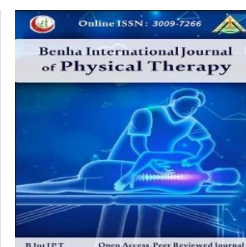


Benha International Journal of Physical Therapy

Online ISSN: 3009-7266

Home page: <https://bijpt.journals.ekb.eg/>



Original research

Impact of Tripollar Radiofrequency on Acne Scar Severity and its Impact on Life Quality: A Randomized Controlled Trial

Haidy Nady Ashem Saad¹, Alshymaa Ahmed Kamel Ahmed², Ahmed Shawky Gomaa³, Marwa Mahdy Abd El-Hameed⁴

¹Professor and head of Physical Therapy department for Surgery, Faculty of Physical Therapy, Cairo University.

²Physical Therapist, Mallawi Specialized Hospital, Minia, Egypt.

³Fellow lecturer of dermatology, Venereology and Andrology, Assiut University Hospital.

⁴Lecturer of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University.

*Correspondence to:

Alshymaa Ahmed Kamel Ahmed,
Physical Therapist,
Mallawi Specialized
Hospital, Minia, Egypt.

Email:

omar.mabrouk@deraya.edu.eg

Telephone:

01009946033

Article history:

Submitted: 15-11-2024

Revised: 15-12-2024

Accepted: 24-12-2024

Abstract

Background: Acne scar affects health quality. Radiofrequency (RF) treatments serve as an alternative to traditional acne scar therapies and may be utilized either as standalone interventions or in conjunction with fractional lasers. There is lack of research about effect of TriPollar RF on treatment of acne vulgaris. **Purpose:** The study aimed to find out the therapeutic efficiency of TriPollar RF adding to the medical treatment on acne scar severity and its impact of life quality acne scar. **Methods:** Forty people with a history of acne scarring, aged between 20 and 40, were randomized to one of two matched groups: As directed by their dermatologist, the research group (A) underwent TriPollar RF therapy in addition to their medical care and the control group (B) received sham- TriPollar RF therapy in addition to their medical treatment, for 12 sessions once a week each session for 15 min for each group. All patients were evaluated with a self-assessment of clinical acne related scars (SCARS) questionnaire, facial acne scar quality of life (FASQoL) questionnaire and photography pre and post treatment. **Results:** Substantial enhancement has been observed between the two groups in favor of group A in SCARS (mean difference: - 5.9, $p < 0.001$) as well as FASQoL (-5.3, $p < 0.001$). Group (A) exhibited a notable reduction in the SCARS as well as FASQoL scales post-treatment ($p < 0.001$), with decreases of 43.5% and 38.93%, respectively, exceeding group (B), which showed reductions ($p < 0.001$) of 15.76% and 14.37%, respectively. **Conclusion:** TriPollar RF incorporation into traditional treatment over a 12-week period was advantageous and effective for individuals with acne scars.

Keywords: Acne scars, TriPollar radiofrequency (RF) therapy, self-assessment of clinical acne related scars (SCARS) questionnaire, facial acne scar quality of life (FASQoL) questionnaire.

INTRODUCTION:

Acne scars are the product of tissue response to inflammation caused by acne. Acne scarring is a prevalent issue, especially in females and darker skin types, which proves to be rather difficult to treat. It is estimated that acne affects 85% of the population at some point in their life, and roughly 20% of these patients will be left with permanent acne scars¹.

Acne scars are a major outcome associated with acne, impacting nearly 95% of individuals, even with suitable and prompt treatment. Clearly visible depressed scars are known to negatively influence a person's mental health and overall quality of life. Scarring that occurs after acne may be a contributing factor for depression, anxiety, and even suicidal thoughts².

Management of acne scars necessitates a comprehensive physical assessment of the individual, coupled with a conversation regarding the patient's objectives, worries, and their willingness to undergo various treatment options. Factors to consider include erythema, the type, depth, as well as location of scarring, along with the patient's baseline skin phototype (SPT)³.

A variety of treatment approaches are conventionally employed for addressing acne scars. This includes a variety of ablative methods, such as chemical peels, subcision, laser treatments that are ablative, dermabrasion, dermal grafting, punch excision, punch elevation, punch grafting, and various surgical procedures. Furthermore, less invasive microneedling via a dermaroller can effectively address acne scars⁴. These traditional interventions carry the risk of post-inflammatory hyperpigmentation and related issues, so alternative therapies are needed⁵.

