xlase PLUS

DOSSIER ETUDES CLINIQUES



FDA CE 1370

XLASE PLUS

SLP Nd:YAG - 1064 nm

DOSSIER D’ÉTUDES CLINIQUES

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Abstract

Hirsutism treatment in Fitzpatrick Skin Types V and VI with SLP Nd:YAG laser Handpiece of XLase Plus device

Laser hair removal is based on the principal of selective photo thermolysis and the goal of selectively heating a target chromophore, in this case follicular melanin, with minimal damage to surrounding tissue. In darker-skinned (Fitzpatrick skin types IV-VI), there is an increased risk of damaging epidermal melanin with solid and diode lasers.
By using a laser or light source with a longer wavelength, deeper penetration, and with less melanin absorption, such as 1064-nm light, less energy is absorbed by epidermal melanin and can be delivered to deeper dermal structures like the hair follicle. The objective of this study was to evaluate efficacy and safety of treating hirsutism in Fitzpatrick type IV-VI skin using The SLP ND YAG handpiece of XLase Plus Laser Platform (manufactured by Biotec Italia) wavelength 1064/532 nm with pulse duration range from 250 us to 50 ms with frequency 1-10 Hz. data was collected from twenty-nine patients with Fitzpatrick IV_VI. This included area treated, parameters and number of treatments and outcome. Data was also gathered on patient satisfaction and complications. The most treated area was face and under arm.
Patients and methods : This study included 15 patients with Fitzpatrick type IV–VI skin. The Device used was a 1064/532 nm SLP ND YAG handpiece (Biotec Italia, Vicenza). the treatment was repeated every 4 weeks for 3 months. The parameters were adjusted based on Skin type, hair color and hair thickness. Pulse duration 25ms was used in all treatments and the spot size was selected base on treatment area.
Quantification of treatment result was done by subjective assessment by the patient and doctor after last treatment. All subjects underwent a detailed interview to assess treatment result, treatment satisfaction, hair reduction, and any adverse effects from the treatment.
Results: A total of 15 case records were analyzed of which 10 were females and 5 were males. The mean fluence of the treatments ranged from 10 to 28 J/cm2 .the higher fluency was used for treatment of facial hair than non-facial hair . 82 % patient showed hair reduction in treated area. There were no adverse effects except 1 patient had dry skin who resolved problem by Applying hydrating cream. There were no long-term complications in patients.
Conclusion : SLP ND YAG handpiece are safe for unwanted hair removal in darker skin types even when higher fluence settings are used. The possibility of use of higher fluence settings with a low complication rate makes it efficacious for use in skin types IV–VI.

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09/01/2023

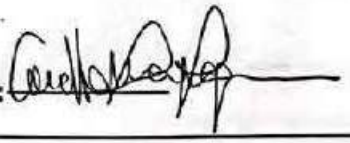
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Doctor and patients' evaluation scale: 0=no hair reduction, 1=mild hair reduction, 2=moderate hair reduction, and 3=complete hair reduction

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

Treatment area	Doctor score after 3 months	Patient score after 3 months	patient's satisfaction from treatment	Mean parameters using during3 treatments	Side effects
1.Face (upper lip and Jaw line)	2	3	2	Frequency =2Hz Spot size= 6 mm Fluence=14J/cm2 Fitzpatrick =VI	-
2.Face (upper lip and Jaw line)	3	3	3	Frequency =2Hz Spot size= 6 mm Fluence= 14 J/cm2 Fitzpatrick =VI	-
3.Face (upper lip and Jaw line)	3	3	3	Frequency =2Hz Spot size= 6 mm Fluence= 14 J/cm2 Fitzpatrick =VI	-
4.Face (upper lip and Jaw line)	2	1	3	Frequency =2Hz Spot size= 6 mm Fluence= 14 J/cm2 Fitzpatrick =VI	-
5.Legs	2	2	2	Frequency =2Hz Spot size= 6 mm Fluence= 14 J/cm2 Fitzpatrick =VI	-
6.Abdomen	3	2	2	Frequency =2Hz Spot size= 10 mm Fluence= 11 J/cm2 Fitzpatrick =V	-
7.Face (Chin and Jaw line)	3	2	2	Frequency =2Hz Spot size= 6 mm Fluence= 18 J/cm2 Fitzpatrick =V	-
8.Neck	3	2	4	Frequency =2Hz Spot size= 6 mm Fluence= 17 J/cm2 Fitzpatrick =V	-
9.Face (whole area)	3	3	3	Frequency =2Hz Spot size= 6 mm Fluence= 21J/cm2 Fitzpatrick =IV	-
10. Face (cheek area)	2	3	4	Frequency =2Hz Spot size= 6 mm Fluence= 14 J/cm2 Fitzpatrick =VI	Dry skin After applying hydration cream, we resolved problem
11. Abdomen	3	3	4	Frequency =2Hz Spot size= 10 mm Fluence= 11 J/cm2 Fitzpatrick =VI	-
12. Abdomen	3	3	4	Frequency =2Hz Spot size= 10 mm Fluence= 11 J/cm2 Fitzpatrick =VI	-
13. Face (upper lip and Jaw line)	2	2	3	Frequency =2Hz Spot size= 6 mm Fluence=24J/cm2 Fitzpatrick =IV	-
14. Face (upper lip and Jaw line)	3	3	4	Frequency =2Hz Spot size= 6 mm Fluence=24J/cm2 Fitzpatrick =IV	-
15. Legs	3	3	4	Frequency =2Hz Spot size= 6 mm Fluence= 14 J/cm2 Fitzpatrick =VI	-
	M=2.73	M=2.53	M=3.13		

