

A Retrospective Analysis of Radiofrequency Microneedling for Melasma Management in the Japanese Population

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Background: Melasma is a chronic pigmentary disorder with multifactorial pathogenesis and significant psychosocial impact. Although radiofrequency microneedling has emerged as a dermal-targeting adjunctive therapy, real-world evidence regarding its clinical effects and safety is limited.

Objective: To evaluate the real-world clinical response and safety of POTENZATM radiofrequency microneedling for melasma treatment.

Methods: A retrospective observational before-and-after study was conducted at a private dermatology center in Japan. Adult patients with clinically diagnosed melasma who underwent POTENZATM radiofrequency microneedling treatment were included in the analysis. Melasma severity was assessed using the modified Melasma Area and Severity Index (mMASI) score. Patient-reported satisfaction, qualitative clinical improvement, and adverse events were analyzed descriptively.

Results: A total of 29 female patients (mean age, 45.2 ± 7.9 years) were included in the study. The median baseline mMASI score was 6 (IQR 4–12) and remained 6 (IQR 4–8) after treatment, with no statistically significant difference between the time points ($p = 0.16$). Overall, 26 patients (89.7%) demonstrated stable or improved mMASI scores post procedure. Percentage-based analyses showed substantial interindividual variability: 27.6% of patients achieved $\geq 25\%$ and $\geq 30\%$ reductions in mMASI, and 10.3% achieved $\geq 50\%$ reduction. Patient satisfaction was reported in 62.1% of the cases. All patients experienced mild, transient erythema that resolved without sequelae, and no serious adverse events were observed.

Conclusion: In this real-world study involving Japanese patients, POTENZATM radiofrequency microneedling demonstrated a favorable safety profile and provided clinically meaningful improvements in selected patients, supporting its role as a complementary treatment in multimodal melasma management.

Keywords: melasma, MASI, hyperpigmentation, radiofrequency microneedling, POTENZA, mMASI

Introduction

Melasma is a chronic pigmentary disorder characterized by hyperpigmented macules that predominantly affect photo-exposed facial areas. Its pathogenesis is multifactorial and closely linked to ultraviolet (UV) exposure, hormonal changes such as pregnancy and oral contraceptive use, and genetic predisposition. All these factors favor melanocyte activation.¹ UV radiation promotes melanogenesis by stimulating reactive oxygen species and activating melanin-related genes, whereas a positive family history is reported in up to 60% of patients, supporting a genetic predisposition.^{2,3} Hormonal changes during pregnancy further contribute to disease development, as increased placental, ovarian, and pituitary hormones stimulate melanocytic enzyme activity and melanin synthesis.⁴

Melasma primarily affects women with Fitzpatrick skin types III–V and is more prevalent among individuals of Latin American, South and Southeast Asian, Middle Eastern, and intertropical descent.^{2,5} Although the global prevalence is estimated at approximately 1% in Western populations, reported rates range from 9% to 40% among women with dark skin



and up to 41% in high-sun-exposure occupational groups, such as agricultural workers in India. Japanese skin is predominantly classified as Fitzpatrick phototypes III–IV,⁶ consistent with the skin types associated with melasma. In a study of 223 Japanese women aged 30–69 years, ultraviolet photography detected subclinical melasma in 28.3% of the participants, suggesting that the true burden of disease in this population may be underestimated.⁷

While melasma predominantly affects women, female-to-male ratios as high as 39:1 have been reported, particularly among men with significant sun exposure or genetic susceptibility to melasma.^{5,8} Beyond its dermatological manifestations, melasma is associated with a substantial psychosocial impact. Systematic reviews and observational studies have demonstrated a high prevalence of depression among affected individuals, emphasizing the need for comprehensive treatment approaches.^{9,10}

Current treatment strategies aim to reduce hyperpigmentation and prevent its recurrence. Photoprotection using broad-spectrum sunscreens with a Sun Protection Factor (SPF) of 50+ remains a cornerstone of treatment, as both UV radiation and visible light exacerbate pigmentation, especially in darker skin types.^{5,11} Topical therapies include hydroquinone, azelaic acid, retinoids, and vitamin C, whereas systemic tranexamic acid has demonstrated efficacy as an adjunctive option in refractory cases.¹² In recent years, procedural interventions have emerged as adjunctive treatments. Chemical peels enhance epidermal turnover,¹³ and technologies such as laser devices, radiofrequency (RF), ultrasound, electroporation, and microneedling aim to increase skin permeability and improve transdermal delivery of topical agents.¹⁴

Radiofrequency microneedling (RFMN) combines dermal collagen stimulation with enhanced transdermal delivery of depigmenting agents. Clinical studies have reported improved melasma severity with RF-based combination therapies, including RF with arbutin or cysteamine, with superior outcomes observed in combination regimens compared with RF monotherapy.^{15,16} However, evidence regarding the real-world clinical effects and safety of POTENZATM RFMN remains limited, particularly in populations with Fitzpatrick skin types III–V, who are more susceptible to both melasma and treatment-related adverse effects.

