xlase PLUS

DOSSIER ETUDES CLINIQUES

1370

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

Dott. Luanna Leggieri **Date: 10/09/2022** **Signature:**

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

Dott. Luanna Leggieri **Date: 10/09/2022** **Signature:**

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	

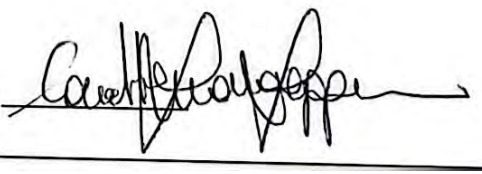
Dott. Luanna Leggieri **Date: 10/09/2022** **Signature:**

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.

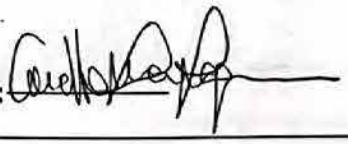
Dott.Luanna Leggieri _____
09/01/2023

Dott. Luanna Leggieri **Date: 09/01/2023** **Signature:** 

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		

Dott. Luanna Leggieri **Date: 09/01/2023** **Signature:** 

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 .

Dott.Luanna Leggieri _____
06/10/2022

Dott. Luanna Leggieri **Date: 06/10/2022** **Signature:**

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

Dott. Luanna Leggieri **Date: 06/10/2022** **Signature:**

February 2023

VIVASKIN BY ANTONIO VIRZI'

XLASE - ALEXPRO

Epilation on subjects of phototype lii with dark brown hair Background

The demand for epilation of large areas of the body is constantly growing, but the technologies used to date have shown some limitations, due in many cases to the excessive time required to achieve definitive results, safety and tolerability, and the difficulty of treating different phototypes.

In the face of this development in Aesthetic Medicine, the biggest application limitation remains being able to universalize treatment to different phototypes, for different hair types and textures without causing skin damage. For this reason, the use of the latest technologies may prove decisive.

Goals

To show how through the use of dual-wavelength laser technology with cooled optics and repeated laser pulses up to a frequency of 10 pulses per second, rapid and successful results were achieved in reducing hair growth.

Evaluate four months after completion of the treatment protocol the treatment efficiency and patient satisfaction with Likert scale questionnaire {5-point scale, 1 Not Satisfied at all 5, Extremely Satisfied).

In addition, the tolerability of the treatment was assessed by Vas scale questionnaire (How painful do you rate the treatment? From 1 to 5 where: 1- No pain; 2- Very mild pain; 3- Mild pain; 4- Severe pain; 5- Very severe pain).

Materials and Methods

The technology used was Biotec Italia's Xlase Plus platform with AlexPro handpiece, dual wavelength 760/808nm diode, which allows the emission of a single wavelength or both at the same time, dosing to the desired percentage of each in relation to the patient's phototype and hair characteristics (color and texture).

A homogeneous cohort of 20 female patients, aged 25-35 years, with phototype lii classified according to the Fitzpatrick scale and dark brown hair color and medium texture was recruited.

Patients who were pregnant, lactating and being treated with photosensitizing drugs were excluded from the study.

The body areas treated were thigh and leg.

Each patient underwent a protocol of 5 epilation sessions, at intervals of 4 weeks apart, with fluences between 9 and 17 J/Cm 2 for the 808 nm wavelength and between 7 and 12 J/Cm 2 for the 760nm wavelength.

The procedure used was "motion speed," with an emission frequency of l0Hz.

All patients were asked to shave 24 hours before the treatment. Before starting the hair removal treatment, the skin was cleansed with "Oxyclear cleansing Mousse" from the Rejuve line and then "Oxylaser" also from the Rejuve line was applied to the area to be treated.

Tattoos, nevi, and spots were covered.

After each treatment, patients were applied soothing balm "Skin Rehab" and cream with protection factor "SF Face Block 50" by Rejuve.

The safety of the procedure was monitored during the study.

All patients completed and signed informed consent before treatment.

The study was performed at the aesthetic medicine clinic "Vivaskin" in Catania, Italy.

Results

The study demonstrated a 98 percent reduction in hair growth four months after the protocol was completed.

100% of patients were Extremely Satisfied d'zl result obtained at Four months since the last session.
100% of patients of patients would like to treat other areas and would recommend the treatment.
No adverse events occurred and the treatment was well taJlerated by 100% of patients.

Conclusions
AlexPro hair removal treatment for permanent hair growth reduction was well tolerated and proved effective, with highest level of satisfaction, in all patients.

Dr. Antonino Virzi
O.d.M. 5573
P. I. 00431830827

Initials Pz	Age	Sex	Likert at 4 months	SEA scale	Do you recommend the treatment?	Would you treat other areas?
A.V.	27	F	5	1	yes	yes
F.L.	31	F	5	1	yes	yes
G.L.	26	F	5	1	yes	yes
M.E.	25	F	5	1	yes	yes
G.L.	30	F	5	1	yes	yes
G.E.	29	F	5	2	yes	yes
BC.	25	F	5	1	yes	yes
BC.	25	F	5	2	yes	yes
D.M	28	F	5	1	yes	yes
F.M.	29	F	5	1	yes	yes
B.M.	27	F	5	1	yes	yes
G.T.	27	F	5	1	ye	yes

					s	
G.A.	30	F	5	2	y e s	yes
G.G.	30	F	5	1	y e s	yes
R.M.	25	F	5	1	y e s	yes
V.P.	25	F	5	1	y e s	yes
L.G.	27	F	5	1	y e s	yes
L.C.	28	F	5	2	y e s	yes
P.M.	25	F	5	1	y e s	yes
M.S.	35	F	5	1	y e s	yes
media			5	1,2		

LIKERT QUESTIONNAIRE: How satisfied are you with the result? From 1 to 5 where:
1- very dissatisfied; 2- insodd dissatisfied; 3-neither dissatisfied nor satisfied; 4- satisfied; 5- very satisfied

SEA SCALE: How painful do you rate the treatment? From 1 to 5 where: 1- No pain; 2- Very mild pain; 3- Mild pain; 4- Severe pain; 5- Very severe pain

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XLASE PL US - LPG

Background
Pulsed light is also used to rejuvenate v so tissues. Data about the efficacy and safety of this procedure on oazienli with phototypes I ll and IV are insufficient.

