xlase PLUS

DOSSIER ETUDES CLINIQUES



FDA CE 1370

XLASE PLUS

NPP Q-switch Nd:YAG - 1064/532 nm

DOSSIER D’ÉTUDES CLINIQUES

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Abstract

NPP Q-switched Nd:YAG 532-nm of Xlase Plus Device for the treatment of benign pigmented lesion

NPP QS ND YAG lasers are effective treatment options for treatment of pigmented lesion. The objective of the study is to confirm the efficacy and safety in benign pigmented lesion treated by NPP Qs ND YAG handpiece potassium titanyl phosphate (KTP) 532-nm (manufactured by Biotec Italia) laser. 18 patients were enrolled. All subjects treated with a single treatment of NPP Qs ND YAG KTP 532-nm laser. In terms of efficacy, score was evaluated at 6 and 60 th days. Degree of pigment clearance was assessed by the physician and the patients. Satisfaction score was rated by patients using visual analogue scale. Adverse events were also recorded. All patients completed the study.

Patients and methods : 18 patients aged 18 years or older who had at least 1 benign pigmented lesions. Exclusion criteria included pregnant or lactating women, patients with history of keloids or hypertrophic scars, as well as patients with photo dermatoses.
Before treatment, each lesion was cleansed .one lesion from each patient was treated with a single session of NPP QS ND YAG KTP 532-nm (Biotec Italia, Vicenza) with the following settings :2.5 mm spot size, Energy of 0.6-1.0J at 1 Hz until was achieved (immediate whitening). all subject were asked to apply sunscreen with sun protection factor 50+. Patients were asked to return for follow-up visits at 6 and 60 days after the treatment. Doctor rated degree of pigmented lesion improvement by scale: 0=no improvement ,1=mild improvement, 2=moderate improvement, and 3=complete improvement. Any possible adverse events were recorded in every visit. Patient self-assessment was completed at 60 days follow-up: 0=no improvement ,1=mild improvement, 2=moderate improvement, and 3=complete improvement. Patient satisfaction was also evaluated on the last visit by scale: 1-not satisfied 2-satisfied 3-enough satisfied 4-extremly satisfied. Pain score was evaluated immediately after laser treatment using scale 0=pain at all 1=discomfort 2=slightly painful 3=extremely painful. Time until the crust peeled off were also recorded.

Results: In terms of degree of pigment clearance assessed by doctors and patients more than 72 % of subjects showed excellent results with NPP QS ND YAG handpiece .there were no adverse effect during treatments. There were some rare cases with redness and erythema.
Based on patients' score treatment was not painful.

Conclusion : collected data shows efficiency and safety of NPP QS ND YAG Hand piece of XLase Plus used with KTP 532 nm for treating superficial benign pigmented lesion such as lentigines.

Dott.Luanna Leggieri _____
10/09/2022

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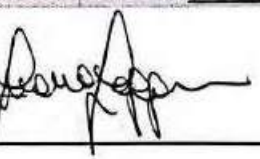
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Level of patient's satisfaction during the treatment: 1-not satisfied 2-satisfied 3-enough satisfied 4-extremly satisfied

patients' evaluation scale: 0=no improvement ,1=mild improvement, 2=moderate improvement, and 3=complete improvement

patients' pain scale 0=pain at all 1=discomfort 2=slightly painful 3=extremely painful

Paient	patient's satisfaction after 60 days	patients' pain score	patients' evaluation sore
1 M 18	3	0	2
2 F 25	4	1	3
3 F 35	3	0	3
4 F 45	3	0	3
5 M 20	3	1	3
6 F 24	3	1	3
7 F 19	4	1	2
8 M 25	4	1	2
9 M 45	4	2	2
10 M 48	4	2	2
11 F 38	4	2	2
12 F 32	4	1	3
13 F 36	4	2	3
14 F 25	4	2	3
15 F 36	3	2	2
16 M 42	3	0	3
17 M 28	4	1	3
18 F 30	3	1	3
	M=3.55	M=1.1	M=2.61

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Doctor and patients' evaluation scale: 0=no improvement ,1=mild improvement, 2=moderate improvement, and 3=complete improvement

Paient	Doctor score after 6 days	Patient score after 60 days	Side effects during visits
1 M 18	0	2	-
2 F 25	1	2	-
3 F 35	1	3	-
4 F 45	1	3	-
5 M 20	2	3	-
6 F 24	1	3	-
7 F 19	1	3	-
8 M 25	0	2	Erythema
9 M 45	0	3	-
10 M 48	0	3	-
11 F 38	0	2	-
12 F 32	0	3	Redness
13 F 36	1	2	-
14 F 25	1	3	Redness
15 F 36	1	3	-
16 M 42	1	3	-
17 M 28	1	3	-
18 F 30	1	3	-
	M=0.72	M=2.73	

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Dermatology Practical & Conceptual

Carbon Peel Laser Technique to Improve Skin Quality: Back to Science!

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Key words: carbon peel laser, Q-switched laser, carbon suspension, enlarged pores

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Introduction

There is increasing interest in procedures to improve skin quality with short downtime. Specifically, topical carbon suspension combined with Q-switched Nd:YAG laser treatment (carbon peel laser technique) has gained popularity in the last few years. The aim of this case report is to present the use of the carbon peel laser in the treatment of a patient with enlarged skin pores and comedones.

