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Efficacy of Skin Needling Device versus Placebo in Treatment of Melasma

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ABSTRACT

Background: Melasma is a common acquired condition of symmetric hyperpigmentation, which typically happening on the face with higher prevalence in females and darker skin types. Multiple causes as light exposure, hormonal changes and family history have been implicated in the melasma pathogenesis.

Objective: To assess the efficacy of microneedling with dermapen in the treatment of melasma compared to placebo.

Patients and methods: The study comprised 17 patients with melasma. They were collected from Dermatology Outpatient Clinics of Zagazig University Hospital. Each patient had five sessions for treatment of facial melasma in split face manner with two weeks interval between the sessions. Right side: each patient was applied with microneedling (dermapen) while, left side was with placebo. A modified MASI (melasma area and severity index) scoring system was assessed. **Results:** There was a significant difference in mMASI score between baseline and after sessions in right side (Dermapen) ($p<0.001$*), while no significant change between baseline and after sessions in left side (placebo). Physician global assessment in right side (Dermapen) showed a significantly lowered mean physician global assessment than left side (placebo) ($p<0.001$*). According to the pattern of melasma either (malar or centrofacial), there was a significant decrease in mMASI score among right side (Dermapen) compared to placebo. Regarding the clinical pattern of melasma either epidermal or mixed melasma, there was no statistical significant difference between the right side (Dermapen) and left side (placebo)**.**

Conclusion: Microneedling technique alone using dermapen provides significant lightening effect with a satisfactory results compared to placebo.

Keywords: Dermapen, Melasma, Needling device.

INTRODUCTION

Melasma, formerly known as chloasma, is an acquired pigmentary condition, occurring most commonly on the face with a three predominant facial patterns: centrofacial, malar, and mandibular. This disorder, which is more prevalent in females and darker skin types, is predominantly attributed to ultraviolet exposure and hormonal influences [(1)]. The centrofacial pattern affects the forehead, nose, and upper lip, excluding the philtrum, cheeks, and chin. The malar pattern is restricted to the malar cheeks on the face, while mandibular melasma is present on the jawline and chin and occur in older individuals and related to severe photodamage [(2,3)].

Various epidemiologic studies have estimated the prevalence of melasma in the general population at 1% and in higher-risk populations at 9–50% [(4, 5)]. These wide ranges are secondary to variations in prevalence among darker skin types, different ethnic heritages. As such, the true prevalence across the entire population is unknown. The average age ranging being between 20 and 30 years [(6)].

The etiology of melasma is multifactorial as ultraviolet (UV) light has been shown in clinical and laboratory studies to trigger and exacerbate the condition through inducing reactive oxygen species (ROS) by activating inducible nitric oxide and promoting melanogenesis [(7)]. Hormonal influences play a significant role in the pathogenesis of melasma by the increased prevalence with pregnancy, oral contraceptive use and other hormonal therapies [(8,9)]. Extra-facial melasma is also associated with a peri-menopausal state [(10)].

On dermoscopic examination, a pronounced hyperpigmentation is found in the pseudo-rete ridges of the skin. Using a Wood's lamp, the hyperpigmentation can be accentuated when the pigment is epidermal [(11)]. However, this accentuation may be seen with dermal or mixed melasma [(12)].

Melasma has not been consistently associated with other clinical conditions. In a case control study, melasma was shown to be associated with an increased number of lentigines and nevi [(13)]. Endocrinological conditions such as thyroid disease are also not associated with melasma when compared to the general population [(14)].

This study aimed to assess the efficacy of microneedling with dermapen in the treatment of melasma compared with placebo.

PATIENTS AND METHODS

A clinical trial that carried out at outpatient clinic of Dermatology, Venereology and Andrology Department, Zagazig University Hospitals during the period from November 2019 to April 2020. It included 18 patients, their ages ranged from 18-60 years old.

Inclusion criteria: Patients with melasma of more than 18 years of age, who were not on any medications for melasma since at least 2 weeks for topical therapy, 1

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month for systemic steroids, 3 months for cosmetic procedures such as laser, dermabrasion, or peels, were included.