The POTENZATM RFMN system is a versatile platform that enables physicians to set parameters tailored to each patient's needs. It offers monopolar and bipolar radiofrequency, as well as a combination of the two, at 1 MHz and 2 MHz. Furthermore, it comes with invasive (insulated, semi-insulated, and non-insulated) tips, a single-needle tip for acne management, a topical drug delivery pumping tip, and non-invasive tips for superficial ablation (SFA) and deep dermal rejuvenation (DDR) (Figure 1a–e).

Therefore, this study aimed to evaluate the clinical response and safety of the POTENZATM RFMN system for melasma using real-world data, addressing an important gap in the current evidence base and potentially informing future treatment strategies for this condition.

Methods

Study Design and Setting

A retrospective, observational before-and-after study was conducted to evaluate the clinical response and safety of the POTENZATM RFMN system (Jeisys Med Inc., Seoul, Republic of Korea) in the treatment of melasma. The study was conducted at a private dermatology center in Tokyo, Japan, where all treatments were administered as part of the standard dermatologic care. Eligible medical records were identified for adult patients treated between 2022 and 2025. This study adhered to the principles of the Declaration of Helsinki and was approved by the Clinical Research Ethical Review Board of Shido, Inc. [S20250731-2]. The study involved a retrospective review and analysis of existing, de-identified patient records for which an informed consent waiver was granted.

Participants

Eligible participants were adults (≥ 18 years) with a clinical diagnosis of melasma who had received at least one POTENZATM RFMN treatment session. Inclusion criteria required standardized pre- and post-treatment facial photographs and/or detailed clinical records documenting melasma severity and treatment outcomes. Patients were excluded if they had received treatment with other energy-based devices for melasma during the same treatment cycle, had insufficient medical documentation or follow-up, or presented with general contraindications to RF procedures, including pregnancy, pacemaker implantation, or active cutaneous infections at the time of treatment.



Figure 1 (a) POTENZA™ RFMN System, (b) Semi-insulated invasive tip S-16, (c) Pumping Tip CP-25, (d) noninvasive superficial ablation SFA Tip, and (e) deep dermal rejuvenation DDR Tip.

Intervention

The POTENZA™ RFMN system was set to operate in melasma mode at 2 MHz in a bipolar configuration, with a power output of 3–5 Watts (3 pulses; 10ms on time). Treatment was performed using a semi-insulated (S-16) microneedling tip. Before the procedure, the patient's skin was cleaned with antiseptic soap and lukewarm water, and a topical anesthetic cream was applied for approximately 30 minutes. The microneedling depth was adjusted to 0.5–1.0 mm (levels 3–5; 2–3 passes), depending on the treatment area, lesion characteristics, and patient comfort. After the treatment, a cold facemask was applied, and patients were advised to continue their usual skincare routine, including regular use of moisturizers and sunscreen.

Outcome Measures

The primary outcome was clinical improvement in melasma severity following POTENZA™ RFMN treatment, as documented by the treating dermatologist in routine medical records and, when available, supported by a visual comparison of standardized pre- and post-treatment photographs. Improvement was defined as a reduction in pigmentation severity or lesion extent, and the modified Melasma Area and Severity Index (mMASI) was used to assess improvement.¹⁷ Although the mMASI was used as the primary outcome measure owing to its widespread acceptance, its known limitations in detecting subtle changes in mild disease were acknowledged a priori.

The mMASI evaluates four facial regions: the forehead, right malar region, left malar region, and chin. For each region, the area of involvement was scored from 0 to 6 according to the estimated percentage of affected skin (0 = absent; 1 = <10%; 2 = 10%–29%; 3 = 30%–49%; 4 = 50%–69%; 5 = 70%–89%; 6 = 90–100%), and darkness was graded from 0 to 4 (0 = absent; 1 = slight; 2 = mild; 3 = marked; 4 = severe). The total mMASI score ranged from 0 to 24. In the present retrospective study, the mMASI score was based on available standardized clinical photographs and medical records. The detailed scoring protocol is provided in [Supplementary Table S1](#).

