How to Cite:
Shehata , M., Elshazly, M. M., Bebars , S. M. M., & Eloteify, M. M. (2022). A comparative study of effectiveness of microneedling with and without topical corticosteroids in post-burn hypertrophic scars of face and neck. *International Journal of Health Sciences*, *6*(S7), 4141–4153. https://doi.org/10.53730/ijhs.v6nS7.12788

A comparative study of effectiveness of microneedling with and without topical corticosteroids in post-burn hypertrophic scars of face and neck

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***Abstract*---**Background: The standard treatment of post-burns scars has unsatisfactory outcomes and required several treatments. Objective: To evaluate efficacy of the microneedling with or without topical steroids on treatment of post-burn hypertrophic scars in face and neck. Patients and Methods: We included patients with post-burn hypertrophic scar of face and neck, caused by burn within the 1st year after burn, we excluded patients with coagulation defects. Patients were divided into 3 groups; *Group A:* microneedling once/month for 5 months, *Group B:* microneedling with topical steroids once/month for 5 months, and *Group C:* control group for just conservative treatment. Histopathological study was used for evaluation. Results: we included 60 participants; the mean age was 20 ± 9 years. After 3 & 6 months microneedling significantly decrease the Vancouver scar scale (VSS), and adding steroids significantly improve the results. Microneedling group significantly decreased the VSS after 3 and 6 months. Moreover, adding steroids significantly improved the results. Histopathologicaly, after 6 months, there was statistically difference between the three groups in thickness (p= <0.001), Nodules (p= 0.02) and inflammation (p= 0.02) of the scar. Conclusion: Microneedling with or without

topical steroids found to improve the outcomes of post-burn hypertrophic scars.

***Keywords*---**Microneedling, facial burn, steroids, wound healing, collagen thickness, Masson Trichrom stain

Introduction

Cutaneous scarring remains the pathognomonic and the commonest feature following burns to the skin and characteristically underlies post-burn physical and psychosocial morbidity; the prevalence of scar has been reported to be 70% following burn. (1) Hypertrophic scars (HTS) differ clinically and histologically, they are fibrous tissue outgrowth with excessive scarring, confined to the original wound margins. They grow rapidly for several months and then gradually regress over the next few years. (2,3)

Distinct and persistent changes in skin color are often related to burn scars and categorized as scars with pathological erythema. Deep degree burns destroy the epidermal structure and affect dermal layers containing important skin cells such as keratinocytes and fibroblasts. Widespread and deep damage through burns leads to the formation of scar tissue within the conventional wound healing process. The initial phase of post-inflammation is marked by a vasodilatation and an increased number of blood vessels due to the active processes of angiogenesis. Thus, the locally intensified vascularization favors blood circulation, which enhances the development of erythema. (2)

There are numerous available treatment lines including surgical excision, intralesional steroid injection, radiation therapy, lasers and pressure therapy. (4,5) However, outcomes have remained unsatisfactory and several treatments were required to achieve satisfactory results.

Microneedling technique has become a novel strategy for the treatment of scars since 2007; it acts through producing micro punctures which induce a controlled skin injury without actually damaging the epidermis. These microinjuries lead to minimal superficial bleeding and set up a wound healing cascade with release of various growth factors. (6). Moreover, corticoids have been used in the treatment of keloids and HTS since 1960. Steroids have been shown to cause HTS and keloid regression in vivo, mainly by decreasing collagen and glycosaminoglycan synthesis, by reducing the inflammatory process in the wound, by decreasing fibroblast proliferation, and by increasing hypoxia. (7)

Head and neck region is the most frequent site where a burn injury occurs. The percentages vary between 27 to 60%. The face is a psychologically significant area of the body and its disfigurement has been found to have numerous potential psychosocial consequences for patients. (8)

We aim to evaluate the efficacy and safety of microneedling with and without topical steroids in treatment and prevention of post-burn hypertrophic scars in face and neck.