RF treatments serve as an alternative to traditional acne scar therapies and may be utilized either as standalone interventions or in conjunction with fractional lasers. There are three main types of RF treatments: unipolar, bipolar, and fractional. The most fundamental type is the unipolar or monopolar RF device, which consists of one electrode and a grounding pad placed on the skin. This RF method enhances skin penetration but can result in

increased discomfort for the patient. Bipolar RF serves as an alternative to unipolar or monopolar RF by delivering a more concentrated current to the dermis while reducing pain, as it operates at lower energy levels to achieve the same thermal effect⁶.

There is minimal evidence that RF could cause adverse consequences, making it a potentially safe approach and has been used in acne scarring, with good results. TriPollar RF is the most advanced form of RF to date in dermal heat manipulation⁷. However, there are limited researches about the effects of TriPollar RF on acne scars and previous authors suggest doing more research⁸.

As a result, the aim of this study is to explore the effectiveness of TriPollar radiofrequency acne scar severity and its impact on life quality.

METHODS:

Study design

The research was conducted as a randomized controlled clinical trial

This study has the necessary ethical clearances from the faculty of physical therapy at Cairo University's research ethical committee (NO:P.T.REC/012/004643) before it can begin. Research involving human participants was conducted in accordance with the standards established in the Declaration of Helsinki and the CONSORT guidelines.

From January to April of 2024, the research was carried out. A written consent form was requested of all participants prior to the commencement of the trial. Registration of the research was completed through the clinical trial registry (ID: NCT 06492356).

Research subjects were randomly assigned to either the study (A) or control (B) groups. Both groups received topical treatment (Adapalene 0.1 gel, Tretinoin 0.025 cream, Adapalene 0.1 plus benzoyl peroxide 0.25 gel, and Isotretinoin 0.5 plus Erythromycin 2% gel) as a medical treatment prescribed by the dermatologist. In addition to the medical treatment, group A (n=20) patients received TriPollar radiofrequency (RF) therapy and group B (n=20) patients received sham-treatment by the TriPollar radiofrequency (RF) therapy. The treatment period was 12 sessions,

once a week for 12 weeks. All patients were evaluated with SCARS questionnaire, FASQoL questionnaire and photography prior to and after 12 weeks of successive treatment program.

Recruitment and randomization:

Initially fifty-five participants with acne scar were referred to the study by a dermatologist. Five who declined to participate and ten did not fulfill the requirements for inclusion.

As a result, forty participants were chosen at random using a computer-generated block randomization process and divided into two equal groups to reduce selection bias and ensure uniformity across the two data sets, a block size of four was used. The opaque envelopes were sealed and numbered sequentially to accomplish the concealed allocation.

Figure 1 shows number of patients who were screened, enrolled, treated, and analyzed.