Exclusion criteria: Patients with history of any other depigmenting treatment in the past three months, pregnant and/or lactating females, and patients on hormone replacement therapy or oral contraceptives.

All participants were subjected to the following:

A) Detailed history taking such as age, sex, family history of melasma, duration of disease and occupation.

B) General examination: for other systems affection either before or with melasma.

C) Dermatological examination including: Skin type was done according to Fitzpatrick's classification, Wood's lamp examination was done to determine the type of melasma (epidermal, dermal and mixed). A modified MASI (melasma area and severity index) scoring system was calculated according to **Kimbrough-Green *et al.* [15].**

Therapeutic intervention:

Each patient had five sessions for treatment of facial melasma in split face manner with two weeks interval between the sessions. Right side: each patient was applied with microneedling (dermapen) while, left side was with placebo.

Physician's global assessment and patient satisfaction were also assessed. Follow up was continued every session for recording adverse effects.

Patients were followed up once in 2 weeks to assess the improvement and to look for any adverse effects. Hemi-mMASI score was calculated at each visit and two weeks after last session.

Ethical considerations:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of sharing in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

Data were analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution. Quantitative data were described using range, mean, standard deviation, median and interquartile range (IQR). Friedman test for abnormally distributed quantitative variables, to compare between more than two periods or stages and Post Hoc Test (Dunn's) for pair wise comparisons. Wilcoxon signed ranks test for abnormally distributed quantitative variables, to compare between two periods. McNemar Test was used to analyze the significance between the different stages. Mann Whitney test for abnormally distributed quantitative variables was used to compare between two studied groups. Spearman coefficient was used to correlate between two distributed abnormally quantitative variables. $P<0.05$ was considered significant.

RESULTS

In current study, at baseline: mMASI score between right and left sides was the same. While in the 2nd sessions (midline) and after session: Right side (Dermapen) showed a significantly lower mMASI score than left side (placebo). There was a significant difference in mMASI score between baseline and after sessions in right side (Dermapen), while no significant change between baseline and after sessions in left side (placebo) (Table 1).

Table (1): Comparison between three studied session according to mMASI score in each side (n = 17)

mMASI score	Baseline	Midline sessions	After session	Fr	p
Right side (Dermapen)					
Mean ± SD.	1.71 ± 0.76	1.09± 0.59	0.49± 0.49	33.522*	<0.001*
Median (IQR)	1.80 (1.20–1.80)	0.90 (0.60 – 1.20)	0.30 (0.30 – 0.60)		
Sig. bet. Sessions.	$p_1=0.006^*$, $p_2<0.001^*$, $p_3=0.003^*$				
Left side (placebo)					
Mean ± SD.	1.75 ± 0.75	1.69± 0.76	1.69± 0.76	4.000	0.135
Median (IQR)	1.80 (1.20–1.80)	1.80 (1.20 – 1.80)	1.80 (1.20 – 1.80)		

Fr: Friedman test, Significance between periods was calculated using Post Hoc Test (Dunn's), IQR: Interquartile range, SD: Standard deviation, *: Statistically significant.

Regarding, physician global assessment, right side (Dermapen) showed a significantly lowered mean physician global assessment than left side (placebo) (Table 2).

Table (2): Distribution of the studied cases according to physician global assessment, patient satisfaction and patient tolerability (n = 17)

	Right side (Dermapen)		Left side (placebo)		Test of Sig.	p
	No.	%	No.	%		
Physician global assessment						
Mean ± SD.	2.18 ± 1.13		6.0 ± 0.0		Z= 3.671*	<0.001*
Median (IQR)	2.0 (2.0 – 3.0)		6.0 (–)			
Patient satisfaction						
Not satisfied	0	0.0	17	100.0		
Fairly satisfied	3	17.6	0	0.0		
Moderately satisfied	8	47.1	0	0.0	χ^2=34	<0.001*
Highly satisfied	6	35.3	0	0.0		
Patient tolerability						
Irritation /pain	0	0.0	0	0.0	–	–
Erythema (Mild)	5	29.4	5	29.4	χ^2=0.000	^{McN}p=1.000
Hyperpigmentation	0	0.0	0	0.0	–	–

IQR: Interquartile range, SD: Standard deviation, Z: Wilcoxon signed ranks test, McN: McNemar test, *: Statistically significant

According to the pattern of melasma either malar or centrofacial, there was a significant decrease in mMASI score among right side (Dermapen) compared to placebo (Table 3).