Goals
Following a protocol of 6 sessions with CPL pulsed Iuce whose facial tissues to evaluate the safety of the method and the results obtained using the GAIS scale (Global Aesthetic Improvement Scale where 1=very noticeable improvement 2'moderate improvement 3'mild migliation 4-no improvement 5=worsening) dooo the fourth and seska treatment sessions. To assess the maintenance of the risul'tate, the GAIS scale was exploited at two months after the last session. To assess whether there are differences between the results obtained according to phototype

Materials and Methods
A cohort of 20 patients (100% women) with a mean etò of 40.4 years (etò comDresa between 38 years and 64 years) with a medium to severe degree of aging, and phototiDo I II and IV was recruited for this study. Excluded from the study were p atients who were pregnant or lactating. with ongoing Datolog ie cutan ee, with neurological and autoimmune diseases, in teraoia cortisone, collagenopathies, and taking photosens b zzan medication
Patients were subdued toa treatment protocol of six sessions with pulsed Iuce every three weeks (ores so Egidi Sara's S.M. center in Palombara Sabina IT with XLASE PLUS technology by Biotec Italia srl) using the CPL handpiece (calibrated pulsed Iuce1. No anesthetic cream was a oplicated.
pre-treatment. The skin before sed uta was cleansed with Spray Mist Cleanser, and a generous layer of Oxylaser Conjuctive Gel (Aqua. Carbomer. Sodium Hyaluronate, Sod ium H ydroxide, Imid azolidinyl Urea, Disodium EDTA, Methylch loroisothiazolinone. Methylch loroisothiazolinone) is both to aDplicated on the treatment area. Moles, dark lesions, and tattoo aggi were co oert.
The parameters suggested by Br otec Italia related to the Volumetrie Toning program i oendon o from the patient's phototype. II phototioo I II be treated with Filter 550-1200, Fluence 1 2J/cm2, IMDulse Duration 2ms, Pulse Train 15, Delay 30ms. II type IV photo is treated with' Filter 695-1 200 luency 1 2J/cm 2 Duration Pulse 2ms, Pulse Train 15. Delay 35ms.
The treatment technique, according to the corporate ali guidelines. pre sees to keep the handpiece perpendicular to the skin super ficie. with the guide glass in contact with the skin. Areas of the face such as the frontal and periocular areas were treated a oplicand or on the guide glass of mini -soot adapters of square and rectangular shape. The area was evenly treated with multiple passes until homogeneous heating and mild erite ma were achieved. II posi-treatment involves the application of soothing Skin 'ehab crerra and so a e protection.
The safety of the procedure was monitored during the study.

Results
The study showed significant improvements in reducing facial wrinkles. improving lexuti firmness. Dooo 4 sedulas of lrattement, the mean GAIS score is 2.8 After G sessions of treatment. the mean GAIS score is 2.05 At* the fourth sed uta only 15% of the oatients had no improvement isi known count are patients o\ er 60 years). At the sixth session no patient reported a GAIS score ùi 4 or higher. Forty-five percent of the patients had oropressive improvement in the two months following completion of the protocol (GAIS score meiiO .s 0 Two months after the end of the orotocollo, no differences in mean suore GAIS were recorded among the group of patients with phototioo I II or IV. Only one patient recorded a GAIS store 4 one month after treatment. and the same a GAIS suore 2 eight weeks later. Twenty-five percent of patients reported an improved outcome at 8 weeks after treatment, compared with the pia positi o obtained at 4 weeks after treatment. No patients at two months after treatment had a GAIS score of 4 or 5 (laughably, no improvement and worsening).
No undesirable effects were detected, while a transient IepSero erythema (for more than 24 oren was detected in 5% of cases (1 oazientj.

Conclusions
Volumetrie Toning treatment of the face with PL pulsed light in patients with phototioo I II and IV is an effective and safe procedure. And a protocol that has been steto well tolerated and showed improvement in 100% of treated patients.

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DOCTOR ESTE/I "ICO
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Patient initials	Age	Sex	Phototype	GAIS at 4 session	GAIS at 6 session	GAIS at 2 months	
D.I.	38	F	Iii	2	2	2	100%WOMEN.
R.S.	43	F	Iii	3	2	1	
P.G.	42	F	Iii	3	2	1	
F.G.	49	F	Iii	3	2	2	
S.S.	62	F	Iii	4	2	1	
A.B.	39	F	Iii	3	2	1	
CE.	44	F	Iii	3	2	2	
H.S.	56	F	Iii	3	2	2	
L.L.	45	F	Iii	2	2	2	1.6 average Iii
L.U.	59	F	Iii	3	3	2	
T.G.	58	F	IV	3	2	2	1.6 average IV
R.C.	47	F	IV	2	2	1	
F.M.	45	F	IV	2	1	1	
S.T.	64	F	IV	4	3	2	
R.L.	55	F	IV	3	2	2	
P.I.	41	F	IV	2	2	2	
D.P.	44	F	IV	2	2	2	
I.L.	61	F	IV	4	2	1	
A.I.	57	F	IV	3	2	1	
E.F.	39	F	IV	2	2	2	
media	49,4			2,8	2,05	1.6	

GAIS SCALE: How do you rate the improvement? 1 to 5 where:
1 - very noticeable improvement: 2 - moderate improvement; 3 - slight improvement; 4 - no improvement; 5 - worsening

December 2022 Dr. Egidi

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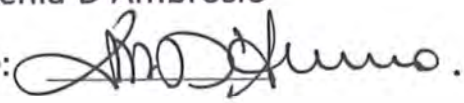
The Efficacy of 810 nm Diode Laser ALEX PRO with Xlase Plus Plattform in Reducing Hirsutism

Doctor Ylenia D'Ambrosio

Signature: 

Introduction

Hirsutism, characterized by excessive hair growth in areas where men typically grow hair (such as the face, chest, and back), can cause significant distress, especially in women. This condition is often driven by hormonal imbalances, including elevated androgens.. This white paper explores the efficacy, safety, and patient satisfaction of ALEX PRO 4000 W 810 nm diode laser treatment for hirsutism in 25 women aged 18 and above..

Mechanism of Action

The Alex Pro 810 nm from Xlase Plus platform diode laser selectively targets melanin in hair follicles. The laser energy is absorbed by the pigment in the hair shaft, which converts light into heat. This heat destroys the hair follicle without damaging surrounding tissue, resulting in long-term hair reduction. The 810 nm wavelength is particularly effective for treating medium to dark skin tones and coarse hair, making it an ideal choice for reducing excessive hair growth in women with hirsutism.

Methodology

This study was conducted with 25 women aged 18 and above, who were diagnosed with moderate to severe hirsutism. All participants underwent 6 laser treatment sessions over a span of 3 months.

Treatment Protocol

- **Session Frequency**: Participants received treatments once every 3-4 weeks.
- **Laser Parameters:** Energy settings were adjusted based on skin type and hair color for each participant. Pulse durations ranged from 10 to 50 ms, and the fluence (energy per unit area) ranged between 10 and 40 J/cm² and frequenzy from 1-10 Hz.
- **Cooling Mechanism:** A contact cooling system was used during the laser treatment to minimize discomfort and reduce the risk of skin damage.

