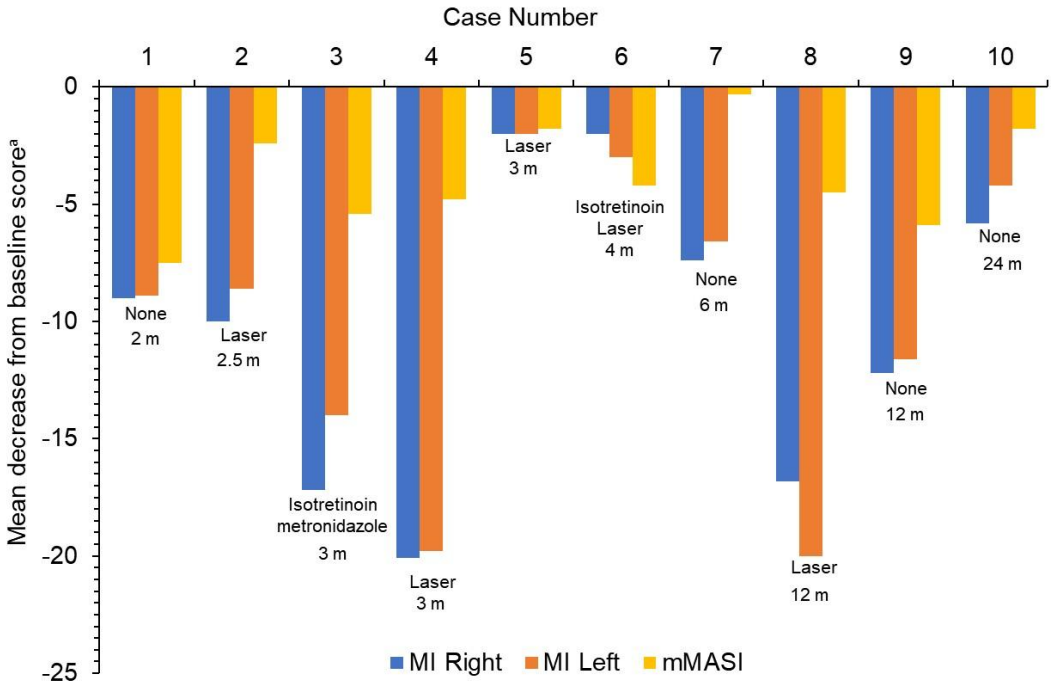

Figure 2. Change from baseline in Melanin Index and modified Melasma Area and Severity Index (mMASI) scores.
[a]Mean change from baseline in MI and mMASI scores.
Abbreviations: m, months; MI, Melanin Index; mMASI, modified Melasma Area and Severity Index.

Secondary Outcomes

Improvements in dermoscopic and QuantifiCare grading were observed in all cases, with concordant findings between both assessment methods (**Table 2**). While most cases with larger reductions in MI and mMASI scores demonstrated a score of 4 in dermoscopic and QuantifiCare grading (Cases 3, 4, and 8), similar improvements were also observed in cases with smaller reductions in MI and mMASI scores (Cases 5, 6, and 10). At baseline, all cases had a PGA score of 2, which improved to 0 or 1 at the end of treatment (**Table 2**). These improvements did not consistently correspond to the magnitude of MI or mMASI reductions.

Patient-reported feedback (data not shown) indicated that all patients were either satisfied or very satisfied with the SPB kit and would continue its use. No cases of ochronosis, dyschromia, or other adverse events were reported during the treatment period. Three patients were followed for 3 months post-treatment, while seven were followed for up to 24 months. During follow-up, no plateauing of response or recurrence of melasma was observed.

Table 2. Melasma improvement based on dermoscopy, QuantifiCare grading, and Physician's Global Assessment score

Case	Duration of SPB kit Use (months)	Dermoscopy grading[a] Change from baseline (0)		QuantifiCare grading[a] Change from baseline (0)		Post-Treatment Physician's Global Assessment score	Concomitant Treatments During SPB kit Use
		Right Side	Left Side	Right Side	Left Side		
1	2	3	3	3	3	1	None
2	2.5	4	4	4	4	1	Monthly 577 nm laser[b]
3	3	4	4	4	4	0	Low-dose oral isotretinoin[c]; metronidazole cream 0.75%[c]
4	3	4	4	4	4	0	Monthly 577 nm laser[b]
5	3	4	4	4	4	1	Monthly 577 nm laser[b]
6	4	4	4	4	4	0	Low-dose oral isotretinoin[c]
7	6	3	3	3	3	0	None
8	12	4	4	4	4	1	Monthly 577 nm laser[b]
9	12	2	3	3	3	1	None
10	24	4	4	4	4	0	None

[a]Dermoscopy and QuantifiCare grading changes were assessed relative to a baseline score of 0, where 0 = 0%, 1 = 20%, 2 = 40%, 3 = 60%, 4 = 80%, and 5 = 100%.
[b]QuadroStar Pro Yellow (Asclepion, Jena, Germany), used for treatment of facial erythema and telangiectasia.
[c]Treatment for rosacea

DISCUSSION

Melasma can be psychologically distressing and may significantly affect social and emotional well-being [5]. Consequently, many patients seek treatment for the condition. Among the available treatment modalities, topical therapies are commonly preferred due to their accessibility and affordability.