Patients and Methods

This is a parallel 1:1:1 allocation ratio randomised trial conducted on patients attended to Plastic Surgery outpatient clinic, Aswan University Hospital from August 2019 to August 2021, and approved by institutional review board (IRB), Faculty of Medicine, Aswan University.

Participants

We included patients with post-burn hypertrophic scar of face and neck, caused by burn within the 1st year after burn; we excluded patients with coagulation defects. Patients were divided into 3 groups; ***Group A:*** microneedling once/month for 5 months, ***Group B:*** microneedling with topical steroids once/month for 5 months, and ***Group C:*** control group for just conservative treatment.

A proper evaluation of the patient, including a detailed history and physical examination: ***Full patient history*** (Name, Age, Sex, cause of scar and onset of scar), ***lab investigation*** (Complete blood count, Coagulation profile and Histopathological study) and ***photography*** (Before starting and during follow up)
We used topical anesthetic containing Lignocaine and Prilocaine used under occlusion for 45 minutes to 1 hour before the session and disinfection of the area using Povidon Iodine then antiseptic and saline. Patients follow up was done after 3 and 6 months.

Technique:

Group A: A drop of lubricant applied to the scar surface, stretch skin with one hand then we performed microneedling using derma pen (Derma pen 3™), the depth is 1.5 mm to 3 mm according to the thickness of the scar comparing to the surrounding normal skin. The treatment took an average of 15 mins to 20 mins. The area was wet with saline or ice packs.

Group B: Microneedling took place by the same technique used in group A for 10 minutes using derma pen3, then prednisolone ointment applied over the affected area. After that, another session of microneedling is used in this group to confirm good penetration and distribution of the ointment in the hypertrophic scar. The session took an average of 20 mins to 25 mins.

Group C: Control group for just conservative treatment and follow up the normal physiological process of hypertrophic scars.

Evaluation

To evaluate risk factors for the development of HTS and to assess the effectiveness of treatment we used Vancouver Scar Scale (VSS) before treatment, after 3 and 6 months. Moreover, to evaluate histopathological change of the scar before starting of the study and after 6 months with bunch biopsy. Hematoxylin-eosin staining chosen for demonstrating the light microscopic features of

hypertrophic scars. In addition, special staining with Masson Trichrome stain to visualize collagen fibers was done. Collagen orientation, thickness, nodule formation and inflammation were evaluated in the three groups prior and after treatment completion.

Statistical Analysis: *data was collected in a predesigned questionnaire. Numerical data was presented as mean and Standard deviation (± SD), or median, range and Interquartile range (IQR). While categorical data was presented as frequency and percentage. To assess the difference between categorical variables we used Chi ^2. For numerical variable we used ANOVA and Repeated-ANOVA. Moreover, we used planned contrasted to detect the difference between each group. P- value was considered significant if it was < 0.05.* ***S****tatistical analysis* ***was*** *done using SPSS* ***version*** *25, and R* ***version*** *4.1.1.*

Results

In this randomised clinical trial, we included 60 participants, with mean age ±SD 20 ± 9 years. Participants were divided into three groups according to the intervention into group A (Microneedling without corticosteroids), group B (Microneedling with corticosteroids) and control group. The demographics data of the included participants by group are reported in Table 1.

Table 1: The demographic characteristics of patients and the burn characteristics

	Group A	**Group B**	**Group C**
Age (years) - Mean ±SD - Median (IQR)	 21.3 (9.87) 21 (13.5- 28.5)	 20.45 (9.49) 19 (15- 25)	 23.1 (9.13) 24 (18-29)
Onset of Scar formation (Weeks) - Mean ±SD - Median (IQR)	 5.3 (1.49) 5 (4- 6)	 5.7 (1.75) 6 (4- 8)	 5.4 (1.73) 4 (4- 7.5)
Gender - Male - Female	 8 12	 9 11	 9 11
Cause of scar - Flamed - Scaled	 9 11	 10 10	 9 11