The Efficacy of 810 nm Diode Laser ALEX PRO with Xlase Plus Plattform in Reducing Hirsutism

Data Collection

- **Hair Reduction Percentage:** Hair counts were measured in the treatment areas before the first session, after the final session, and at the 12-week post-treatment follow-up.
- **Patient Satisfaction:** Participants completed satisfaction surveys to rate their overall experience, comfort level, and perceived improvement.
- **Skin Tolerance and Side Effects:** Participants were monitored for side effects such as erythema (redness), swelling, hyperpigmentation, and burns. Any adverse reactions were recorded.

Participant Profile

Age: 18 years and older

Gender: Female (n = 25)

Skin Type: Fitzpatrick skin types II to IV (fair to medium-dark)

Hair Color: Dark and coarse hair, which is typical in women with hirsutism.

Health Status: All participants were free of any contraindications to laser therapy, such as active skin infections, recent sun exposure, or photosensitive medications.

Results

Hair Reduction

- **Percentage Hair Reduction**: On average, participants experienced a 60-75% reduction in hair density after the final session. At the 12-week follow-up, 80-90% of hair reduction was maintained, indicating long-term efficacy.
- **Hair Regrowth**: In areas treated with the Alex Pro 810 nm diode laser, the regrowth was significantly finer and lighter in color. Complete hair regrowth was prevented in most cases.

The Efficacy of 810 nm Diode Laser ALEX PRO with Xlase Plus Plattform in Reducing Hirsutism

Skin Tolerance and Side Effects

- **Minimal Side Effects**: Mild side effects such as temporary redness and swelling were reported in 5% of participants, but these resolved within a few hours to a day. One participant experienced mild hyperpigmentation. which resolved after 2 weeks.
- **No Major Adverse Effects**: No major complications such as blistering or scarring were observed. The contact cooling system helped in minimizing discomfort and protecting the skin during treatments.

Participant Satisfaction

- **High Satisfaction**: 90% of participants were satisfied with the results, reporting significant reduction in unwanted hair and improvement in self-esteem.
- **Comfort**: The majority of participants reported mild discomfort during the treatment, but rated the procedure as tolerable. The cooling system was especially appreciated for reducing pain.

Conclusion

The Alex Pro 810 nm diode laser is an effective, safe, and well-tolerated treatment for hirsutism in women. In this study, participants experienced significant and long-lasting hair reduction, with minimal side effects and high levels of satisfaction. This treatment offers a non-invasive, reliable solution for women seeking to manage excessive hair growth caused by hirsutism.

Data Summary

Measure	Baseline	After Treatment	12-Week Follow-Up
Hair Reduction (%)	-	60-75%	80-90%
Adverse Effects (%)	-	5% (mild)	0%
Skin Reaction (Redness, Swelling)	-	5%	-
Participant Satisfaction (%)	-	90%	-
Measure	Baseline	After Treatment	12-Week Follow-Up

Doctor Ylenia D'Ambrosio

Signature:

The treatment of pigmented and vascular lesions CPL

(Calibrated PulsedLight)

Dr.Arianna Facchini

Date 01/18/2023

signature

Device :

Xlase Plus Laser Plattform With CPL (Calibrated Pulsed Light) handpiece

Manfactured by Biotec Italia

CPL

(Calibrated PulsedLight)

CPL Handpiece Mechanism Of Action

CPL (Calibrated Pulsed Light) works on the principle of selective absorption of energy by components of the hair follicle. The target chromophore is melanin in the hair bulb and outer root sheath zones of the hair follicle, while the competing chromophores are any other melanin-containing components of the skin and other light-absorbing components such as hemoglobin in blood vessel. Because of the wide range of wavelengths and pulse durations, CPL has effect on both superficial and deep pigmented and vascular lesions. The system operates by selective photo thermolysis. It supplies sufficient energy in order to raise the temperature of the blood vessel to induce coagulation without causing damage to the healthy tissue that surrounds it.

Parameters and specification Of CPL Handpiece

Many factors influence the efficacy of CPL handpiece such as spot size, divergence/convergence of the beam and wavelength that determines the depth of penetration, pulse duration, fluence and the adjacent cooling system. The amount of energy absorbed by the target and surrounding tissue is measured by fluence (J/cm2) and can be delivered in pulses.

	Specification of CPL handpiece
Frequency Hz	1-3 Hz
Fluence J/CM2	Up to 36 J/CM2
Wave length (cutt of filters) nm	410-1200 nm 550-1200 nm 550-950 nm 650-950 nm 595-1200 nm 755-1200 nm
Pulse Duration	1-50 ms
Spot size	10X50 mm
Cooling methode	Sapphire cooling

Material and Methods

This study was designed to show the efficiency of CPL handpiece for treatment of benign pigmented and vascular Lesion .30 patients, with ages ranging from 25 to 57 years and with Fitzpatrick skin types ranging between II and IV participated in this study. These patients had no history of dermatological disorders such as photosensitivity or inflammatory, pre-malignant or malignant skin diseases. 18 vascular lesions and 12 pigmented lesions were located on the different area of face and body. All subjects underwent 5 CPL treatments at 4 weeks intervals. Collecting data was done 6 months after the last session. The parameters were adjusted base on skin Fitzpatrick and type of lesion a depth of lesion. The fluence was used in range of 8-11J/cm2 with a pulse duration of 4-10 ms. According to the skin type, a single pulse was used as a test. If there was no erythema or burning sensation or hyperpigmentation of the stains within 2 h, a suitable treatment protocol was selected. Clinical assessment was carried out before starting the treatment and 6 months after the last session. The choice of cut-off filters did not change for treating lesions with both vascular

and pigmented components, whereas in the cases of pigmented lesions only, a 550 nm cut-off filter was selected for patients with Fitzpatrick skin types II-III, and a 650 nm cut-off filter was preferred for patients with skin type IV. The results assessed with clinical observations immediately after 6 months after last session. Doctor divided the results into four categories:0- no results, 1-slight improvement ,2-moderate improvement and 3-marked improvement. Also, patient self-assessment was documented.

Results

In our study, a total of 30 subjects (28 women and 2 men) completed the treatments. The results assessed with clinical observations immediately after 6 months after last session. There was no adverse effect. All patients were satisfied from treatments and wanted to continue with the treatment. More than 70 % achieved the complete improvements after 6 months.

Conclusion

From the data we conclude that The CPL are effective for numerous therapeutic options in the field of cutaneous conditions. This study confirms that CPL is effective for pigmented and vascular Lesion both. It is also evaluated patient satisfaction at 6 months after CPL treatment and all patients were completely satisfied from treatment and they showed willing to continue with CPL.