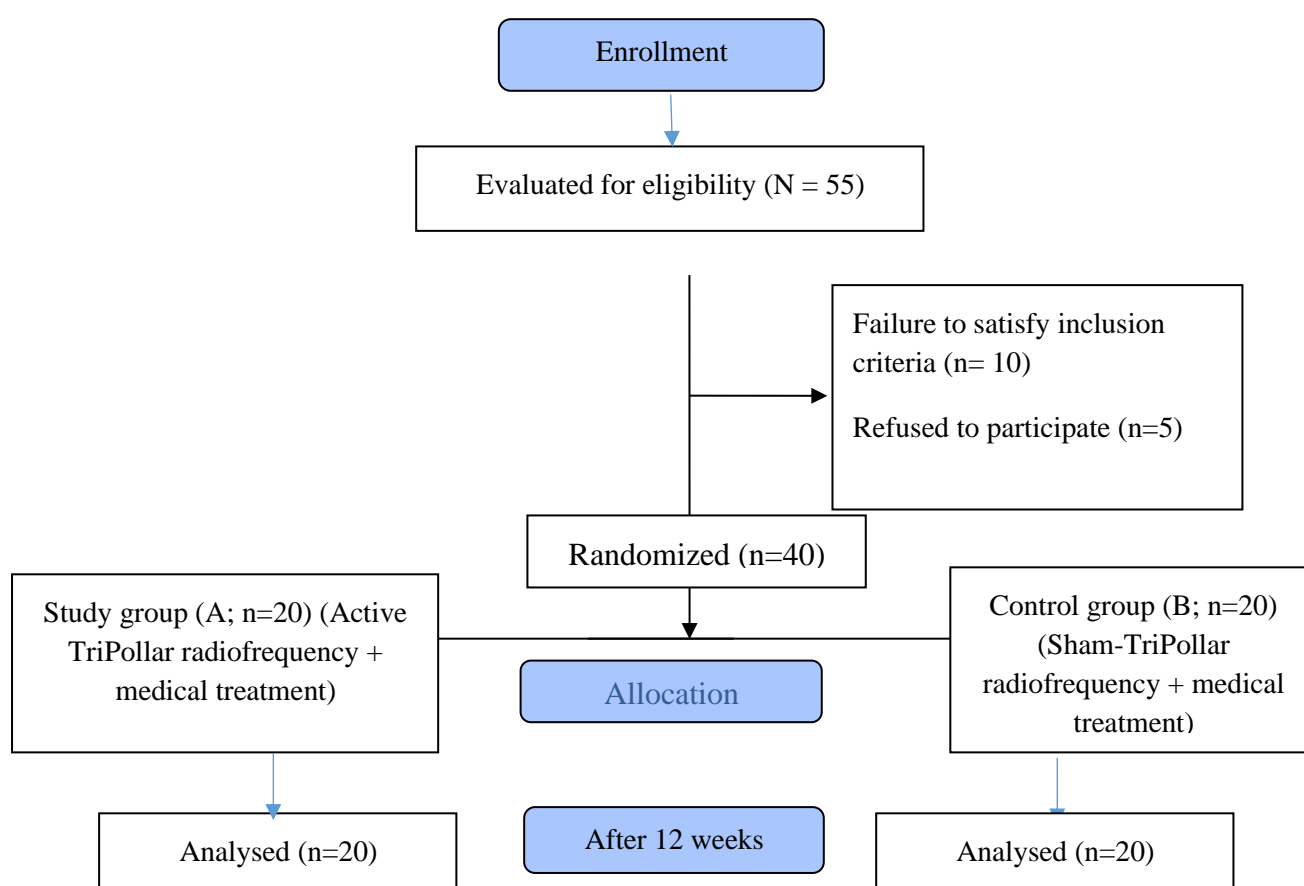


Fig. (1). Flow chart of the patients

Subjects

The inclusion criteria consisted of the following: (1) diagnosed with acne scar by dermatologist (2) age from 20 -40 years old; (3) participants who were medically and psychologically stable.

The exclusion criteria consisted of the following: (1) Patients with hypertrophic or keloids; (2) Patients with dermatological issues related to acne scarring (e.g., psoriasis, tattoo, birthmark); (3); Patients with medical red flags as severe psychiatric disorder or cognitive deficits; (4) patients whose implanted electronic

devices, such as pacemakers, are susceptible to the effects of RF radiation; (5) medically unstable and uncooperative patients; (5) Untreated and active ongoing acne vulgaris; (6) immune compromised status; (6) History of skin cancer; (7) recurrent herpes viral infection; (8) pregnancy or breastfeeding status; (9) females take contraceptive pills or even any disorder cause hormonal disturbance.

Outcome measures:

Before the commencement of the study, all patients were educated about its purpose, methodology, possible advantages, privacy,

and data use. They were then asked to approve and sign a consent form. Outcome assessments were conducted before to the commencement of the initial session and subsequent to the completion of the last session (12th) after a duration of 12 weeks. The assessed variables encompassed scar severity and life quality using SCARS and FASQoL questionnaires, respectively. As well, photographs were taken to identify the clinical effects on cosmetics.

Self-assessment of clinical acne related scars (SCARS) questionnaire: The SCARS questionnaire consists of five questions, each with five potential responses that can be rated from 0 to 4. Higher scores indicate a more severe acne scar. The following is how SCARS scores are clinically interpreted: The scarring can be classified as follows: 0-2, clear or almost clear; 3-6, mild; 7-10, moderate; 11-20, severe or extremely severe⁹.

Facial acne scar quality of life (FASQoL) questionnaire: The FASQoL has 10 items evaluating the effects of atrophic acne scars. It evaluates the effects of scars on emotional well-being, social functioning, as well as occupational/school performance via 5-point rating scales across a recall interval of the preceding seven days¹⁰. High score indicates high negative impact on life quality.

Both scales were shown to be valid in patients with acne scars¹⁰. In addition, both tools had excellent reliability²¹. No minimal clinical important difference (MCID) values were found in literature for these scales.

Samsung Galaxy note 10 plus mobile: Photography was taken before and after 12 sessions of the treatment program using the camera of Samsung Galaxy note 10 plus mobile.