To compare the efficacy of each intervention in comparison to the control group, the mean score was the same at baseline over th 3 groups, p =0.9. After 3 and 6 months there was very highly statistically difference between the groups (p < 0.001, and p<0.001 respectively) Table 2. Planned contrasts revealed that having any maneuver significantly decrease the Vancouver Scar Scale compared to no intervention, (for 3 months MD = -2.4 [95%CI- 3.2/-1.6], p < 0.001 and for 6 months MD = -3 [95%CI -3.9/ -2.2], p < 0.001). Moreover, having a Microneedling with corticosteroids techniques significantly decrease Vancouver Scar Scale

compared to having a Microneedling only, (for 3 months MD= -1.2, [95%CI -0.3/ -2.1], p < 0.01 and for 6 months MD= -1.1, [95%CI -0.13/ -2.1], p < 0.05)

Table 2: comparison Vancouver Scar Scale between groups

		Mean (95%CI)	**P-value**
at admission	Group A	7.15 (6.36- 7.9)	0.926
	Group B	7.3 (6.6- 7.9)	
	Control group	7.35 (6.5- 8.1)	
after 3 Months	Group A	6.3 (5.7- 6.9)	< 0.001***
	Group B	5.15 (4.6- 5.9)	
	Control group	8.1 (7.3- 8.9)	
after 6 Months	Group A	5.1 (4.5- 5.7)	< 0.001***
	Group B	4 (3.4- 4.6)	
	Control group	7.6 (6.7- 8.5)	

Group A= Microneedling, Group B= Microneedling with corticosteroids, Group C= Control.

The value of Vancouver Scar Scale in control group increased from the baseline, however this effect is not statistically significant p- value = 0.092. regarding to Microneedling group, the Scale significantly decreased from the baseline p- value = <0.001 (**Error! Not a valid bookmark self-reference.**). Planned contrasts revealed that Microneedling technique significantly decreases the Vancouver Scar Scale after 3 months compared to the baseline, MD_{3-0} = -0.85 [95%CI -0.336 /-1.36], p < 0.001. Moreover, the scale highly significantly decreases after 6 months compared to baseline, and to 3 months MD_{6-0}= -2.05 [95%CI -1.108 /-2.99], p < 0.001, MD_{6-3}= -1.2 [95%CI -0.379 /-2.02], respectively.

The value of Vancouver Scar Scale very highly statistically significant decreases if the patients treated with Microneedling + corticosteroids, p- value = <0.001. Planned contrasts revealed that Microneedling+ corticosteroids technique significantly decreases the Vancouver Scar Scale after 3 months compared to the baseline, MD_{3-0} = -2.15 [95%CI -1.231/-3.07], p < 0.001. Also, after 6 months compared to baseline, and to 3 months MD_{6-0}= -3.3 [95%CI -2.327 /-4.27], p < 0.001, MD_{6-3}= -1.15 [95%CI -0.673/-1.63], respectively.

Table 3: comparison Vancouver Scar Scale between over time in each group

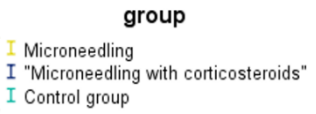
		Mean (95%CI)	**P-value**
control group	Baseline	7.35 (6.6 - 8.1)	0.092
	After 3 Months	8.10 (7.34- 8.86)	
	After 6 Months	7.60 (6.74- 8.5)	
Microneedling group	Baseline	7.15 (6.4-7.9)	<0.001
	After 3 Months	6.30 (5.7- 6.9)	
	After 6 Months	5.1 (4.5- 5.7)	
Microneedling with Corticosteroids group	Baseline	7.3 (6.48- 8.12)	<0.001
	After 3 Months	5.15 (4.6- 5.68)	
	After 6 Months	4 (3.39- 4.6)	

Group A= Microneedling, Group B= Microneedling with corticosteroids, Group C= Control.