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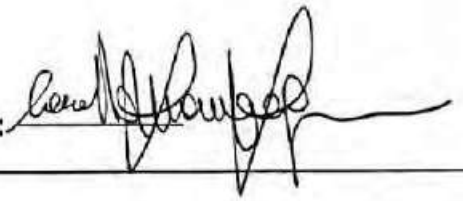
Abstract

SLP ND:YAG HANDPIECE'S EFFECT ON BENIGN PIGMENTED LESION

The wavelengths of the Nd:YAG laser(ND YAG SLP handpiece of xlase plus device, Biotec Italia) penetrate deeper into the dermis with great absorption by oxyhemoglobin and melanin making them useful for treating both epidermal and dermal benign pigmented lesion.
The aim of current study is to evaluate the efficacy and safety of a long-pulsed 1064/532 nm Nd:YAG laser in the treatment of benign pigmented lesion

Patients and methods :23 patients, clinically diagnosed with pigmented lesion, of skin type III–VI, were included in this study. They all received two treatment sessions, 3 weeks apart, using a long-pulsed 1064 nm Nd-YAG laser with a fluence ranging between 40 and 208 J/cm², 2.5 mm spot size, and two stacking pulses of 12 ms pulse duration. Patients were followed up at 1 and 4 months after the second session. Side effects and recurrence, if any, were reported. Clinical assessment was performed by doctor who were asked to determine the degree of improvement, which was graded using a five-point scale: −1=adverse effects (pigmentary changes, textural changes or scarring), 0=no improvement, 1=mild improvement, 2=moderate improvement, and 3=complete clearance. Patient self-assessment was also performed with the same scale.
Results: More than 82% improvement in the size and number of the treated lesions was reported by the patients and doctor, which was maintained until the end of the follow-up period at 4 months, with no side effects .
Conclusion :Long-pulsed Nd-YAG laser has proven to be a promising alternative safe treatment modality for benign pigmented lesion .

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06/10/2022

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Doctor and patients' evaluation scale: −1=adverse effects (pigmentary changes, textural changes or scarring), 0=no improvement, 1=mild improvement, 2=moderate improvement, and 3=complete clearance

n.	Doctor score after 1 month	Doctor score after 4 months	Patient score after 1month	Doctor score after 4 months
1	1	2	1	2
2	2	3	1	2
3	1	2	0	3
4	1	2	1	3
5	1	2	2	3
6	1	2	1	3
7	2	3	1	3
8	0	2	1	2
9	1	2	2	3
10	1	2	1	3
11	2	3	2	3
12	2	3	2	3
13	2	3	2	3
14	2	3	2	3
15	1	2	2	3
16	0	3	2	3
17	2	3	2	3
18	2	3	0	1
19	2	3	1	2
20	1	2	1	2
21	0	2	2	2
22	1	2	2	2
23	1	2	2	2
	M=1.26	M=2.43	M=1.43	M=2.56

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Use of short Long Pulse Nd:YAG 1064nm Laser for Treatment of vascular Lesions

Background: 1064 nm short -long-pulsed Nd:YAG laser has been proven to be effective for the treatment of Vascular Lesions because of its deep penetration into the skin and homogenous heating of large vessel walls.

Objective: The aim of this study was to evaluate the efficiency of SLP ND YAG handpiece for treating various vascular disorders such as port wine stain, hemangioma, telangiectasia and leg veins , angioma rubino and spider nevus . In this study, it is evaluated the clinical efficacy, side effects, and subjective satisfaction of patients after SLP Nd:YAG Handpiece 's treatment for diverse vascular disorders.