In the present case series, use of the SPB kit containing 0.3% kojic acid and 5.7% glycolic acid was associated with improvement in melasma, including in patients with recalcitrant disease, prior treatment failure, hydroquinone-induced ochronosis, and coexisting dermatologic conditions such as rosacea and sensitive-skin syndrome. Notably, clinical improvement was observed as early as 2 weeks after initiation of treatment (dermatologist observation, data not shown).

Overall, reductions in mMASI scores ranged from 0.3 to 7.5 across treatment durations of 2 to 24 months, although no clear relationship was observed between treatment duration and magnitude of response. Studies investigating kojic

acid in patients with melasma and similar Fitzpatrick skin phototypes in India have also reported comparable reductions in mMASI scores, ranging from 0.7 (2% for 16 weeks) [18], 2.4 (0.75% for 12 weeks) [19], to 5.6 (1% for 12 weeks) [20]. For glycolic acid, most evidence has been derived from chemical peel studies. However, a study using 13% glycolic acid cream for 8 weeks reported a mean mMASI reduction of 2.0 [21]. Collectively, these findings suggest that both kojic acid and glycolic acid contribute to improvement in melasma. Evidence regarding their combined use remains limited; however, a previous study evaluating a formulation containing 5% glycolic acid and 2% kojic acid demonstrated reductions in pigment intensity comparable to those achieved with a hydroquinone-based regimen (2% hydroquinone and 5% glycolic acid) although mMASI was not assessed [12].

Hydroquinone remains a standard therapy for melasma [7], and a recent meta-analysis demonstrated that hydroquinone has greater efficacy compared with kojic acid alone [22]. However, its use is limited by a higher incidence of adverse effects, including irritation, contact dermatitis, post-inflammatory hyperpigmentation, and ochronosis [7,22]. Notably, patients with hydroquinone-induced ochronosis and hydroquinone-dependent recalcitrant melasma in the present case series demonstrated clinical improvement following SPB kit use, suggesting a potential alternative treatment option in such cases.

Although kojic acid has been associated with irritation in some reports [10], the SPB kit was generally well tolerated in the present case series, including when used in combination with adjunctive laser therapy or other dermatologic treatments, without additional adverse events. This finding is consistent with previous studies reporting good tolerability and high patient satisfaction with the SPB kit [8,9].

The SPB kit has previously been evaluated in individuals with Fitzpatrick skin phototypes II–III, demonstrating significant improvements in mMASI scores, dark spot area, pigmentation intensity, and colour contrast after 28–90 days of use [7–10]. The present findings extend these observations to patients with Fitzpatrick skin phototype IV, suggesting comparable improvements in melasma severity in a darker-skinned population. It is important to note that some patients received concomitant therapies, including 577-nm laser treatment [23] and oral isotretinoin [24], which were not specifically indicated for melasma but may have contributed to clinical improvement. However, the greatest improvements in MI were not consistently associated with adjunctive treatments, as some patients receiving additional therapies demonstrated only modest changes.

Additionally, other assessment tools, including dermoscopy, PGA, and QuantifiCare imaging, demonstrated general improvement trends; however, these findings did not consistently correspond with changes in MI and mMASI scores. Further studies are warranted to validate the role of these modalities in melasma assessment and to establish standardized outcome measures for treatment response evaluation. Overall, the findings suggest that the SPB kit may provide clinical benefit in melasma management. However, due to variability in melasma subtype, baseline severity, treatment duration, and coexisting dermatologic conditions, treatment outcomes should be interpreted with caution.

Limitations

This case series included a selected group of patients with melasma of varying etiologies. The study was non-blinded, with heterogeneous treatment durations and the use of concomitant therapies in some but not all patients. Therefore, direct statistical comparisons between cases were not performed. Another limitation is the absence of direct comparison with standard treatments such as hydroquinone, which limits interpretation of relative efficacy and safety.

Future studies should include well-designed clinical trials with predefined inclusion criteria, placebo or active comparators, standardized treatment duration, and statistical analysis. In addition, further investigation is warranted to evaluate the effects of the SPB kit in combination with other therapies compared with monotherapy. Head-to-head comparative studies would also be valuable to better position the SPB kit within existing treatment algorithms for melasma.

CONCLUSION

In this case series of 10 women with predominantly Fitzpatrick skin phototype IV, the SPB kit containing kojic acid and glycolic acid was associated with clinical improvement in melasma and was generally

well tolerated. These findings suggest that the SPB kit may represent a potential treatment option for melasma and associated hyperpigmentation. Further well-designed clinical trials are warranted to evaluate its efficacy and safety across a broader range of skin phototypes, with appropriate placebo or active comparators, and to assess its use as monotherapy and in combination with other treatments.

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CONFLICT OF INTEREST

JFD is a regional Key Opinion Leader for the Menarini Group and Relife, and serves as a Board Director of the International Society of Dermatology. PGPL reports being a Key Opinion Leader and member of the speaker bureaus for the Menarini Group, Relife S.r.l., Galderma, Johnson & Johnson, Karihome, Eli Lilly, Zuellig Therapeutics, Creative Skin Med Equipment Inc., and D'mark Multisales, as well as a global trainer and regional speaker for Menarini/Relife. EB declares no conflicts of interest.

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