Regarding the histopathological results were reported in **Error! Not a valid bookmark self-reference.**. At baseline there was statistically difference between the three groups in Nodules (p= 0.02) and inflammation (p= 0.02). While there was not statistically difference in collagen orientation or thickness of the scar. After 6 months, there was statistically difference between the three groups in thickness (p= <0.001), Nodules (p= 0.02) and inflammation (p= 0.02) of the scar. However, there was not statistically difference between the 3 groups in collagen orientation of the scar.

Table 4: Histopathology of the scars at baseline and after 6 Months

Parameters		**Group A (n= 20)**		**Group B (n= 20)**		**Group C (n= 20)**		P value
		Pre	Post	Pre	Post	Pre	Post	
Collagen orientation	Parallel	7 (35%)	15 (75%)	9 (45%)	9 (45%)	12 (60%)	11 (55%)	0.1466
	Random	13 (65%)	5 (25%)	11 (55%)	11 (55%)	8 (40%)	9 (45%)	
Thickness	Decrease	2 (10%)	11 (55%)	4 (20%)	5 (25%)	2 (10%)	0 (0%)	< 0.001*
	Increase	6 (30%)	2 (10%)	8 (40%)	0 (0%)	4 (20%)	13 (65%)	
	Stable	12 (60%)	7 (35%)	8 (40%)	15 (75%)	14 (70%)	7 (35%)	
Nodules	No	4 (20%)	4 (20%)	0 (0%)	0 (0%)	3 (15%)	0(0%)	0.0204*
	Present	13 (65%)	15 (75%)	20(100 %)	18(90%)	17 (85%)	15 (75%)	
	Multiple	3 (15%)	1 (5%)	0 (0%)	2 (10%)	0 (0%)	5 (25%)	
inflammation	No	18 (90%)	19 (95%)	19 (95%)	20(100 %)	13(65%)	15(75%)	0.0205*
	Present	2 (10%)	1 (5%)	1(5%)	0(0%)	7 (35%)	5 (25%)	



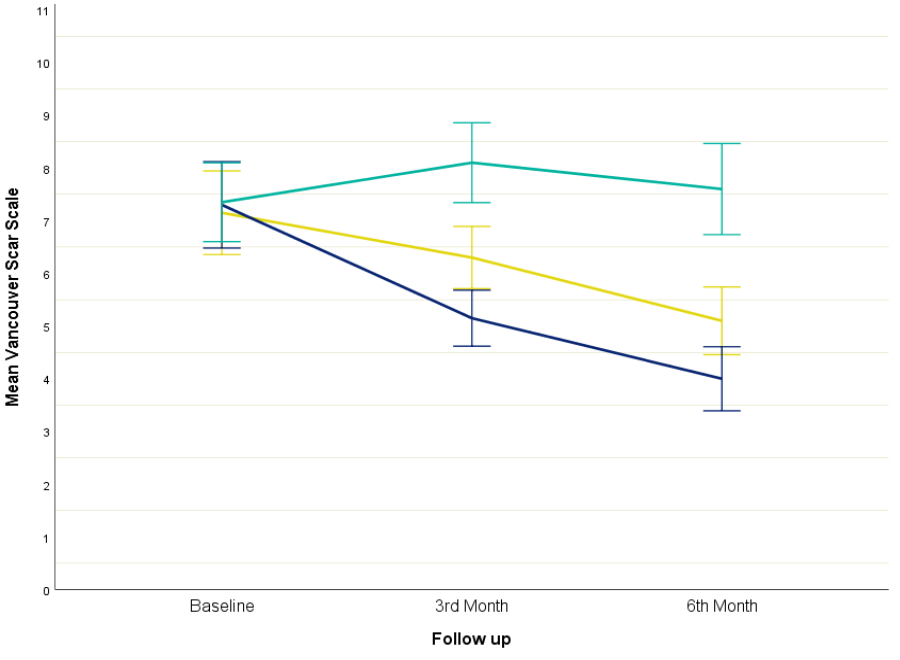
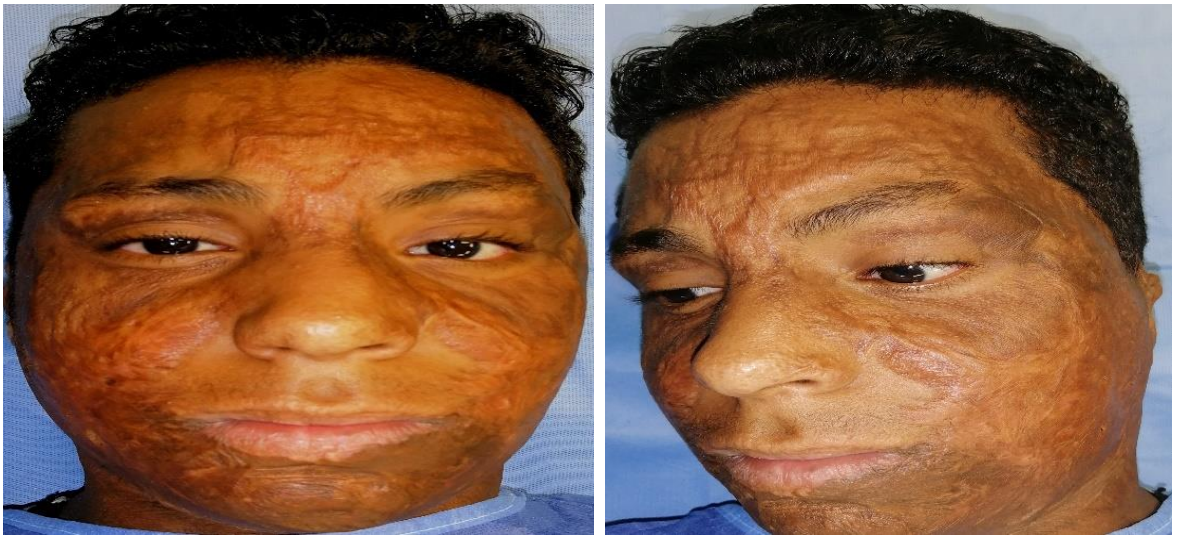