Case Presentation

We present herein the case of a 42-year-old woman who complained of oily skin, dilated pores, and noninflammatory comedones. The patient was treated with the carbon peel laser technique after acquiring the informed consent. Before treatment, the patient's face was washed, and the carbon lotion (carbon pigments; Renlive Cosmeceuticals, Dueville, VI, Italy) was applied evenly over the face, except for the upper eyelids, eyebrows, and lips, and allowed to penetrate the skin and hair follicles for 10 minutes. The excess of carbon was removed and then the Q-switched 1064-nm Nd:YAG laser was employed to vaporize the skin surface. The Q-switched Nd:YAG laser (Xlase Plus, Biotec Italia srl, Dueville, VI, Italy) energy was delivered with a 7-mm diameter spot-sized handpiece at a repetition rate of 6 Hz. A single pass was carried out on face with the laser. The pulse width was of 9 nanoseconds and fluence was 2.6 J/cm2. Three sessions of treatment were performed at monthly intervals. Clinical pictures were taken before the laser sessions and 1 month after the last laser session.

Figure 1 shows clinical pictures before and after treatment, showing the improvement in the skin, mainly with a reduction of skin pore size. No severe adverse events were reported. Only a mild erythema after treatment was observed.

Conclusions

The carbon peel laser technique was originally described in 1997 by Goldberg et al for laser hair removal. After providing

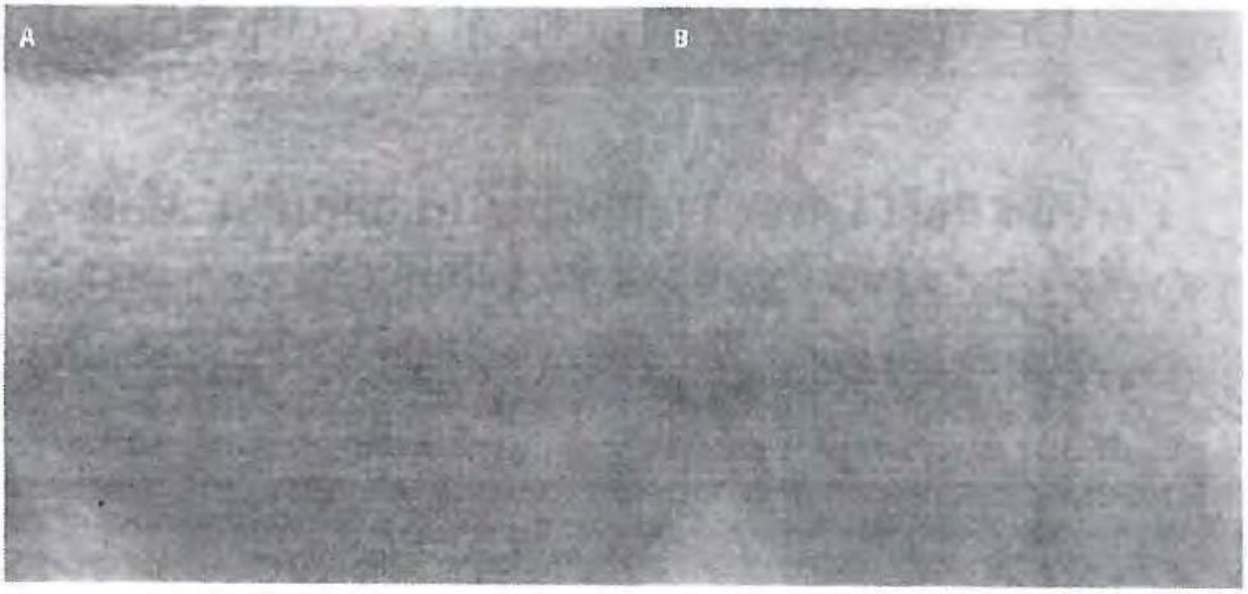


Figure 1. Clinical pictures of a 42-year-old woman (A) before and (B) after treatment with carbon peel laser.

the evidence for the effect on the hair follicle, the technique has been extended to treat acne vulgaris and pores [1,2].

In one study, different laser protocols were employed involving a small number of patients, and only a single experience for each indication was reported. Nevertheless, common mechanisms of action were hypothesized related to the peeling effect of the procedure, such as the reduction of microbial colonization of *P. acnes*, sebaceous gland function, together with the histologically proven thinning of the stratum corneum of the epidermis. Taken together, all these mechanisms might contribute to reduced inflammation [2].

Interestingly, the carbon peel laser technique has been proven to provide a peeling effect, cleaning off the skin surface and the plugged pores, thereby correcting the hypercornification of follicular epithelium that might block the physiologic outflow of sebum to the skin surface and reducing skin inflammation [2].

However, despite the popularity of this technique and much information accessible on the Internet, little scientific data are available on the literature. The last publication was reported in 2012. Our case report showed that treatment with carbon peel laser was effective for acne prone skin and had an excellent safety profile. Further studies are needed in order to find adequate protocols of treatment.

References

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