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FDA CE 1370

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Er:YAG - 2940 nm

DOSSIER D’ÉTUDES CLINIQUES

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Dermatology Practical & Conceptual

Ablative Fractional Erbium:YAG Laser Resurfacing: A Treatment Option for Acne

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Introduction

Acne vulgaris is a disease of the pilosebaceous unit, characterized by a hyper keratinization process, comedo formation, and inflammatory reactions [1]. The use of lasers for the treatment of acne has been described, but the role of resurfacing lasers for active acne has not been clarified yet.

Case Presentation

We present the cases of 3 women with noninflammatory and inflammatory acne lesions. They received laser therapy because they refused prolonged topical treatments or other systemic acne therapies. No treatment was given to the patients in the previous 6 months prior to laser treatment. The patients gave informed consent to mild laser rejuvenation therapy with ablative fractionated erbium:YAG laser, (Xlase plus; Biotec Italia srl, Dueville, VI).

These patients were treated using the standard protocol for mild resurfacing and rejuvenation. Employed parameters were 1.5 ms, 3.5 mJ/cm^2, 5 Hz on the cheeks and the chin, and the rest of the face was treated with 1.0 ms, 2.8 mJ/cm^2, 6 Hz. One laser session per month for 3 months was performed for each patient. Overlapping pulses were performed over inflammatory lesions. After the laser sessions, the patients were instructed to apply sunscreen SPF 50+ and a hydrating cream for 30 days. All 3 patients tolerated the treatment without any reported side effects. They showed a visible improvement of the skin texture and a reduction of active acne.

The average value for the Investigator Global Assessment scale (IGA) was indicative of a mild-moderate acne at baseline (IGA 1-2) and decreased consistently to the almost-clear stage (IGA 0-1) at the last follow-up visit 3 months after the last laser session (Figures 1 and 2).

One paper describes the application of multiple sessions of erbium:YAG laser treatment for active acne on 2 patients with inflamed cystic acne [2]. Singh et al hypothesized that the mechanism of action of this laser source might be related to the photothermal effect acting on follicular hyperkeratosis and contributing to skin microbe modulation.

The short follow-up period of our patients represents a limitation of this case report. Further studies are needed to investigate the anti-acne effect of erbium: YAG laser and its mechanism of action with respect to comedogenesis and inflammation.

Conclusions

Acne is one of the most common skin diseases. Many therapeutic approaches are currently available for active acne, including laser treatments. However, the role of resurfacing