Table (3): Relation between patterns of melasma with decrease in mMASI score

Decrease in mMASI score	Pattern of melasma		U	p
	Malar (n = 13)	Centrofacial (n = 4)		
Right side (Dermapen)				
Mean ± SD.	1.36± 0.54	0.75± 0.12	5.0*	0.015*
Median	1.20	0.75		
Left side (placebo)				
Mean ± SD.	0.05± 0.17	0.08± 0.15	22.0	0.703
Median	0.0	0.0		

U: Mann Whitney test, SD: Standard deviation, *: Statistically significant

Regarding the clinical pattern of melasma either epidermal or mixed melasma, there was no statistical significant difference between the right side (Dermapen) and left side (placebo) (Table 4).

Table (4): Relation between melasma types with decreases in mMASI score

Decrease in mMASI score	Melasma type		U	p
	Epidermal (n = 12)	Mixed (n = 5)		
Right side (Dermapen)				
Mean ± SD.	1.15± 0.49	1.38± 0.69	23.50	0.506
Median	1.05	1.50		
Left side (placebo)				
Mean ± SD.	0.03± 0.09	0.12± 0.27	26.0	0.721
Median	0.0	0.0		

U: Mann Whitney test SD: Standard deviation

There was no significant correlation between duration of melasma and decrease in mMASI score (Table 5).

Table (5): Correlation between duration of melasma and decrease in mMASI score (n = 17)

Decrease in mMASI score	Duration of melasma	
	r_s	p
Right side (Dermapen)	-0.195	0.453
Left side (placebo)	-0.038	0.885

r_s: Spearman coefficient

DISCUSSION

Microneedling or mesotherapy, creates small channels in the skin to deliver small amounts of topical drugs intradermally [(16)]. The skin punctures induced by microneedling can also stimulate a beneficial wound-healing response with fewer side effects compared to conventional resurfacing procedures [(17)]. This technique may result in a deeper and more even placement of the medication to the epidermis and dermis. Topicals with microneedling demonstrated a significant improvement in MASI scores when administered with microneedling [(18)].

This study was conducted on 17 female patients with melasma. Each patient had five sessions for treatment of facial melasma in split face manner with two weeks interval between the sessions. Right side: each patient was applied with microneedling (dermapen) while, left side was with placebo. The study aimed to evaluate the efficacy of microneedling with dermapen in the treatment of melasma compared to placebo. Our attainable results agree with parallel studies.

Budamakuntla *et al.* [(19)] observed enhanced results of microneedling in treating moderate to severe melasma in 60 patients. After three treatment sessions (at 0, 4, and 8 weeks), the patients were followed for 3 months. There was 35.72% improvement in the mean Melasma Area and Severity Index (MASI) score in the microinjection group ($p < 0.01$) compared to 44.41% in the microneedling (MN) group ($p < 0.001$). Notably, only 26% of patients in the microinjection group achieved 50% improvement compared to 41% in the MN group.

In a study of **Fabbrocini *et al.*** [(20)] conducted the use of microneedling with serum in 20 female patients (Fitzpatrick Skin Type III–IV) with melasma. In the MN + serum group, baseline mean MASI score decreased by 9.9 points ($p < 0.001$) compared to a 7.1 point decrease ($p < 0.05$) in the serum only group; 2 months post-treatment. Results were confirmed by the significant increase in brightness of patients receiving combination treatment in comparison to the group receiving serum alone (17.4% vs 11.2%; $p < 0.05$).

Therefore, our results concur with **Iriarte *et al.*** [(21)] who stated that the enhanced transdermal drug absorption seen with microneedling has achieved better results than skin lightening agents alone in the treatment of melasma.

CONCLUSION

Our study concluded that microneedling technique alone using dermapen provides significant lightening effect with a satisfactory results compared to placebo.

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