Tabel

Tabe 1

Phsician valuation 0- no results, 1-slight improvement ,2-moderate improvement and 3-marked improvement

Type of lesion	Skin type	Valuation score At 6 month	Side effects
Vascular	III	2	No
Pigmented	II	3	No
Pigmented	IV	3	No
Pigmented	III	3	No
Vascular	IV	3	No
Vascular	IV	3	No
Vascular	IV	2	No
Pigmented	IV	3	No
Pigmented	III	3	No
Pigmented	III	3	No
Pigmented	II	2	No
Vascular	III	2	No
Vascular	II	2	No
Vascular	III	2	No
Vascular	II	2	No
Vascular	II	2	No
Vascular	II	3	No
Vascular	II	3	No
Vascular	II	3	No
Vascular	III	3	No
Vascular	III	3	No
Vascular	IV	3	No
Pigmented	III	3	No
Pigmented	IV	3	No
Vascular	IV	3	No
Vascular	III	3	No
Vascular	III	3	No
Pigmented	III	3	No
Pigmented	IV	3	No
Pigmented	IV	3	No
		M=2.73	

Tabe 2

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

Type of lesion	Skin type	Valuation score At 6 month	Do you continue the treatment ?
Vascular	III	2	Yes
Pigmented	II	2	Yes
Pigmented	IV	3	Yes
Pigmented	III	3	Yes
Vascular	IV	3	Yes
Vascular	IV	2	Yes
Vascular	IV	2	Yes
Pigmented	IV	3	Yes
Pigmented	III	2	Yes
Pigmented	III	3	Yes
Pigmented	II	3	Yes
Vascular	III	3	Yes
Vascular	II	3	Yes
Vascular	III	3	Yes
Vascular	II	3	Yes
Vascular	II	3	Yes
Vascular	II	3	Yes
Vascular	II	3	Yes
Vascular	II	3	Yes
Vascular	III	2	Yes
Vascular	III	2	Yes
Vascular	IV	2	Yes
Pigmented	III	2	Yes
Pigmented	IV	3	Yes
Vascular	IV	3	Yes
Vascular	III	3	Yes
Vascular	III	3	Yes
Pigmented	III	3	Yes
Pigmented	IV	3	Yes
Pigmented	IV	3	Yes
		M=2.70	

Effect of Alex Pro Diode dual Wave length (760/810nm) handpiece on treatment of hirsutism

Background: Hirsutism is a common disorder in women. Hirsutism is usually the result of an underlying endocrine imbalance, which may be adrenal, ovarian, or central. It can be caused by increased levels of androgen hormones.

Objective: The aim of this study was to evaluate the effects and efficiency of the Alex pro handpiece XLASE Plus device Manufactured by Biotec Italia on Hirsutism treatment .it is evaluated the degree of discomfort, satisfaction experienced by patients after Hirsutism treatment.

Methods: Thirty-one hirsute women above 18 years were treated 3 sessions with 2 months of intervals with the handpiece Alex pro from XLASE Plus device. Endpoints were reduction in hair regrowth counts assessed by Patients' satisfaction in 6 months after final treatment. Patients evaluated reduction in hair regrowth, satisfaction, treatment-related pain and adverse effects.

The Fitzpatrick of patients presents in current study were II_IV. Treatment areas included: face, neck, axilla, upper and lower limbs, suprapubic, and bikini line. Patients excluded were those who were lactating or pregnant, having skin injuries in the area to be treated, had used other hair removal methods within the last 6 months, history of photosensitivity, or on any photosensitive drugs.

Chilled gel was applied to allow easy movement of the handpiece and topical cooling of the epidermis.

Treatments parameters included fluency was up to 60 J/cm2, and pulse repetition rate of 10 Hz. parameters were set according to the skin type, color, site, density, and thickness of the hair.

Treatment technique was motion speed where handpiece kept in full contact with the skin and moved continuously over the entire treatment area until the endpoint (a little redness in the area) was reached.

Hair reduction was assessed using the physician GAIS (global esthetic improvement scale) score: 0_ no results reduction, 1_poor reduction, 2_average reduction ,3_good reduction and 4_excellent reduction.

Results: All 31 patients (mean age 32 years, range 18-50 years old) completed all three sessions of the study**.** The satisfaction of patient showed significant improvements 6 month after treatment.

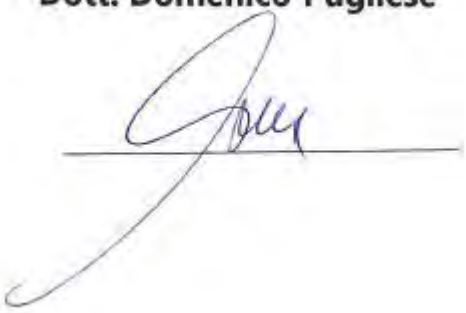
For most patient the treatment was painless, they felt the heat during the treatments.

No serious adverse effects were observed during this study.

Conclusion: This current study shows that Alex Pro Dual wavelength (760, 810) Hand piece of XLase Plus used for hirsutism treatment is effective and safe to use in patients with skin types from II to IV for facial and body hair. Another effective feature of Xlase Plus is its usage of motion speed technique of the hand piece to provide high frequencies and short pulses resulting in gradual heating of the dermis to reduce hair growth and cause minimal damage to skin and less pain.

FEBRUARY 2023

Dott. Domenico Pugliese



Patient score after 2 and 6 months

0_ no results reduction, 1_poor reduction, 2_average reduction ,3_good reduction and 4_excellent reduction.

Patient satisfaction score		The treatments was painful	Any adverse effects	Recommended Alex Pro to others	Continue with Alex Pro
After 2 months	After 6 months				
1	3	No	No	Yes	Yes
2	3	No	No	Yes	Yes
2	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
2	4	No	Yes, after first treatment redness last for 3 hours	Yes	Yes
3	4	No	No	Yes	Yes
2	3	No	No	Yes	Yes
1	3	No	No	Yes	Yes
2	3	No	No	Yes	Yes
3	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
2	4	No	No	Yes	Yes
1	3	No	No	Yes	Yes
0	3	No	No	Yes	Yes
2	3	No	No	Yes	Yes
2	4	No	No	Yes	Yes
2	3	No	No	Yes	Yes
3	4	No	No	Yes	Yes
2	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
2	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
2	4	No	No	Yes	Yes
2	3	No	No	Yes	Yes
3	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
3	4	No	No	Yes	Yes
Media =2.29	**Media =3.67**	**100%**		100%	100%