Interventions:

All patients in groups A and B got medicinal treatment as prescribed by their dermatologist (Topical treatment: Adapalene 0.1 gel, Tretinoin 0.025 cream, Adapalene 0.1 plus benzoyl peroxide 0.25 gel, Isotretinoin 0.5 plus Erythromycin 2% gel).

Active TriPollar radiofrequency therapy for group A: Twelve, once weekly sessions of

TriPollar RF were administered to twenty individuals who had acne scars. Glycerin was applied to the treatment area prior to each session and then removed at the end of the session. Using the applicator at a power of 12.5 watts, the process focused on problematic acne areas and took around 15 minutes¹¹. Twenty patients in group B who had acne scars got twelve weeks of weekly sham-inactive treatment of TriPollar RF.

Sample-size calculation:

To be sure there weren't any type II errors, the sample size was calculated before the investigation even started. The sample size was determined by G*POWER statistical analysis (G*power version 3.1), with a power of 80%, an α -level of 0.05, with an effect size of 0.91¹¹, for the purpose of investigating the effects of monopolar RF on acne scars. Twenty participants from each group were needed for this investigation.

Statistical analysis:

An unpaired t-test was used to compare the groups' ages. A chi-squared test was employed to compare how the sexes were distributed throughout the groups. To determine if the data was normally distributed, we employed the Shapiro-Wilk test. Levene's test for homogeneity of variances was used to evaluate the equality of variances between groups. When comparing groups on SCARS as well as FASQoL, we used an unpaired t-test; when comparing pre- to post- treatment data, we used a paired t-test. A significance level of $p < 0.05$ was set for all statistical tests. Statistical Package for the Social Sciences (SPSS) version 25 for Windows (IBM SPSS, Chicago, IL, USA) was used for all statistical analyses.

RESULTS

Subject characteristics:

This study involved forty participants with acne scars. The characteristics of the subjects in groups A and B are shown in **Table (1)**. Regarding the distribution of sexes and ages, there were no notable differences between the groups ($p > 0.05$).

Table 1. Comparison of subject characteristics between group A and B:

	Group A	Group B	p-value
	Mean \pm SD	Mean \pm SD	
Age (years)	30.55 \pm 5.16	29.85 \pm 5.64	0.68
Sex, n (%)			
Female	17 (85%)	17 (85%)	1
Male	3 (15%)	3 (15%)	

SD, Standard deviation; MD, Mean difference; p value, Probability value

Impact of treatment on SCARS as well as FASQoL:**Within group comparison:**

Following treatment, both groups' SCARS and FASQoL significantly decreased as compared to their pre-treatment levels ($p > 0.001$). Groups A and B had different percentages of change in SCARS in addition to

FASQoL: 43.50 and 38.93%, respectively, and 15.76 and 14.37%, respectively (**Table 2**).

Between group comparison:

Before treatment, there was no substantial difference between the groups ($p > 0.05$). After treatment, a comparative examination of the groups showed that group A had significantly lower SCARS and FASQoL than group B ($p < 0.01$) (**Table 2, figure 2**).

Table 2. Mean SCARS and FASQoL pre and post treatment of group A and B:

	Pre treatment	Post treatment	MD	% of change	t- value	p value
	Mean \pm SD	Mean \pm SD				
SCARS						
Group A	26.55 \pm 6.20	15 \pm 4.61	11.55	43.50	10.51	0.001
Group B	24.75 \pm 4.22	20.85 \pm 4.26	3.90	15.76	10.99	0.001
MD	1.8	-5.85				
t- value	1.07	-4.17				
	<i>p = 0.29</i>	<i>p = 0.001</i>				
FASQoL						
Group A	28.90 \pm 6.03	17.65 \pm 5.34	11.25	38.93	10.94	0.001
Group B	26.80 \pm 5.43	22.95 \pm 4.86	3.85	14.37	13.16	0.001
MD	2.1	-5.3				
t- value	1.16	-3.28				
	<i>p = 0.25</i>	<i>p = 0.002</i>				