Figure 1: Mean change of Vancouver Scar Scale over time

Case presentation

Group A



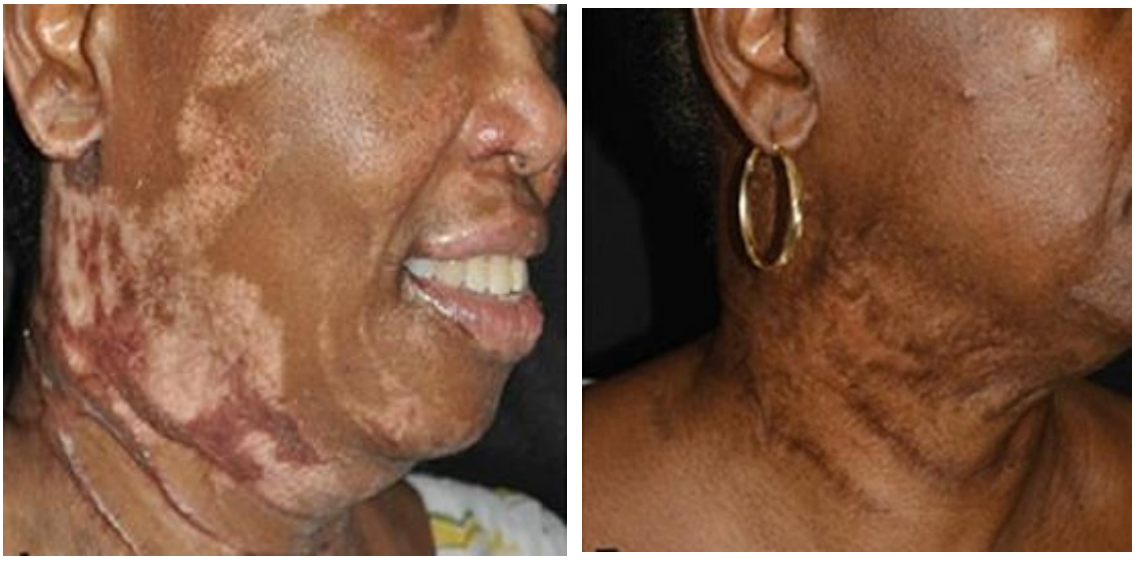
A ***B***

Figure 2: Male patient 16-year, post burn facial hypertrophic scar, 7 months. Post burn, pre (A), and post 6 months with Microneedling only(B).