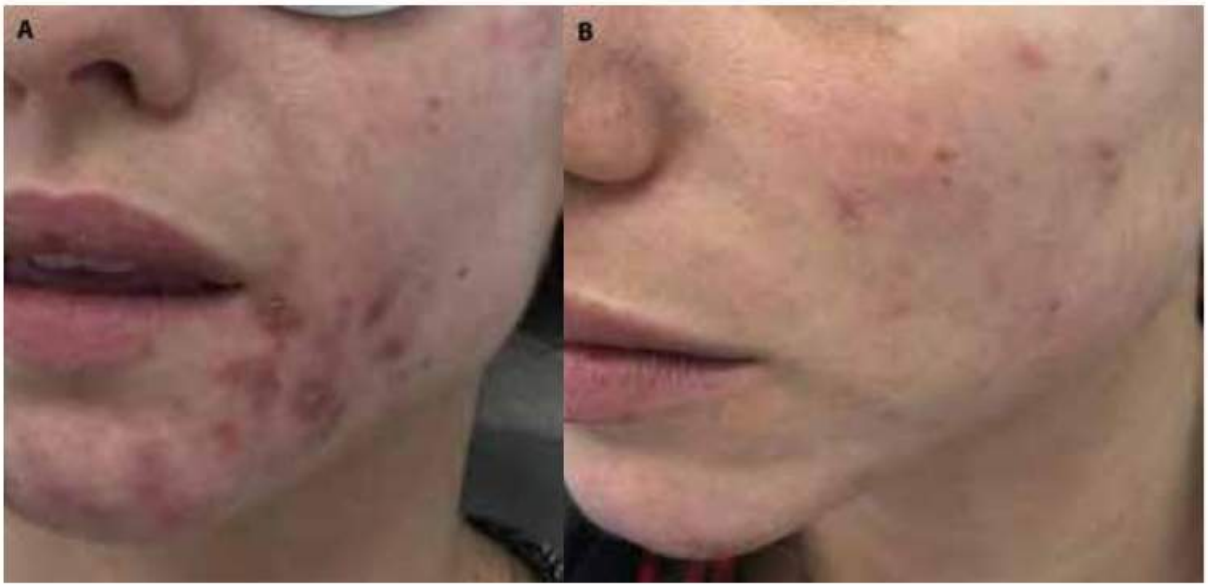


Figure 1. Clinical pictures of a 34-year-old woman. (A) Before the last erbium:YAG laser session. (B) 3 months after the last erbium:YAG laser session, showing the reduction of active acne lesions.



Figure 2. Clinical pictures of a 25-year-old woman. (A) Before the last erbium:YAG laser session. (B) 3 months after the last erbium:YAG laser session, highlighting a consistent reduction of both inflammatory and noninflammatory acne skin lesions.

with erbium:YAG laser has not been clarified yet. Results from clinical practice, such as in the cases presented herein, highlight the importance of further investigations in this field.

Informed consent: Written informed consent for publication of their clinical details and clinical images was obtained from all patients.

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Melasma treatment using Erbium Yag 2940 nm

Dr.Arianna Facchini

Date 10/01/2023

signature

Device :

Xlase Plus Laser Plattform With ER Yag 2940 nm (ablative and fractional spacer)handpiece

Manfactured by Biotec Italia

Melasma treatment using Erbium Yag 2940 nm

Er Yag 2940 nm Handpiece Mechanism Of Action

Er YAG 2940 laser works by emitting high-energy light that is absorbed by the water in the skin cells. This leads to the vaporization of the top layers of the skin, which stimulates the production of collagen and promotes the growth of new, healthy skin cells. In the case of melasma, the laser targets the excess melanin (pigment) in the affected areas, breaking it down into smaller particles that can be absorbed by the body's natural processes.

Overall, the mechanism of action of Er YAG 2940 laser on melasma involves both the removal of the damaged top layers of the skin and the targeted destruction of excess melanin

Parameters and specification Of Er yag 2940 Handpiece

Many factors influence the efficacy of Er Yag 2940 nm handpiece such as spot size(ablative or fractional), pulse duration, energy per microbeams.

	Specification of ER yag 2940 handpiece
Frequency Hz	1-4 Hz
Energy J	Up to 2 J
Wave length nm	2940 nm
Pulse Duration	0.5-2 ms

Material and Methods

The aim of the present study was to evaluate the efficacy of the Er Yag 2940 laser in the treatment of Melasma.25 subjects with ages ranging from 32 to 52 years with dermal and

epidermal melasma participated in this study. All the patients had skin phototypes II–IV. These patients had no history of dermatological disorders such as photosensitivity or inflammatory, pre-malignant or malignant skin diseases. An explanation about the risks, benefits, and complications was given to all patients. Protective goggles were placed on the patient. The full face treated with two passes. For the first pass, the fractional spacer was adjusted with 1.5 ms ,1 Hz and 2.1J/Cm2 and for second pass the parameters were 1 ms,1 Hz and 0.7 J/Cm2.during the treatment the handpiece was placed perpendicularly on the skin. For the first pass handpiece were placed pulse by pulse from upper to lower face and for second pass were placed from left to right. All subjects were treated monthly for a total of 2 months. After crusting completely healed (12-15 days), subjects were instructed to wear sunscreen (SPF 50+) and avoid any topical preparations on the face for the duration of the study. Any possible complications such as edema, erythema, hypopigmentation, hyperpigmentation, infection, and scarring were recorded. Patients were evaluated at baseline, before and after each treatment, and at 1 months after the final treatment.

