xlase PLUS

DOSSIER ETUDES CLINIQUES



FDA CE 1370

XLASE PLUS

AlexPRO / Diode

DOSSIER D’ÉTUDES CLINIQUES

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Diode double longueur d’onde : 760/808 nm.

Certaines études source indiquent 810 nm.

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.

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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

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

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.

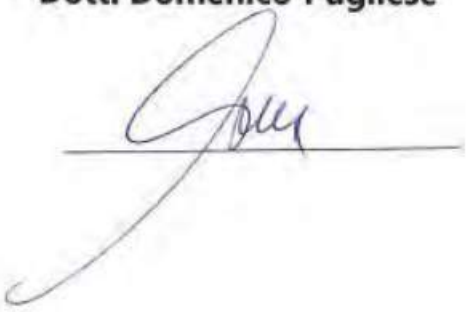
For most patient the treatment was painless, they felt the heat during the treatments.

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%



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.

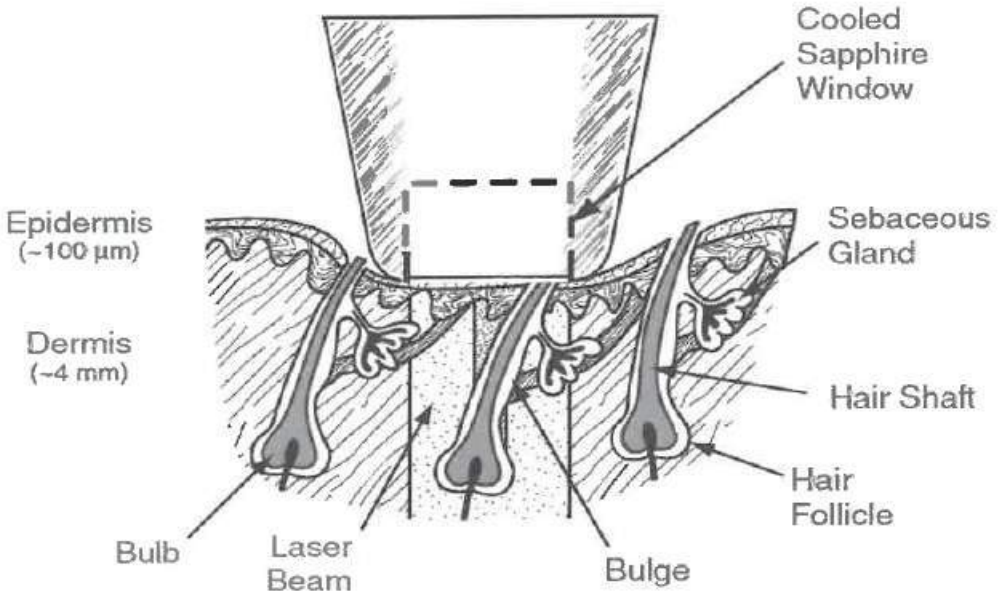


Fig.1

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

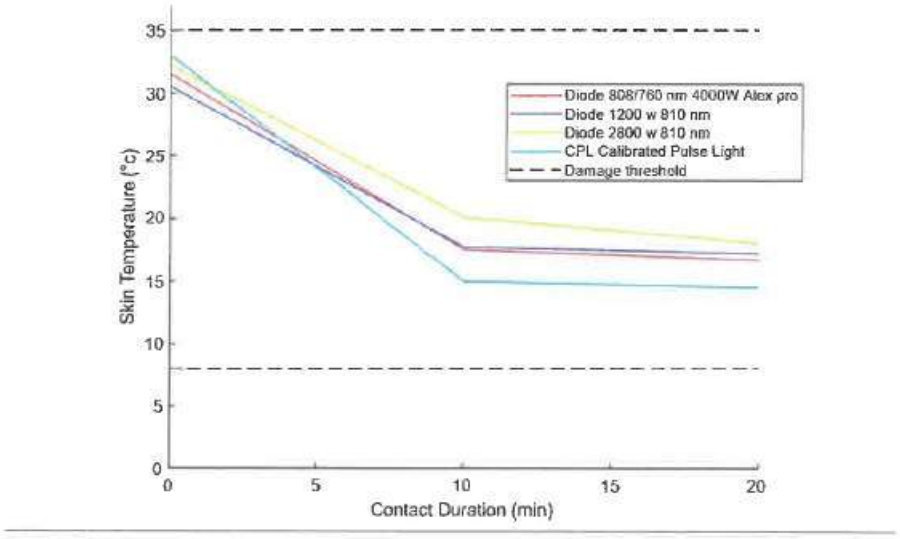


Fig 2.

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.

2.6 References

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