Group B

A **B**

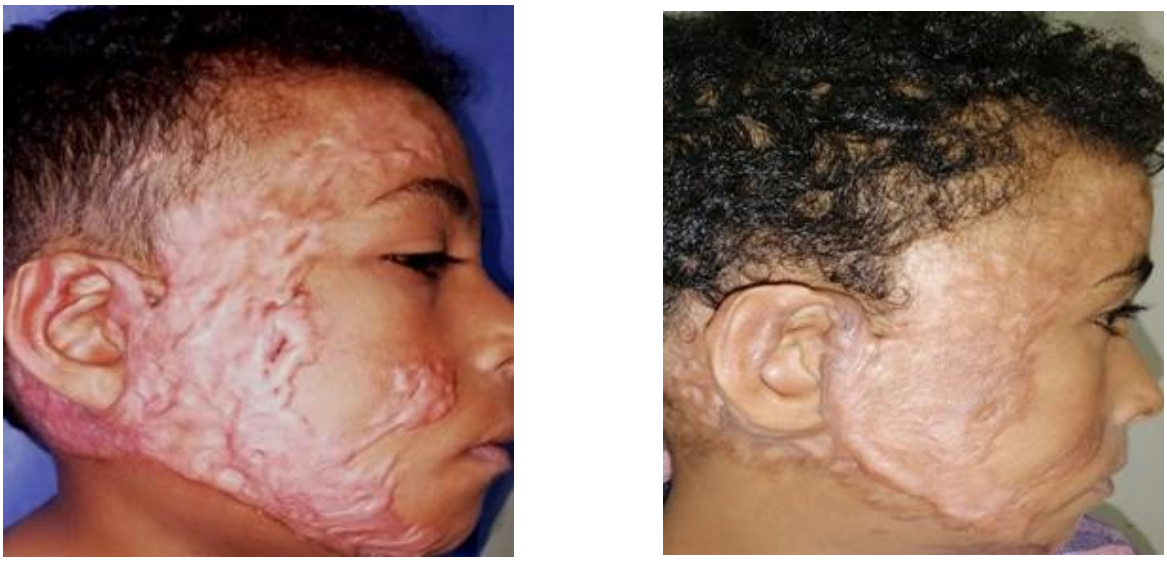
Figure 3: Female patient 7-year, post burn facial hypertrophic scar, 5 months. Post burn, pre (A), and post 6 months with Microneedling with corticosteroids (B).



A **B**

Figure 4: Female patient 56-year, post burn facial hypertrophic scar, 2 months. Post burn, pre (A), and post 6 months with Microneedling with corticosteroids (B).

