

A Pilot Study to Compare Therapeutic Efficacy and Safety of Combined Treatment of Skin Microneedling and Depigmenting Cream versus Depigmenting Cream Alone in Facial Melasma at Tertiary Care Center

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Abstract

Background: Melasma is a commonly acquired, chronic, and relapsing disorder that results in symmetrical, brownish facial pigmentation. It is more common in women than in men, which generally starts between 20 and 40 years of age, and it can lead to considerable embarrassment and distress. Managing melasma is a difficult challenge that requires long-term treatment with a number of topical agents. Microneedling has been described as a new technique to enhance the drug's transdermal penetration, and has also been reported to result in sustained long-term improvement of recalcitrant melasma. **Aim:** The aim of this article was to compare the therapeutic efficacy and safety of combined treatment of skin microneedling and depigmenting cream versus depigmenting cream alone in the treatment of melasma. **Materials and Methods:** A prospective study was conducted with a sample size of 40 patients, with twenty in each of the treatment arms; 20 patients were treated with combined skin needling and depigmenting cream and 20 with depigmenting cream alone. The outcome was evaluated periodically for up to 2 months using the modified Melasma Area and Severity Index (MASI) score. **Results:** Significant reduction was observed in modified MASI score in the combined treatment, with P value <0.05 . **Conclusion:** Combining microneedling with Kligman's regimen gives better results in melasma treatment compared to topical treatment alone.

Keywords: Dermaroller, melasma, modified Kligman's regimen, modified Melasma Area and Severity Index

INTRODUCTION

Melasma is a commonly acquired condition of hypermelanosis, occurring most commonly on the face. This disorder, which is more prevalent in females and darker skin types, is predominantly attributed to ultraviolet (UV) exposure and hormonal influences.^[1] Melasma is generally a clinical diagnosis consisting of symmetric hypermelanosis in three predominant facial patterns: centrofacial, malar, and mandibular. On the basis of histopathologic findings, three variants of melasma are identified: epidermal melasma, when the pigment is deposited in the basal and suprabasal layer; dermal melasma, when melanophages filled with melanin are found in the superficial and middle dermis; and mixed melasma, when findings of the two previous types of melasma are present.

Different treatment modalities, such as topical depigmenting agents, chemical peels, dermabrasion, and laser therapies, have been used in different studies with varying but not so satisfactory outcomes.^[2]

Microneedling is minimally invasive procedure. It uses short fine needles to puncture the skin, thereby enhance the transdermal penetration of topical drugs and also

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stimulates fibroblast proliferation, collagen production and release of growth factors.^[3]

The aim of our study was to compare the therapeutic efficacy and safety of combined treatment of skin microneedling and depigmenting cream versus depigmenting cream alone in the treatment of melasma.

MATERIALS AND METHODS

After approval of institutional ethics committee, a comparative study with a sample size of 40, 20 in each of the treatment arms, was carried out at a tertiary care center in the department of dermatology, venereology, and leprosy from January 2019 to May 2019.

Adult males and females between 18 and 50 years of age with moderate-to-severe bilaterally symmetrical distribution of melasma were included in the study after obtaining written informed consent.

Pregnant/lactating women, patients on hormone replacement therapy or oral contraceptives, history of bleeding disorders, concomitant use of anticoagulants, associated medical illnesses, and history of any other depigmenting treatment in the past 1 month were excluded from the study.

Patients were clinically diagnosed with melasma and had the examination performed by Wood’s light to know the type of melasma.

In Group A, 20 patients were subjected with microneedling. Topical anesthesia was applied for 45min before the intervention. An instrument (dermaroller) with needle length of 1.5mm was used. The treatment was proceeded with back and forth movements, approximately 10 times in four directions, drawing four bands that overlapped, resulting in a diffuse erythema and discrete punctuated bleeding. Patients were instructed to use daily the topical sunscreen and depigmenting cream (0.05% tretinoin + 2% hydroquinone + 0.01% floucinolone acetonide) at night. The same procedure was carried out for 30 days after the first treatment.

In Group B, 20 patients were subjected to daily topical sunscreen and depigmenting cream (0.05% tretinoin + 2% hydroquinone + 0.01% floucinolone acetonide) at night.

Photographic documentation was performed by the same investigator and with the same digital camera immediately before the procedure and after 7 days, 1 month, and 2 months.

Both the groups were assessed at baseline and after 7, 30, and 60 days. Data of all the patients were noted in Excel sheet, and were analyzed using STATA software, version 14.2 (StataCorp LLC, TX, USA). Chi-square test was used for categorical variable, and the Wilcoxon signed-rank test was used to compare the mean values of Melasma Area and Severity Index (MASI) scores.