SD, Standard deviation; MD, Mean difference; p value, Probability value

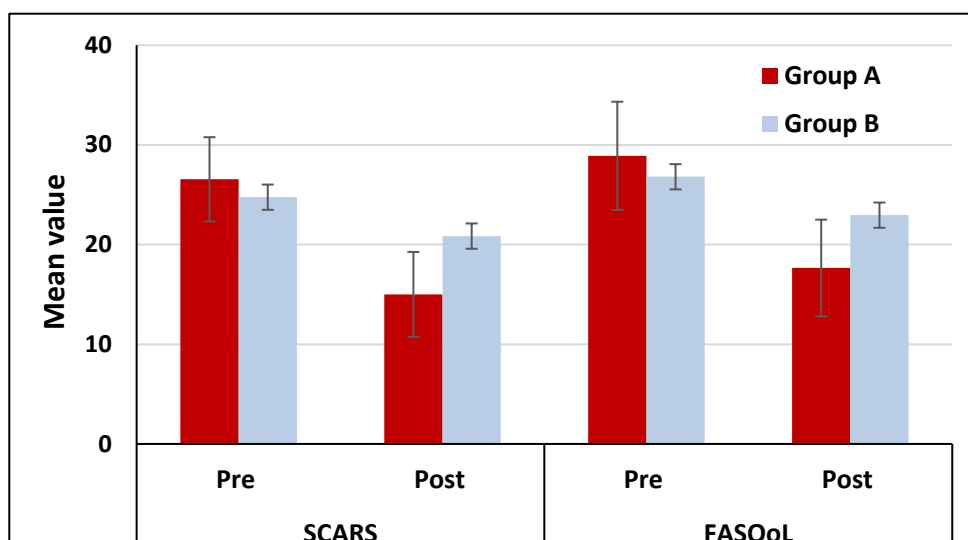


Fig. (2): Mean SCARS and FASQoL pre and post treatment of group A and B.

Clinical effect of treatment on facial cosmetics using photography:

Figures 3 show the effects of TriPollar RF on facial appearance using photographic

method. The photos show significant clinical effect after TriPollar RF treatment compared to before treatment.

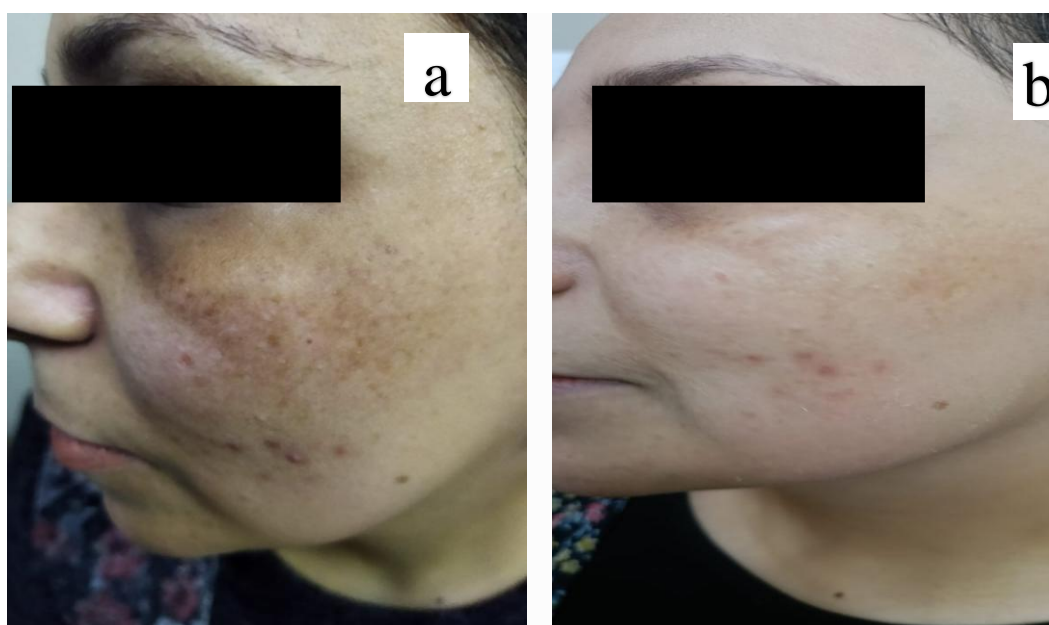


Fig. (3): Female patients showing a decrease in the acne scars (a) before and (b) after. (Consent was taken from the patient)

DISCUSSION:

The aim of the study was to analyze the impact of TriPollar RF on the severity of acne scars. The findings indicated that both groups experienced a substantial reduction in SCARS as well as FASQoL scales from prior to treatment to following treatment. Nevertheless, the following treatment comparison revealed a substantial difference among the two groups, with the study group achieving superior results. These findings confirm that TriPollar radiofrequency is a viable intervention method for reducing the severity of acne scars¹².