The clinical assessment consisted of the physician's overall assessment and patient self-assessment. The physician 's valuations score was divided into 6 grades: – 1 = side effects; 0 = no improvement; 1 =slightly improvement ;2=mild improvement ;3=extremely improvement. Patients' satisfaction score was 0- unsatisfied, 1-not very satisfied, 2-satisfied, 3 -very satisfied.

Results

All patient completed the full course of the study. patients reported an average pain score 2.12 on a scale of 1-10. Marked erythema with slight edema occurred after disappearance of whitening that persists for 12–24 hours. Eighty percent of patients were clearing 100 % of

their melasma according to the evaluator assessment. The results of the physicians' overall assessments and the patients' subjective self-assessments have been summarized in Tables 1 and 2.

Conclusion

This study concluded that Er YAG 2940 nm handpiece resurfacing does effectively improve melasma with minimal downtime.

Tabel

Tabe 1

Phsician valuation

– 1 = side effects; 0 = no improvement; 1 =slightly improvement ;2=mild

improvement ;3=extremely improvement.

Age	Valutation score At 1 month	Valutation score At 3 month	Side effects
35	0	2	No
35	1	3	No
36	0	3	erythema with slight edema
38	0	3	No
40	1	3	No
45	1	2	erythema with slight edema
42	1	2	No
33	1	3	No
32	1	3	erythema with slight edema
35	1	3	No
36	1	3	erythema with slight edema
38	2	3	erythema with slight edema
40	1	2	No
39	1	2	No
41	0	2	erythema with slight edema
50	0	2	No
38	0	2	No
39	0	3	erythema with slight edema
40	0	3	No
40	0	3	No
43	0	3	erythema
45	0	2	erythema
37	0	2	No
35	0	3	erythema
35	0	3	No
	M=0.48	M=2.6	

Tabe 2

Patients' satisfaction 0- unsatisfied, 1-not very satisfied, 2-satisfied, 3 -very satisfied.

Age	Satisfaction Score after 3 month	Pain scale on 1-10	Do you continue with your treatment ?
35	3	2	Yes
35	3	1	Yes
36	2	1	Yes
38	2	1	Yes
40	2	3	Yes
45	2	2	Yes
42	3	3	Yes
33	3	3	Yes
32	3	3	Yes
35	3	3	Yes
36	3	3	Yes
38	3	3	Yes
40	3	3	Yes
39	3	3	Yes
41	3	3	Yes
50	3	2	Yes
38	3	1	Yes
39	3	1	Yes
40	3	3	Yes
40	3	1	Yes
43	3	3	Yes
45	3	2	Yes
37	3	1	Yes
35	3	1	Yes
35	2	1	Yes
	M=2.8	M=2.2	



Riferimenti

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Results of fractional facial skin resurfacing with the ER: YAG 2940 nm handpiece

Background: ER :yag 2940 nm handpiece manufactured by Biotec Italia is used to resurface the epidermis and, at the same time, to heat the dermis to promote safely the formation of new collagen. The untreated healthy skin remains intact.

Objective: The aim of this study was to evaluate the efficiency of ER YAG 2940 nm handpiece for skin resurfacing and wrinkles and scar improvements.

Methods: twenty-two women participated in the study, with ages ranging from 30 years to 55 years (mean age 39.09 years). All patients were with Fitzpatrick II_IV. Patients with pregnancy, lactation , inflammatory skin diseases, open wounds, active herpes simplex, facia congenital/acquired naevi were excluded from current study.