RESULTS

Of the 20 patients in Group A, 16 were female and 4 were male, and the same distribution was present in Group B. The distribution of age group, type of melasma, and types of Fitzpatrick in both the groups are summarized in Table 1. There was no significant difference between the groups in terms of age distribution, gender, and type of melasma as *P* value by chi-square test was >0.05.

After each session of microneedling, mild erythema and edema were noticed but gradually it got subsided in 2–3 days. No other significant side effects were noted.

In both the groups, significant decrease was noted in modified MASI score (*P* < 0.05) [Figures 1 and 2].

When we compared both the groups, more significant and rapid reduction was observed in modified MASI score in Group A (*P* < 0.05) [Table 2].

After two sessions of microneedling, improvement of melasma was perceived in all patients of Group A; in addition, there was a subjective report of overall facial skin smoothness and greater radiance by the participants.

DISCUSSION

Microneedling with dermaroller is a new treatment modality for the treatment of scars, especially acne scars, stretch marks, wrinkles, and for facial rejuvenation. It is a simple and relatively cheap modality that can also be used for transdermal drug delivery.^[4]

Microneedle technology offers a minimally invasive and painless route of drug delivery.^[5] This technology involves the creation of channels in the skin with micron-sized

Table 1: Demographic profile of patients

Variable		Group A	Group B
Gender	Female	16 (80%)	16 (80%)
	Male	4 (20%)	4 (20%)
Age	22–30	7 (35%)	8 (40%)
	31–40	10 (50%)	8 (40%)
	>40	3 (15%)	4 (20%)
Fitzpatrick skin type	III	3 (15%)	2 (10%)
	IV	5 (25%)	7 (35%)
	V	12 (60%)	11 (55%)
Types of melasma	Epidermal	12 (60%)	15 (75%)
	Dermal	2 (10%)	2 (10%)
	Mixed	6 (30%)	3 (15%)

Table 2: Mean MASI score

Parameter	Group A (mean ± SD)	Group B (mean ± SD)	<i>P</i> value
Baseline	7.425 ± 1.35	7.78 ± 1.39	0.4220
1 week	3.47 ± 1.41	6.645 ± 1.33	0.0002
1 month	2.05 ± 0.99	5.365 ± 1.05	0.0001
2 months	0.99 ± 0.60	3.47 ± 1.05	0.0001

SD = standard deviation

dimensions, thereby enabling the delivery of a broad range of therapeutic molecules including proteins, which would not otherwise cross the intact skin.

Microneedling stimulates fibroblast proliferation, collagen production and release of growth factors, thereby induce beneficial wound-healing response with fewer side effects compared to conventional resurfacing procedures^[3]

As it promotes fibroblast proliferation and upper dermal collagenesis, microneedling can restore upper dermal and basal membrane damage in melasma, disfavoring the contact of melanocytes with dermal-released melanogenic stimuli such as endothelin, stem cell factor, and hepatocyte growth factor. In addition, a thickened epidermis can promote additional protection against UV damage.

Long-term improvement of recalcitrant melasma after microneedling was reported in one case series, in which they concluded that microneedling alone, with 1.5-mm needle length, without the addition of any active medication, can cause lightening of skin stains in patients with recalcitrant melasma.^[6]

Gentle dermabrasion with dental motor roller provided persistent clearance of melasma in 97% of 410 patients in a Thailand case series,^[7] in which they concluded that

mechanical dermabrasion is a relatively safe and highly effective means for curing melasma.

In our study, after a period of 7 and 60 days of treatment mean MASI score was reduced significantly in both the groups. When comparison was done between both the groups, the decrease in mean MASI was statistically significant in combined regime as compared to Kligman's regime alone. This was comparable to the pilot study conducted by Lima *et al.*^[8]

The additional effects of microneedling were suggested in a randomized controlled study with 60 patients comparing intradermal tranexamic acid versus its delivery by microneedling in facial melasma.^[9]

Microneedling with vitamin C has also resulted in a better clinical response, followed by Q-switched neodymium-doped yttrium aluminum garnet (Nd:YAG) for facial melasma, in a split-face trial with 16 patients.^[10]

Moreover, several other studies^[3,11] also showed that adjuvant microneedling had led to significant improvement in MASI scores in melasma.

CONCLUSION

Our study concluded that there was a significant improvement in melasma through microneedling as



Figure 1: (A) Group A at baseline. (B) Group A at 1 month. (C) Group A at 2 month



Figure 2: (A) Group B at baseline. (B) Group B at 1 month. (C) Group B at 2 month

an adjuvant therapy, and the effect was rapid than the topical depigmenting cream alone in improving melasma. Thus, microneedles appear to be a promising therapeutic method for melasma.

Limitation of our study was small sample size and short-term follow-up. Hence, further randomized controlled studies are warranted to investigate the treatment regimen of microneedling to maximize its efficacy, as long-term maintenance of the results.

However, our study opens new perspectives for the use of this device to enhance the penetration of depigmenting compounds and to reduce treatment times.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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