Methods: 26 patients with Different cutaneous vascular disorders were treated in current study.

The Fitzpatrick of patients presents in current study were II_IV. Patients with a history of deep vein thrombosis, connective tissue disease, keloids, immunosuppression, or who were pregnant or lactating were excluded from study. All patients underwent a single treatment session using a SLP Nd:YAG handpiece from XLase Plus Device manufactured by Biotec Italia. . To treat vessels with a diameter of <0.5 mm , the following treatment parameters were used: 12.0 ms pulse width and 61-81 J/cm2of fluence using a 2.5 mm spot. Larger dilated vessels with a diameter of 0.5-1 mm were treated with a pulse width of 15.0 ms and 64_80 J/cm2 using a 4 mm spot. vessels with a diameter of >1 mm were treated with a pulse width of 18.0 ms and 56-96 J/cm2 using a 6 mm spot.

When the vessel was treated with the SLP ND YAG handpiece, the immediate vessel response was carefully observed. If the vessel disappeared immediately, the next laser shot was applied at the point where the vanishing point stopped. If the vessel did not show any response after the first shot, the fluence was raised to next step.

The doctor using physician Global Assessment (PGA) of pretreatment and posttreatment after 1 month after the last treatment. Improvement was assessed on a scale from 1to 4 (1 = no improvement, 2 = moderate, 3 = good, 4 = excellent). Also, patients were asked to rate their satisfaction with the cosmetic results (1 = not satisfied, 2 = a little satisfied, 3 = somewhat satisfied, 4 = satisfied, 5 = very satisfied). Side effects after treatment were also assessed.

Results: All 26 patients (mean age 36.38 years, range 27-50 years old) were treated 1 session with SLP ND YAG handpiece from Xlase Plus Device manufactured by Biotec Italia. Eleven patients showed excellent improvement, Fifteen Patients showed good improvement.in some patient.

In some patients, it is observed erythema that disappeared after 2 days.

Conclusion: This current study shows efficiency and safety of SLP ND YAG Hand piece of XLase Plus used for different vascular disorders.

Novembre 2022

Dott. Domenico Pugliese



Doctor evaluation: 1 = no improvement, 2 = moderate, 3 = good, 4 = excellent.

Patient's satisfaction: 1 = not satisfied, 2 = little satisfied, 3 = somewhat satisfied, 4 = satisfied, 5 = very satisfied

Patient information		Vascular disorders	Doctor 's evaluation	Patients' satisfaction	Side effects	Recommended us to others	Continue with treatment
Sex	Age						
M	27	Port wein stein	3	3	-	Yes	Yes
M	27	Facial Telangiectasia	3	4	-	Yes	Yes
F	35	Angioma	4	3	-	Yes	Yes
M	36	Angioma	3	3	Erythema	Yes	Yes
F	32	Angioma	4	5	Redness	Yes	Yes
F	28	Angioma	4	3	-	Yes	Yes
F	29	Port wein stein	4	2	-	Yes	Yes
F	30	Port wein stein	4	5	Erythema	Yes	Yes
F	50	Facial Telangiectasia	3	4	-	Yes	Yes
F	45	Facial Telangiectasia	3	4	-	Yes	Yes
F	49	Facial Telangiectasia	3	4	-	Yes	Yes
M	48	Facial Telangiectasia	3	3	-	Yes	Yes
M	44	Facial Telangiectasia	3	4	-	Yes	Yes
F	32	Facial Telangiectasia	3	3	-	Yes	Yes
M	35	Facial Telangiectasia	3	5	-	Yes	Yes
M	39	Facial Telangiectasia	3	3	-	Yes	Yes
F	27	Hemangioma	4	4	-	Yes	Yes
M	29	Hemangioma	4	3	-	Yes	Yes
F	30	Hemangioma	4	4	Erythema	Yes	Yes
F	35	Port wein stein	4	3	Erythema	Yes	Yes
F	34	Angioma	4	3	Erythema	Yes	Yes
F	38	Angioma	4	4	-	Yes	Yes
M	40	Facial Telangiectasia, Rosacea	3	5	-	Yes	Yes
M	41	Facial Telangiectasia, Rosacea	3	4	-	Yes	Yes



M	42	**Facial Telangiectasia, Rosacea**	**3**	**4**	**Erythema**	**Yes**	**Yes**
M	44	**Facial Telangiectasia, Rosacea**	**3**	**4**	**Erythema**	**Yes**	**Yes**
	Mean:36.38						