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

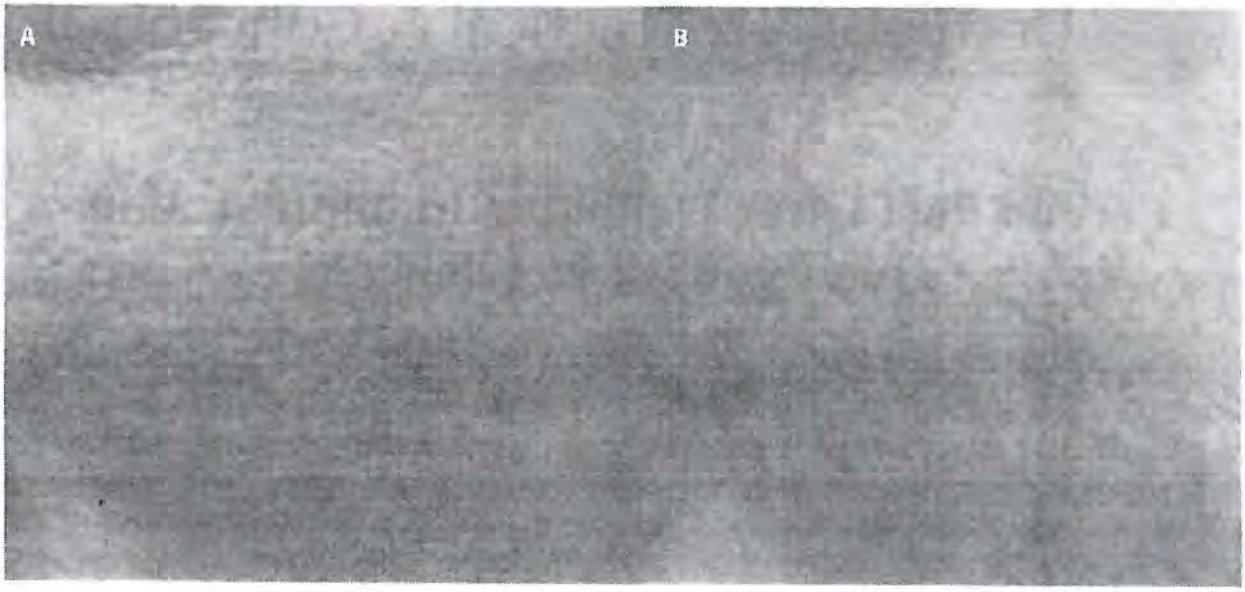

Figure 1. Clinical pictures of a 42-year-old woman (A) before and (B) after treatment with carbon peel laser.

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.

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Dermatology Practical & Conceptual

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

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Key words: acne, laser, erbium:YAG, active 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

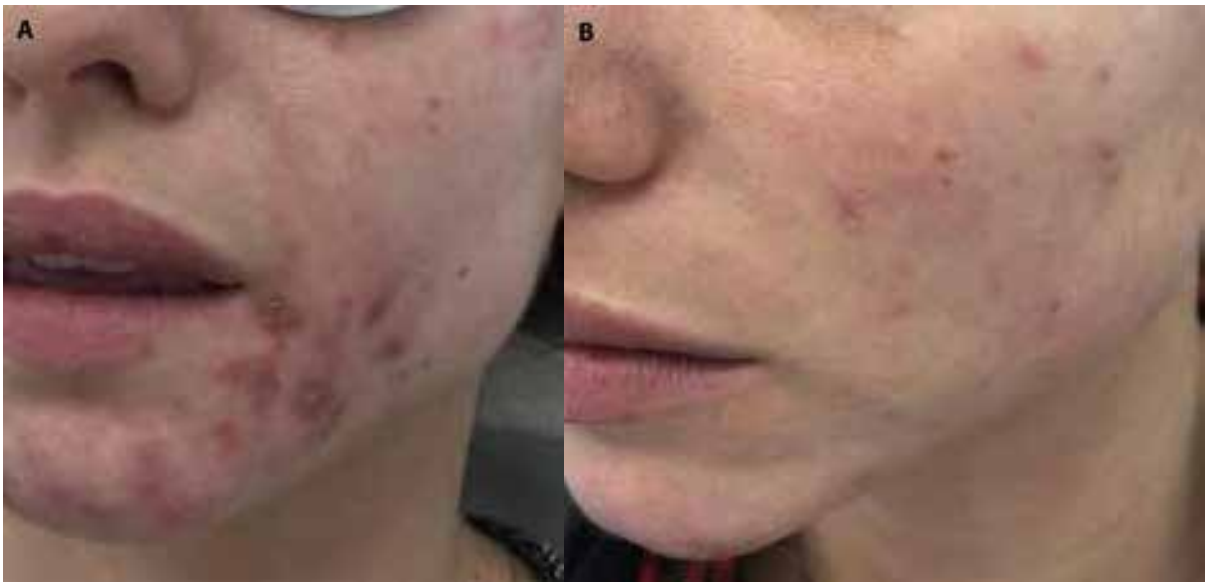

Figure 1. Clinical pictures of a 34-year-old woman. (A) Before the last erbium:YAG laser session. (B) 3 months after the last erbium:YAG laser session, showing the reduction of active acne lesions.