The laser used was Xlase Plus system manufactured by Biotec Italia ER: yag 2940 nm handpiece. The fractional window of the laser handpiece was 9 mm×9mm, supporting 81 microbeams. The system has Four programmes for treatment pulse width: superficial (0.5 ms pulse width), superficial (1 ms) and Medium (1.5 ms) and Deep (2 ms). The fluency range was 0.7-2.1 J/CM2.All patients were treated one session. Each area was treated with one pass in vertical and horizontal directions with 30% overlapping with fractional spacer. Patients were asked to return 7 day and 2 months after treatment for evaluation the results. Scar and wrinkles improvement was assessed using the physician GAIS (global esthetic improvement scale) score: Doctor evaluation: 0= no improvement, 1 = moderate, 2 = good, 3 = excellent.. In addition, each patient scored their satisfaction after treatment and also scored their overall satisfaction with their improvement at the end of the 2 months on a scale of 1 to 5, as follows: 1-not satisfied; 2-slightly satisfied; 3-satisfied; 4-very satisfied; 5-extremely satisfied. This questionnaire also included several questions about the patients' satisfaction of treatment results, their assessment of adverse effects.

Results: All 22 patients (mean age 39.09years, range 30-55 years old) were treated 1 session with ER YAG 2940 nm handpiece from Xlase Plus Device manufactured by Biotec Italia. All patients showed improvements. In some patients, it is observed some side effects like redness and swelling that disappeared after 2 days.

Conclusion: This current study shows efficiency and safety of ER Yag 2940 nm Hand piece of XLase Plus used for scar and wrinkle improvements.



April 2022

Dott. Domenico Pugliese



Doctor evaluation: 0= no improvement, 1 = moderate, 2 = good, 3 = excellent.

Patient information		Doctor 's evaluation after 7 days	Doctor 's evaluation after 2 month	Side effects
Sex	Age			
M	30	1	2	Redness
M	40	2	3	Redness
F	32	1	3	Redness
F	35	1	3	Redness
F	36	0	2	Redness
F	36	1	3	-
F	40	2	3	-
F	41	1	3	Redness
F	42	1	2	Swelling
F	50	2	3	-
F	52	1	3	-
M	50	2	3	-
M	45	1	3	-
F	32	1	2	-
M	35	0	3	-
M	38	1	2	Redness
F	36	0	2	Redness
M	32	0	2	Redness
F	32	1	3	Redness
F	30	1	3	Redness
M	48	1	3	Redness
M	48	2	2	Swelling
	Mean:39.09	Mean: 1.04	Mean :2.6	



Patient's satisfaction: 1-not satisfied; 2-slightly satisfied; 3-satisfied; 4-very satisfied; 5-extremely satisfied

Patient information		Patients' satisfaction after 7 days	Patients' satisfaction after 2 Month	Side effects	Recommended us to others	Continue with treatment
Sex	Age					
M	30	2	3	Redness	Yes	Yes
M	40	3	4	Redness	Yes	Yes
F	32	2	3	Redness	Yes	Yes
F	35	3	4	Redness	Yes	Yes
F	36	3	3	Redness	Yes	Yes
F	36	2	3	-	Yes	Yes
F	40	3	4	-	Yes	Yes
F	41	2	3	Redness	Yes	Yes
F	42	3	4	Swelling	Yes	Yes
F	50	3	4	-	Yes	Yes
F	52	3	4	-	Yes	Yes
M	50	1	3	-	Yes	Yes
M	45	2	3	-	Yes	Yes
F	32	2	3	-	Yes	Yes
M	35	1	2	-	Yes	Yes
M	38	2	3	Redness	Yes	Yes
F	36	1	3	Redness	Yes	Yes
M	32	1	3	Redness	Yes	Yes
F	32	2	3	Redness	Yes	Yes
F	30	2	3	Redness	Yes	Yes
M	48	2	3	Redness	Yes	Yes
M	48	2	3	Swelling	Yes	Yes
	Mean:39.09	Mean :2.1	Mean :3.2			