Secondary outcomes included physician-documented pigmentary response patterns, patient-reported satisfaction documented in clinical charts, qualitative changes in skin texture or overall appearance, results of blinded photographic evaluation when available, and the incidence and characteristics of adverse events. Adverse events were classified by type, severity, and resolution, and exploratory analyses were conducted to assess associations between treatment parameters and clinical outcomes.

Data Collection

Data were retrospectively extracted from electronic medical records using a structured electronic case report form (eCRF) developed on a secure digital data capture platform. Extraction was performed manually by the principal investigator or a trained clinical researcher. Collected variables included demographic characteristics, melasma pattern, Fitzpatrick skin type, treatment parameters, number of sessions, and documented clinical outcomes.

Clinical photographs obtained during standard care were retrieved, anonymized, and labeled using study-specific codes. These images were evaluated in randomized order by an independent dermatologist who was not involved in patient care and was blinded to the treatment stage. The blinded evaluator applied the modified MASI scoring system.

Statistical Analysis

All statistical analyses were performed using R software (version 4.25; R Foundation for Statistical Computing, Vienna, Austria). Descriptive analyses were conducted to characterize the study population and treatment parameters. Continuous variables were assessed for normality using the Shapiro–Wilk test and summarized as means \pm standard deviations or medians and interquartile ranges (IQRs), as appropriate. Categorical variables are reported as absolute and relative frequencies, and ordinal variables are described using medians and IQRs.

Within-subject changes in melasma severity were analyzed using paired t-tests or Wilcoxon signed-rank tests, depending on the data distribution. Secondary outcomes, including patient satisfaction, qualitative pigmentation and texture changes, blinded photographic assessments, and adverse events, were analyzed descriptively. Subgroup comparisons were performed using chi-square or Fisher's exact tests for categorical variables and Mann–Whitney U, Kruskal–Wallis, ANOVA, or non-parametric equivalents for ordinal or continuous variables, as appropriate.

Results

Study Population and Baseline Characteristics

A total of 29 patients with melasma were included in the analysis. All participants were female, with a mean age of 45.2 ± 7.9 years. The malar pattern was present in all cases, and baseline pigmentation intensity was classified as mild in 51.7% ($n=15$), moderate in 41.4% ($n=12$), and severe in 6.9% ($n=2$) of patients. The median baseline mMASI score was 6 (IQR 4–12), indicating mild-to-moderate disease severity at study entry (Table 1). All patients showed improvement, with no worsening (Figure 2).

All patients were treated using bipolar radiofrequency and a semi-insulated microneedling tip (100%). A medium energy level was used in most patients ($n=27$; 93.1%), while energy level information was unavailable in 6.9% ($n=2$) of cases. The median number of treatment sessions was 4 (IQR, 3–6). Sessions were delivered at regular intervals, with a median interval between sessions of 28 days (IQR 28–28), indicating a highly standardized treatment schedule across the study population.

Changes in mMASI Score Following Treatment

Baseline and post-treatment mMASI scores were compared using the Wilcoxon signed-rank test for paired data, which showed no statistical difference between time points ($p = 0.16$). At baseline, the median mMASI score was 6 (IQR, 4–12). Following treatment, the median mMASI score remained at 6 (IQR 4–8) (Figure 3).

The mean absolute change in mMASI score (post-treatment minus baseline) was -1.34 ± 4.36 points, with a median change of 0 (IQR -2 to 0; range -16 to 6). Overall, 26 of 29 patients (89.7%) demonstrated stable or improved mMASI scores after treatment, whereas 3 patients (10.3%) experienced worsening.

Percentage Improvement in mMASI

A patient-level percentage improvement in mMASI was calculated as the relative reduction from baseline. The mean percentage improvement was $3.3 \pm 37.4\%$, with a median improvement of 0% (IQR 0–33.3%) reflecting substantial interindividual variability in treatment response.