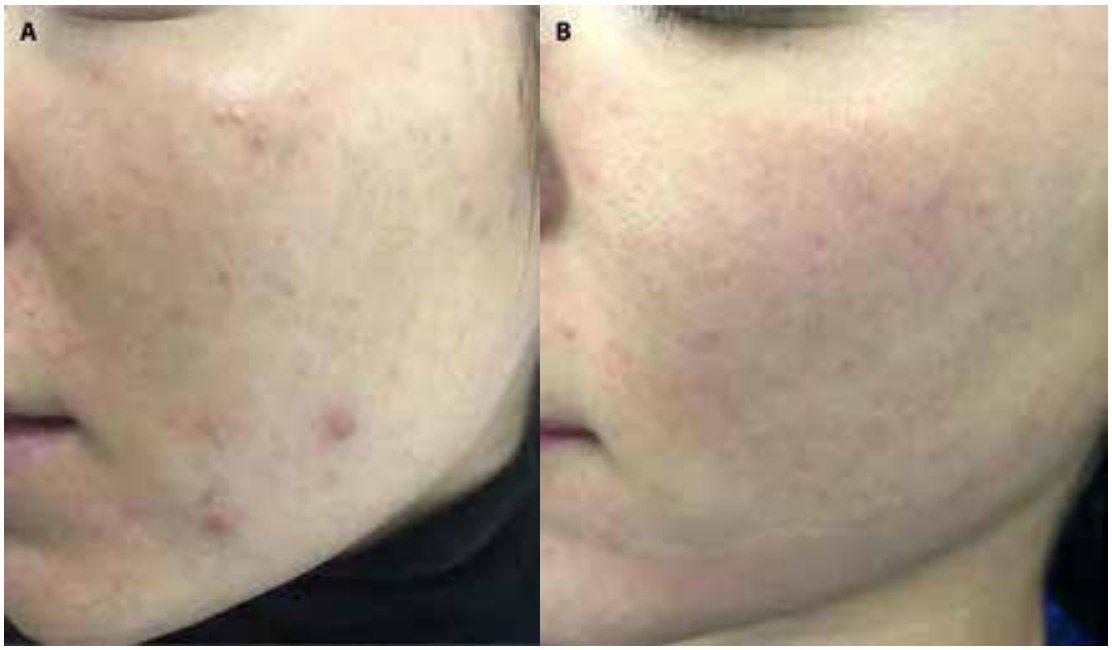

Figure 2. Clinical pictures of a 25-year-old woman. (A) Before the last erbium:YAG laser session. (B) 3 months after the last erbium:YAG laser session, highlighting a consistent reduction of both inflammatory and noninflammatory acne skin lesions.

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.

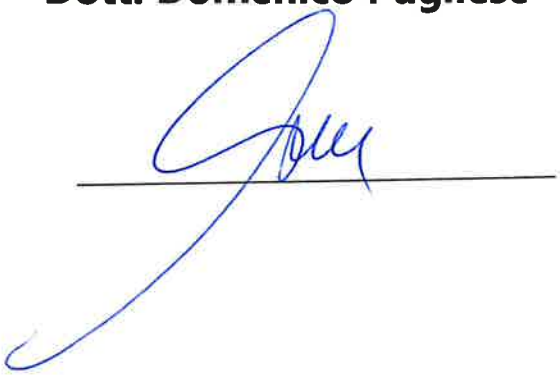
The laser used was Xlase Plus system manufactured by Biotec Italia ER: yag 2940 nm handpiece. The fractional window of the laser handpiece was 9 mm×9mm, supporting 81 microbeams. The system has Four programmes for treatment pulse width: superficial (0.5 ms pulse width), superficial (1 ms) and Medium (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			

XLase Plus
Sapphire Cooling specification

Study conducted by Sheyda Mavisat (Bioengineer) in collaboration with Dr. Vincenzo Bucaria

9th December 2022

Dr. Vincenzo Bucaria

Eng. Sheyda Mavisat

Introduction

The most laser systems have Sapphire Skin cooling. Sapphire Skin cooling can be used to reduce epidermal thermal discomfort in laser procedures (such as hair removal) where the target structures are located up to several millimetres below the skin surface.

Purpose

The purpose of this document is to report and analyze XLase Plus diode and CPL Sapphire Skin cooling and to demonstrate safety of the XLase Plus diode and CPL handpiece cooling system.

1. Sapphire cooling Description

Among solids contact cooling, sapphire is nearly ideal for Skin cooling. Sapphire is transparent in the 0.2–5 m wavelength range, has a high optical damage threshold, and is close to metal with respect to its thermal conductivity. Sapphire cooling assures reliable and constant cooling result for skin surface with maximum comfort and safety. Ref 1

1.1 Principles of Operation

Sapphire cooling arrangement is illustrated in Fig.1. XLase Plus diode and cpl handpieces sapphire cooling System lowers the epidermal temperature through contact of handpiece with its actively cooled sapphire window.

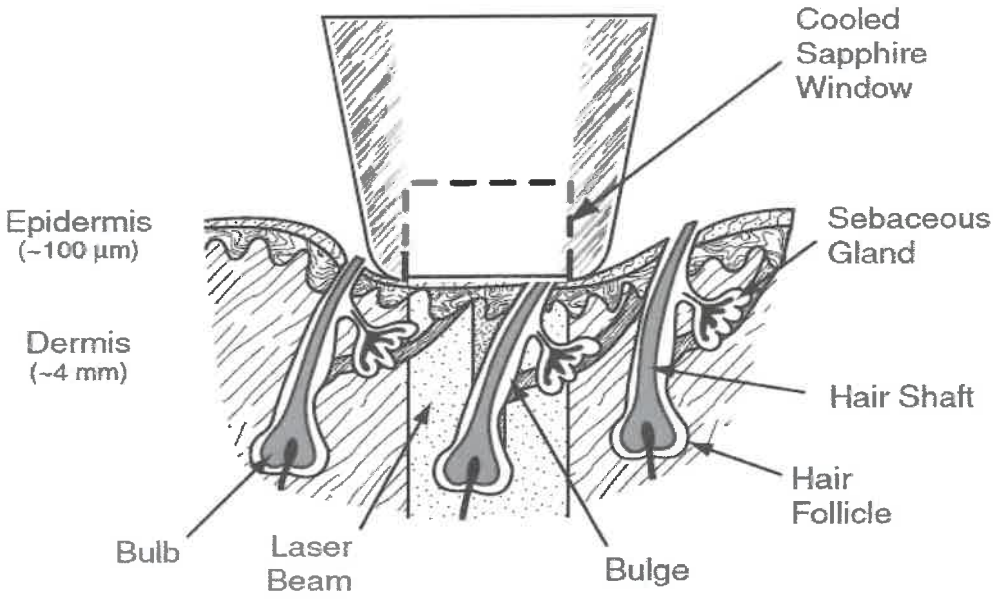


Fig.1

1.2 Handpieces sapphire cooling specs

Subject device			Predicate device		
XLase Plus			Elyson Pro K193367		
Handpiece	**Cooling specs**		**Handpiece**	**Cooling specs**	
Diode 808/760nm AlexPro	***method***	***Temperature***	Elyson diode	***method***	***Temperature***
	Sapphire cooling	5°c		Sapphire cooling	5°c
XLase Plus			**Lightsheer Duet**		
Diode 1200 w 810 nm	***method***	***Temperature***	Lightsheer ET	***method***	***Temperature***
	Sapphire cooling	5°c		Sapphire cooling	5°c Ref 2,3,4
Diode 2800 w 810 nm	***method***	***Temperature***	Lightsheer HS	***method***	***Temperature***
	Sapphire cooling	5°c		—	—
XLase Plus			**Deka Luxea**		
Cpl Calibrated Pulse Light	***method***	***Temperature***	LiLac Pulsed Light handpiece	***method***	***Temperature***
	Sapphire cooling - integrated-provided via the handpiece light guide	15°-25°c		Sapphire cooling - integrated-provided via the handpiece light guide	15°-25°c

VR

2.Skin response to the sapphire cooling

2.1 Methods

A sapphire window is at the tip of the handpieces. For testing the cooling system of the Handpieces , the handpieces are pressed against the patient's skin.
Because the sapphire window is above freezing ,there is no risk of skin damage as a result of overcooling. Cooling system is tested on two different types of skin II and VI . The patients skin are treated with diode and CPL handpieces with below parameters.
The skin surface's temperature is measured before and after treatment by a termocamera during 20 minutes .