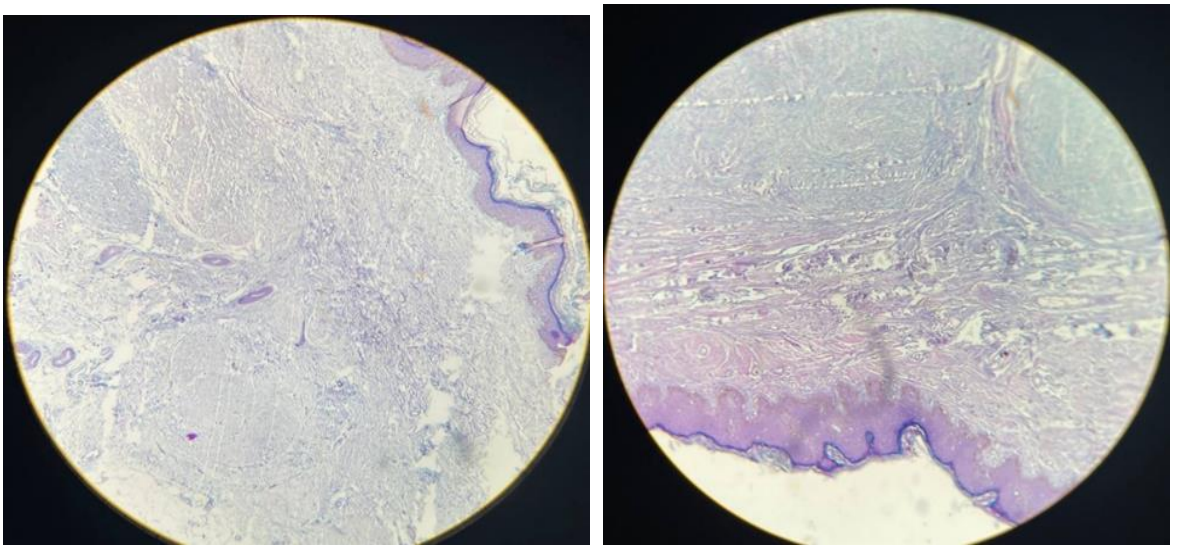
Group C



A **B**

Figure 5: Male patient 12-year, post burn facial hypertrophic scar, 7 months. Post burn, pre (A), and post 6 months with conservative management *(B)*.

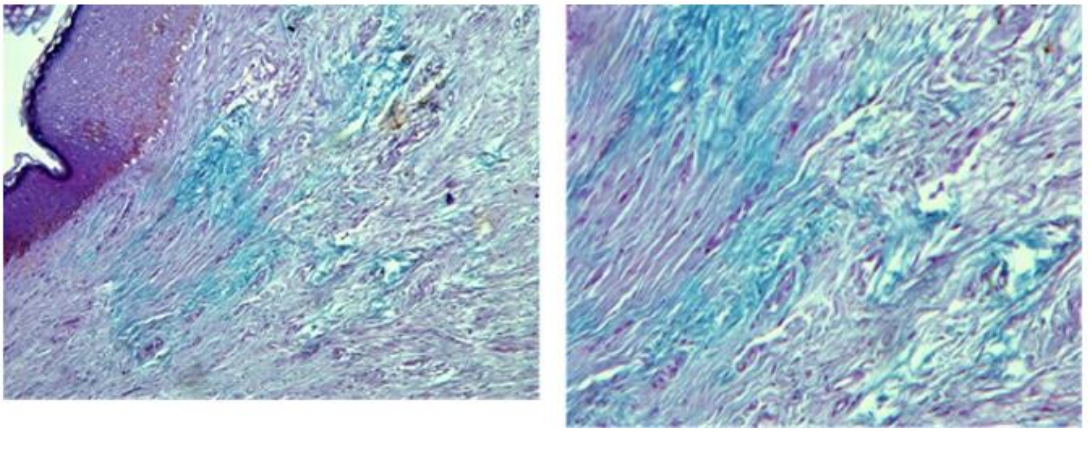
Pathology slides



A **B**

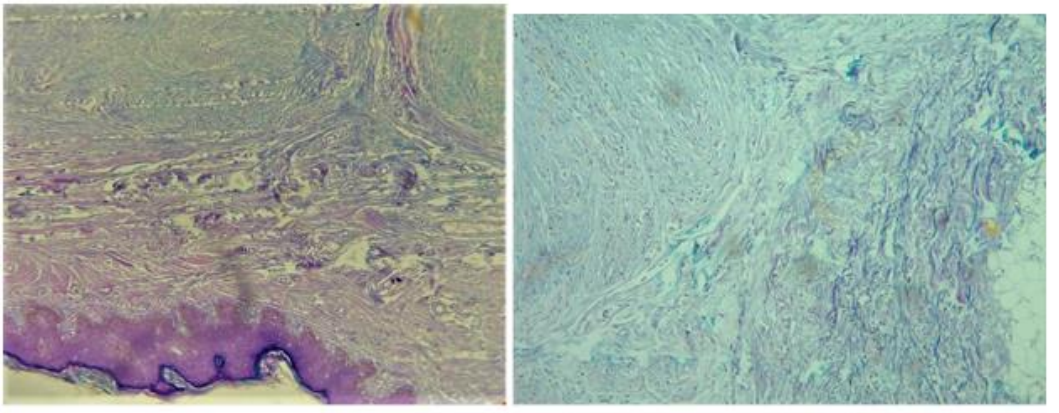
Figure 6: A: Microscopic picture of case biopsy taken from group B before starting our study showing increased thickness of collagen fiber with random orientation and start of formation of collagen nodules.