Our results are corroborated by the study carried out by **Ruiz-Esparza and Gomez**¹³, that included 22 individuals with scarring that were moderate to severe. The outcomes of non-ablative RF treatment were as follows: 82% of patients exhibited a great response, 9% had a moderate response, and 9% showed no response. No adverse effects were documented following the operation. The researchers claimed that non-ablative RF generated heat within the dermis as well as subcutaneous tissue, resulting in skin tightening.

Furthermore, **Ramesh et al.**¹⁴, investigated the effectiveness of radiofrequency on acne scars in 30 teens in a prospective randomized study. Eight patients reported moderate outcomes, four claimed excellent results, and eighteen reported decent results in terms of cosmetics. Radiofrequency technology turned out to be a safe, useful, and efficient way to treat acne scars and promote skin rejuvenation.

The better outcomes in group (A) are consistent with those of **Iyer et al.**¹⁵, who evaluated the effects of RF on 40 patients who had acne scarring on their cheeks, jaws, lower face, and anterior neck. Moderate, bearable discomfort and mild erythema were side effects of the therapy. Acne scars shown notable improvement following consecutive treatments for a period not exceeding 3 months. Three subjects exhibited superficial blisters that healed without scarring. Patient satisfaction improved following treatment.

Also, when comparing among the prior to and following treatment results of SCARS as well as FASQoL scores of group (B) revealed a substantial improvement in the acne scars which

comes in agreement with **Yu and Huang**¹⁶, who said that TriPollar RF therapy offers a quick, easy, and painless way to reduce active acne lesions, improve skin appearance, reduce anxiety related to acne and acne treatment, and stop acne scars from forming while making them less noticeable.

The use of TriPollar radiofrequency therapy in the present study is supported by a study carried out by **Levenberg et al.**¹⁷, who asserted that individuals who received face treatments utilizing TriPollar® RF exhibited enhancements in acne scars, skin texture, as well as wrinkles.

Additionally, the current study supports the findings of **Simmons et al.**¹⁸, who found that radiofrequency treatments are a viable alternative for treating acne scars on all skin types with a limited number of sessions and extra cosmetic advantages. Patients may resume their normal activities the same day because the treatments are less invasive and also encourage a speedy recovery. Within 12 sessions over a 12-week period, TriPollar RF reduced the severity of acne scars, the patients' cosmetics, and their quality of life.

Furthermore, according to a study by **Kaplan and Andrea**¹⁹, TriPollar is a safe and efficient non-invasive technology that helps with body shaping and skin tightening. Histological results show that the dermal and adipose layers change after treatment, which promotes collagen regeneration and increases fat metabolism, which supports the findings of our study.

The TriPollar radiofrequency treatment operates by heating the sebaceous glands, resulting in enhanced metabolism and glandular shrinkage, so reducing sebum production as well as subsequently decreasing acne. Moreover, enhanced blood circulation due to the heat effects of RF may augment available oxygen, potentially benefiting *P. acnes* bacteria. It is thought that the pilosebaceous unit has a higher electrical resistance than the surrounding skin, which causes the follicle and gland to heat up more quickly and precisely while protecting the surrounding dermal and epidermal tissues²⁰. Our study's findings run counter to those of **Allam & Elshorbagy**¹¹, who examined the

effectiveness of pulsed dye laser (PdL) and monopolar radiofrequency (RF) in reducing acne scars and improving cosmetic appearance. They concluded that PdL is significantly more effective than MRF for patients with acne scars. Although the authors of this earlier work employed MRF, further research is need to determine if tripollar type is more successful than laser.

Limitations of the study:

A few limitations need to be mentioned to put this study in perspective. This study was constrained by several factors: individual variations in patients' lifestyles and psychological states during assessment or treatment, disparities in the location and severity of acne lesions among patients, variability in patient responses affecting recovery rates, and the absence of long-term efficacy evaluation of the treatment program.

CONCLUSION:

The outcome results from this study reported that the TriPollar radiofrequency therapy has some potential to improve Scars and FASQoL scores which indicates significant improvement in patients with acne scars. The TriPollar radiofrequency therapy could be used as a safe and effective treatment modality among patients having acne scars. This significant improvement increases those patient's performance in their daily life activities in a result of the improving their psychological status as well as quality of life. So, the TriPollar radiofrequency therapy could be used in the rehabilitation program of patients having acne scars.

Acknowledgement:

We express our gratitude to each and every research participant.

Disclosure statement:

No author has a financial stake in this study or has benefited financially from it.

Funding:

the authors did not receive any funding for the research, authorship and/or publication for this study.

Conflict of interest:

The authors state no conflicts of interest in this work.

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