Instrument Use	S\N	Calibration date:	Next Calibration Due Date
Termocamera FLIR TG167	74701-010672	28/09/2021	28/09/2022

2.2 Parameters

For testing cooling system per each handpiece is used 3 parameters low ,media, high

Diode 808/760 nm 4000W Alex Pro				
Pulse duration	Pulse repetition frequency	Fluency	Spot size	
10 ms	1 HZ	24 J/cm2	9x9	10x15
50 ms	4 HZ	28 J/cm2	9x9	10x15
100ms	8 HZ	32 J/cm2	9x9	10x15

Diode 1200 w 810 nm			
Pulse duration	Pulse repetition frequency	Fluency	Spot size
10 ms	0.8 Hz	8 J/cm2	9X9
40 ms	1HZ	40 J/cm2	9X9
60 ms	2.4 hz	80J/cm2	9X9

Diode 2800 w 810 nm			
Pulse duration	Pulse repetition frequency	Fluency	Spot size
10 ms	0.8 Hz	10 J/cm2	9X9
100 ms	1HZ	40 J/cm2	9X9
400 ms	2.4 hz	100J/cm2	9X9

CPL Calibrated Pulse Light			
Pulse duration	Pulse repetition frequency	Fluency	Spot size
1 ms	0.5 HZ	1 J/cm2	10X50
30 ms	0.5 HZ	15 J/cm2	10X50
50 ms	0.5 HZ	20 J/cm2	10X50

2.3 Specification

According to sapphire cooling studies, the skin epidermis temperature after cooling with sapphire window can't go below 8 °C and above 35°c .REF 1,5,6

2.4 Results

After treatment there wasn't no ice formation on the skin surface. Results from diode and CPL handpieces are shown in Fig 2 and the below tables.

Diode 808/760 nm 4000W Alex pro					Results	
Pulse duration	Pulse repetition frequency	Fluency	Spot size		Contact duration (minutes)	Skin temperature (°c)
10 ms	1 HZ	24 J/cm2	9x9		0	31.8
					10	15.2
					20	14.8
50 ms	4 HZ	28 J/cm2		10x15	0	31.8
					10	18.2
					20	17.8
100ms	8 HZ	32 J/cm2	9x9		0	30.8
					10	19.2
					20	17.5

Average of temperature °C **During 20 minutes**	0min	10min	20min
	31.5	17.5	16.7

Diode 1200 w 810 nm				Results	
Pulse duration	Pulse repetition frequency	Fluency	Spot size	Contact duration (minutes)	Skin temperature (°c)
10 ms	0.8 Hz	8 J/cm2	9X9	0	30.3
				10	12.2
				20	11.6
40 ms	1HZ	40 J/cm2	9X9	0	30.4
				10	20.2
				20	19.8
60 ms	2.4 hz	80J/cm2	9X9	0	30.8
				10	20.9
				20	20.3

Average of temperature °C **During 20 minutes**	0 min	10 min	20 min
	30.5	17.7	17.2

Diode 2800 w 810 nm				Results	
Pulse duration	Pulse repetition frequency	Fluency	Spot size	Contact duration (minutes)	Skin temperature (°c)
10 ms	0.8 Hz	10 J/cm2	9X9	0	32.2
				10	15.2
				20	14.9
100 ms	1HZ	40 J/cm2	9X9	0	33.0
				10	20.2
				20	18.8
400 ms	2.4 hz	100J/cm2	9X9	0	31.4
				10	24.09
				20	20.3

Average of temperature °C During 20 minutes	0 min	10 min	20 min
	32.2	20.1	18

CPCalibrated Pulse Light				Results	
Pulse duration	Pulse repetition frequency	Fluency	Spot size	Contact duration (minutes)	Skin temperature (°c)
1 ms	0.5 HZ	1 J/cm2	10X50	0	32.8
				10	11.2
				20	10.8
30 ms	0.5 HZ	15 J/cm2	10X50	0	33.7
				10	15.8
				20	15.2
50ms	0.5 HZ	20 J/cm2	10X50	0	32.6
				10	18.2
				20	17.5

Average of temperature °C **During 20 minutes**	0 min	10 min	20 min
	33.0	15.0	14.5

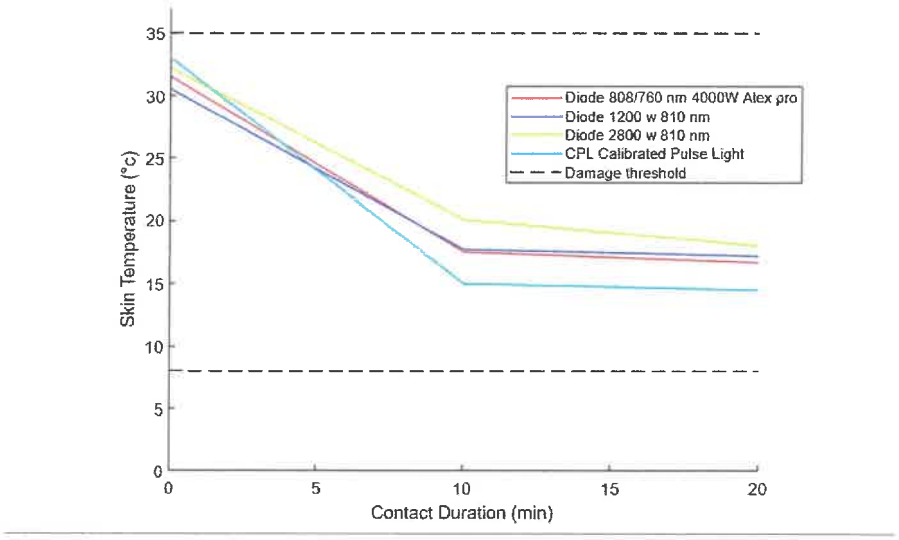


Fig 2.

2.5 Conclusion

According to the results, the skin temperature with cooling system of Diode and CPL handpieces meet the specification and they are safe.

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Unwanted hair removal in Unwanted Hair removal with CPL (Calibrated Pulsed Light)

Dr.Arianna Facchini

Date 10/01/2023

signature

Device :

Xlase Plus Laser Plattform With CPL (Calibrated Pulsed Light) handpiece

Manfactured by Biotec Italia

Unwanted Hair removal with CPL (Calibrated Pulsed Light)

CPL Handpiece Mechanism Of Action

CPL (Calibrated Pulsed Light) works on the principle of selective absorption of energy by components of the hair follicle. The target chromophore is melanin in the hair bulb and outer root sheath zones of the hair follicle, while the competing chromophores are any other melanin-containing components of the skin and other light-absorbing components such as hemoglobin in blood vessel.