Table 1 Demographic and Clinical Characteristics

| Variable | Category | n (%) |
|--|--------------------------------------|------------------|
| Sex | Female | 29 (100) |
| Age (years) | Mean \pm SD | 45.24 \pm 7.87 |
| Genetic predisposition | Unknown | 29 (100) |
| History of pregnancy | Unknown | 22 (75.9) |
| | Yes | 5 (17.2) |
| | No | 2 (6.9) |
| Hormonal disorder | Unknown | 28 (96.6) |
| | Yes | 1 (3.4) |
| Photoexposure | Unknown | 23 (79.3) |
| | Yes | 4 (13.8) |
| | No | 2 (6.9) |
| Melasma during pregnancy | Unknown | 27 (93.1) |
| | No | 2 (6.9) |
| Skin tone homogeneity | Homogeneous | 29 (100) |
| Concomitant medications | Yes | 17 (58.6) |
| | No | 12 (41.4) |
| Topical Adjunct Use | Sunscreen | 10 (34.5) |
| | Hydroquinone | 9 (31) |
| | Azelaic acid | 7 (24.1) |
| | Hydroquinone and Tretinoin | 2 (6.9) |
| | None | 1 (3.4) |
| Medication Class | Antioxidants and Anti-inflammatories | 15 (51.7) |
| | Anti-inflammatories | 5 (10.3) |
| | N/A | 11 (37.9) |
| Medication Format | Oral | 18 (62.1) |
| | N/A | 11 (37.9) |
| Indication for Medications | Photoprotection and PIH | 15 (51.7) |
| | PIH | 5 (10.3) |
| | N/A | 11 (37.9) |
| Melasma characteristics at baseline | | |
| Time with melasma (Months) | Mean \pm SD | 4.48 \pm 8.01 |
| Melasma pattern | Malar | 29 (100) |
| Pigmentation intensity | Mild | 15 (51.7) |
| | Moderate | 12 (41.4) |
| | Severe | 2 (6.9) |
| Baseline mMASI | Median (IQR) | 6 (4–12) |

Abbreviations: N/A, data not available; PIH, post-inflammatory hyperpigmentation.

Most patients (n=26; 89.7%) showed stable or improved mMASI scores, while 10.3% (n=3) experienced worsening. Using predefined response thresholds, 8 patients (27.6%) achieved a $\geq 25\%$ reduction in mMASI, 8 patients (27.6%) achieved a $\geq 30\%$ reduction, and 3 patients (10.3%) achieved a $\geq 50\%$ reduction from baseline.

Clinical Outcomes and Safety

Clinically assessed improvement was reported as none in 51.7% (n=15), mild in 31% (n=9), moderate in 13.8% (n=4), and strong in 3.4% (n=1) of patients, with a median clinical improvement score of 1 (IQR 1–2). Improvements in skin brightness and smoothness were observed in 48.3% (n=14) of patients, while pigmentation improvement was reported in 44.8% (n=13) (Table 2).



Figure 2 50 years old Female showing treatment outcome after 2 sessions with POTENZA™ RFMN. Right cheek showing (a) pre-treatment, (b) 30 days post first treatment, and (c) 30 days post second treatment. Left cheek showing (d) pre-treatment, (e) 30 days post first treatment, and (f) 30 days post second treatment.