B: Microscopic picture of case biopsy taken from group B before starting our study showing decreased thickness of collagen fiber with random orientation and complete formation of collagen nodules.



A **B**

Figure 7: Photomicrograph of hypertrophic scar stained with Masson Trichrome Stain showing parallel orientation of collagen fiber. (A) 10x magnification, (B) 40x magnification.



A B

Figure 8: Photomicrograph of hypertrophic scastained with Masson Trichrome Stain showing collagenous nodules. (A) 10x magnification, (B) 40x magnification

Discussion

Some wounds lead to abnormal scarring, which has a pathological spectrum ranging from stretched, depressed and contracted to raised dermal scars such as hypertrophic and keloid scars (9). Wound depth, age, genetic susceptibility, certain anatomic locations, and prolonged inflammation influence the formation of hypertrophic scars (10). Face being the most evident part of the body, any imperfection has adverse and indelible psychosocial implications (11).

Microneedling is one of the established methods for treatments of scars. (12) Also, steroids represent the first therapy used successfully in scar management alone or as adjuvant treatment. (13)

The difference in our work is the combination of two treatment methods microneedling using Dermapen 3™ and prednisolone ointment in management of post-burn hypertrophic scar of face and neck region.

The combination of these two of treatments showed better improvement compared with a single treatment, as proved by VSS. Normal skin pigmentation increased from 15% to 40%, normal vascularity increased from 0 % to 25%, none of the cases archived normal pliability and increase of scar height (0-2 mm) from 40 % to 70% with flattening of the scar in 15% of cases.

In general, our results are consistent with findings from previous studies. Ma et al. also combined microneedling and steroid, but they used triamcinolone acetonide instead. Follow up of their 32 cases showed the total effective rate cure rate was 100%. The scar color, thickness, texture and feeling was significantly improved. (14)

A recent literature review showed that needling can significantly modulate both mature and actively hypertrophic burn scars at 12-month follow-up with better collagen alignment in the dermis and increased epidermal thickness (15)

Furthermore, results from histopathological evaluation showed that the combination group had a significant favourable course on scar thickness than the other two groups, despite the initial more scar thickness in the combination group than the other two groups before starting of our study which in turn proves the efficacy of combination therapy in cases with thick scars.

Histopathological evaluation in patients treated with microneedling in a previous study showed normalization of the collagen/elastin matrix along with the thickened epidermis. However, still there was no regaining of normal and healthy skin with a decreased cell density in the dermis and epidermis and a partial irregular fiber structure (16). These findings are confirmed in our study. Despite, the improvement in microneedling group, a descent proportion of the patients had random arrangement of the collagen, thick scar and presence of inflammation. But the combination group in our study had better improvement in the skin histology parameters which supports our results regarding combination therapy.
Further research is required to establish this combination as an evidence-based therapeutic option for treating scars and determine the optimal timing for this treatment and its long-term outcome.

Conclusion

Microneedling with topical corticosteroids seems to be a promising and effective therapeutic approach with affordable cost in comparison to other technique such as LASER therapy in post-burn facial scars management, showing significant improvement in scar quality.

Funding Sources: This research received no grant from any funding agency in the public, commercial or not-for-profit sectors.

Conflict of Interest: The Authors declare that there is no conflict of interest

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