Parameters and specification Of CPL Handpiece

Many factors influence the efficacy of CPL handpiece such as spot size, divergence/convergence of the beam and wavelength that determines the depth of penetration, pulse duration, fluence and the adjacent cooling system. The amount of energy absorbed by the target and surrounding tissue is measured by fluence (J/cm2) and can be delivered in pulses.

	Specification of CPL handpiece
Frequency Hz	1-3 Hz
Fluence J/CM2	Up to 36 J/CM2
Wave length (cutt of filters) nm	410-1200 nm 550-1200 nm 550-950 nm 650-950 nm 595-1200 nm 755-1200 nm
Pulse Duration	1-50 ms
Spot size	10X50 mm
Cooling methode	Sapphire cooling

Material and Methods

This study was designed to show the efficiency of CPL handpiece for unwanted hair removal .23 women and 3 men, with ages ranging from 18 to 47 years and with Fitzpatrick skin types ranging between III and V participated in this study. These patients had no history of dermatological disorders such as photosensitivity or inflammatory, pre-malignant or malignant skin diseases. They had not shaved during the week before treatment with CPL (Manufactured by Biotec Italia). a cut of filter wave-guide conducted the filtered light to the target chromophores in the tissue. All subjects underwent 5 CPL treatments at 4 weeks intervals. Collecting data was done 6 months after the last session. The parameters were adjusted base on skin Fitzpatrick and hair color and thickness. The fluence was used in range of 10-25 J/cm2 with a pulse duration of 15-40 ms. According to the skin type, a single pulse was used as a test. If there was no erythema or burning sensation within 2 h, a suitable treatment protocol was selected, usually the lighter the skin color, the higher the energy needed to produce effective results. Clinical assessment was carried out before starting the treatment and 6 months after the last session.

Results

All patients undergoing five treatments achieved hair reduction in different body sites with a mean of 80% as shown in Table 1. Patients tolerated the treatment but a few patients suffered mild pain in the upper lip and bikini line. Transient erythema and redness appeared in most patients immediately after the procedure and disappeared. No post-inflammatory hyper- or hypo-pigmentation and no scarring or burn was detected. Pseudo folliculitis barbae on the face and the bikini line was also treated successfully in three patients with skin type IV.

Conclusion

From the above data we conclude that unwanted hair removal with CPL is effective. CPL treatment of 26 hirsute patients of skin type III–V involved in this study resulted in a hair reduction of about 70–80%. This study confirms that CPl is also effective for hair removal in patients of very dark skin types. pseudo folliculitis was eliminated completely in the beard in two men and in the bikini line in one female patient. It is also evaluated patient satisfaction in 26 patients 6 month after CPL treatment of unwanted facial and body hair and all patients were completely satisfied from treatment and they showed willing to continue with CPL .

Tabel

Tabe 1

Phsician valuation -1=burn and adverse effects 0=no hair reduction 1=slightly hair reduction 2=mild hair reduction 3=extremely hair reduction

Area	Skin type	Valuation score At 6 month	Side effects
Bikin Line	III	3	No
Face	IV	3	No
Face	IV	3	Redness
Axillae	III	2	Redness
Bikin Line	IV	3	Erythema
Axillae	IV	2	Erythema
Legs	IV	3	Erythema
Face	IV	3	Redness
Face	III	3	Redness
Face	III	3	Redness
Face	III	3	Redness
Legs	III	3	Redness
Axillae	III	3	Redness
Axillae	III	3	Redness
Axillae	III	2	Redness
Legs	III	3	Redness
Legs	III	2	Redness
Legs	IV	2	Redness
Bikin Line	IV	3	Redness
Face	V	3	Redness
Face	V	3	Redness
Bikin Line	IV	3	No
Face	V	3	No
Face	V	3	No
Face	IV	3	Redness
Face	IV	3	Redness
		M=2.80	

Tabe 2

Patient valuation -1=burn and adverse effects 0=no hair reduction 1=slightly hair reduction

2=mild hair reduction 3=extremely hair reduction

Area	Skin type	Valuation score At 6 month	Treatment was painful ?	Are you satisfied from yout treatment?	Do you continue with your treatment ?
Bikin Line	III	3	No	Yes	Yes
Face	IV	3	No	Yes	Yes
Face	IV	3	No	Yes	Yes
Axillae	III	3	No	Yes	Yes
Bikin Line	IV	3	No	Yes	Yes
Axillae	IV	2	No	Yes	Yes
Legs	IV	3	No	Yes	Yes
Face	IV	3	No	Yes	Yes
Face	III	3	No	Yes	Yes
Face	III	2	No	Yes	Yes
Face	III	2	Yes ,uper lip	Yes	Yes
Legs	III	2	No	Yes	Yes
Axillae	III	2	Yes ,uper lip	Yes	Yes
Axillae	III	3	Yes ,uper lip	Yes	Yes
Axillae	III	2	No	Yes	Yes
Legs	III	3	No	Yes	Yes
Legs	III	2	No	Yes	Yes
Legs	IV	2	No	Yes	Yes
Bikin Line	IV	3	No	Yes	Yes
Face	V	3	Yes ,bikini line	Yes	Yes
Face	V	3	Yes ,bikini line	Yes	Yes
Bikin Line	IV	3	Yes ,bikini line	Yes	Yes
Face	V	3	Yes ,bikini line	Yes	Yes
Face	V	3	No	Yes	Yes
Face	IV	3	No	Yes	Yes
Face	IV	3	No	Yes	Yes
		M=2.69			

Riferimenti

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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.

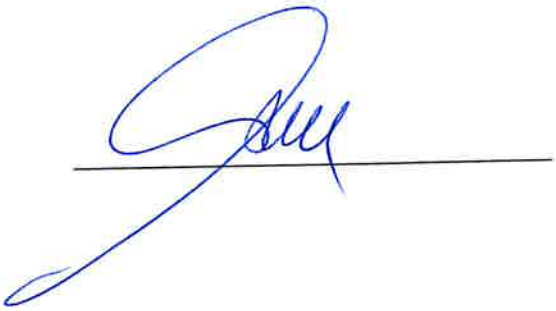
Results: All 26 patients (mean age 36.38 years, range 27-50 years old) were treated 1 session with SLP ND YAG handpiece from Xlase Plus Device manufactured by Biotec Italia. Eleven patients showed excellent improvement, Fifteen Patients showed good improvement.in some patient.

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						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