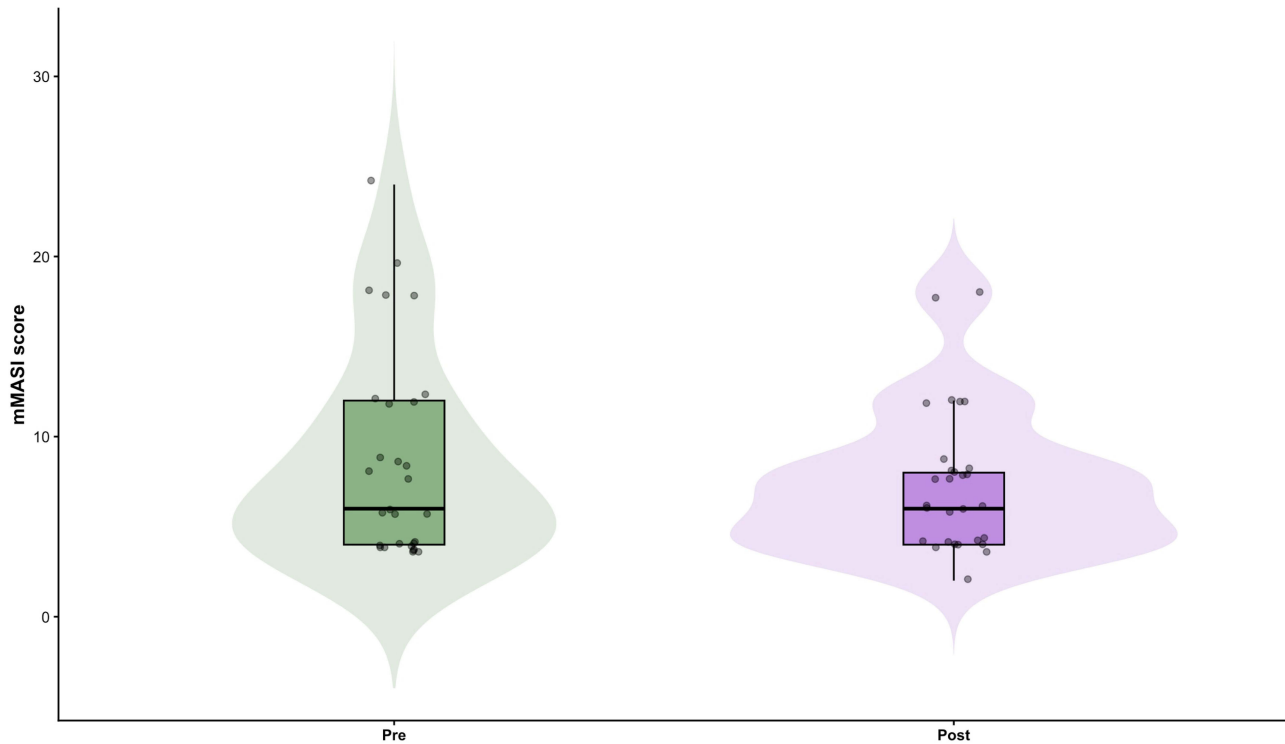


Figure 3 Distribution of mMASI Score Pre and Post Intervention.

Regarding patient-reported outcomes, 62.1% (n=18) of patients reported satisfaction with treatment results. All patients experienced mild erythema, which resolved without sequelae within 60–90 minutes. No serious adverse events were reported.

Discussion

In this retrospective before-and-after study of patients with melasma treated with the POTENZA™ RFMN system, we observed a modest change in mMASI scores, with the median value remaining unchanged after treatment. This apparent

Table 2 Clinical and Safety Outcomes

| Variable | Category | n (%) |
|-----------------------------|--------------|-----------|
| Clinical improvement | None | 15 (51.7) |
| | Mild | 9 (31.0) |
| | Moderate | 4 (13.8) |
| | Strong | 1 (3.4) |
| | Median (IQR) | 1 (1–2) |
| Skin Brightness Improvement | Yes | 14 (48.3) |
| | No | 12 (41.4) |
| | Unknown | 3 (10.3) |
| Skin Smoothness Improvement | Yes | 14 (48.3) |
| | No | 9 (31) |
| | Unknown | 6 (20.7) |
| Pigmentation Improvement | Yes | 13 (44.8) |
| | No | 16 (55.2) |
| Post-treatment mMASI | Median (IQR) | 6 (4–8) |
| Patient satisfaction | Yes | 18 (62.1) |
| | No | 10 (34.5) |
| | NA | 1 (3.4) |
| Adverse events | Yes | 29 (100) |
| AE severity | Grade I | 29 (100) |
| AE resolved | Yes | 29 (100) |

Notes: Values are presented as n (%) unless otherwise specified. Continuous variables are expressed as mean \pm standard deviation or median (interquartile range).

Abbreviation: NA, data not available.

discrepancy reflects both the heterogeneous nature of melasma and the inherent limitations of mMASI in capturing subtle yet clinically meaningful changes, particularly in patients with predominantly mild-to-moderate disease severity.^{17,18}

The mMASI was selected as the primary outcome measure due to its widespread use and greater reliability than the original MASI. However, several studies have highlighted that mMASI may lack sensitivity to detect incremental improvements, especially when baseline scores are low or when changes occur primarily in pigmentation intensity rather than lesion extent.^{17,18} This limitation may partly explain why the median mMASI values remained stable in our cohort, despite nearly 90% of patients showing stable or improved scores and a subset achieving clinically meaningful percentage reductions.

Despite limited changes in central tendency measures, percentage-based analyses revealed that a subset of patients achieved clinically meaningful improvements: approximately 28% achieved $\geq 25\%$ and $\geq 30\%$ reductions in the mMASI, and 10% achieved $\geq 50\%$ reductions. Similar response heterogeneity has been reported in studies evaluating energy-based devices and combination therapies for melasma, where individual variability in melanocyte activity, dermal involvement, and phototype significantly influences treatment outcomes.^{19,20} Similarly, a split-face study combining RFMN with a Q-switched Nd: YAG laser reported greater improvement on the combined treatment side, supporting a potential synergistic effect of RF in melasma treatment.²¹

Recent advances in melasma research have increasingly emphasized the role of dermis as a key driver of disease persistence and relapse. Melasma is widely regarded as a photoaging-related disorder, characterized by solar elastosis, increased dermal vascularity, senescent fibroblasts, and chronic pro-melanogenic signaling in the dermal microenvironment.^{1,19} RFMN targets these dermal abnormalities by inducing controlled thermal injury, promoting collagen remodeling, reducing senescent fibroblast populations, and modulating inflammatory and angiogenic pathways.^{20,22,23}

Compared with other RFMN devices reported in the literature, POTENZA™ offers greater versatility in parameter selection, which may influence treatment outcomes. Previous studies using RFMN systems have demonstrated variable efficacy in melasma, often showing modest improvements when used as monotherapy and enhanced results when combined with lasers or topical therapies.^{21,24,25} In this context, the clinical effects observed in our study are consistent

with prior reports, particularly in cohorts with mild-to-moderate baseline severity and when RFMN was used as an intervention.

The biological plausibility of RF as a therapeutic modality for melasma is further supported by histologic and ultrastructural studies demonstrating melanocyte cytoplasmic shrinkage, loosening of melanocyte–keratinocyte junctions, and enhanced trans-epidermal elimination of melanin following RF treatment.²⁶ Moreover, dermal targeting strategies have been shown to reduce melanocyte activation mediated by fibroblast-derived factors, such as sFRP2, SDF-1, and GDF15, which are increasingly recognized as central mediators of pigmentation in photoaged skin.^{22,25,28}

Importantly, patient-reported satisfaction was high, with > 60% of patients expressing satisfaction with the treatment outcomes. This apparent discrepancy between objective mMASI changes and subjective satisfaction has been consistently reported in melasma research and likely reflects improvements in skin texture, brightness, and overall appearance that are not fully captured by pigment-focused indices, such as the mMASI.²⁷ These findings reinforce the need to incorporate validated patient-reported outcome measures alongside objective scores in future studies.

From a safety perspective, the treatment was well tolerated, with all adverse events consisting of mild erythema that resolved without sequelae. This favorable safety profile is consistent with prior reports on RFMN devices, which demonstrated low rates of serious adverse events when used with appropriate parameters.^{24,25}

This study has several limitations. Its retrospective design and small sample size limit causal inference and generalizability of the results. Additionally, the absence of a control group and reliance on non-validated instruments for certain patient-reported outcomes may introduce potential bias. Moreover, the secondary outcome measures relied predominantly on subjective scoring scales, with limited objective instrumental support, which may have introduced assessor bias and limited the reliability and objectivity of the study's findings. Furthermore, the treatment parameters were relatively homogeneous, precluding the exploration of dose–response relationships. Nevertheless, the use of real-world data provides valuable insights into routine clinical practice and complements the evidence derived from controlled trials. Future studies should incorporate validated objective measurement tools to strengthen the accuracy and reproducibility of outcome assessments.

Conclusion

In a real-world study involving Japanese patients, POTENZATM RFMN demonstrated a favorable safety profile and contributed to disease stabilization, with clinically meaningful improvement defined as a $\geq 30\%$ reduction in mMASI observed in 27.6% of patients, including a subset achieving $\geq 50\%$ reduction. These findings support its role as a complementary, dermal-targeting modality within multimodal melasma management strategies, particularly in patients with mild to moderate disease. Future prospective controlled studies with larger sample sizes, standardized treatment parameters, and the incorporation of objective instrumental assessments are needed to determine its efficacy.

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Disclosure

Dr. Imaizumi and Dr. Fujimaki are speakers for Jeisys Medical Inc. Dr. Fujimaki also reports personal fees, non-financial support from Allergan (AbbVie) and Jeisys Medical Inc., outside the submitted work. Dr. Kumar is a consultant for Jeisys Med Inc. (Seoul, Republic of Korea). The authors report no other conflicts of interest in this work.

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