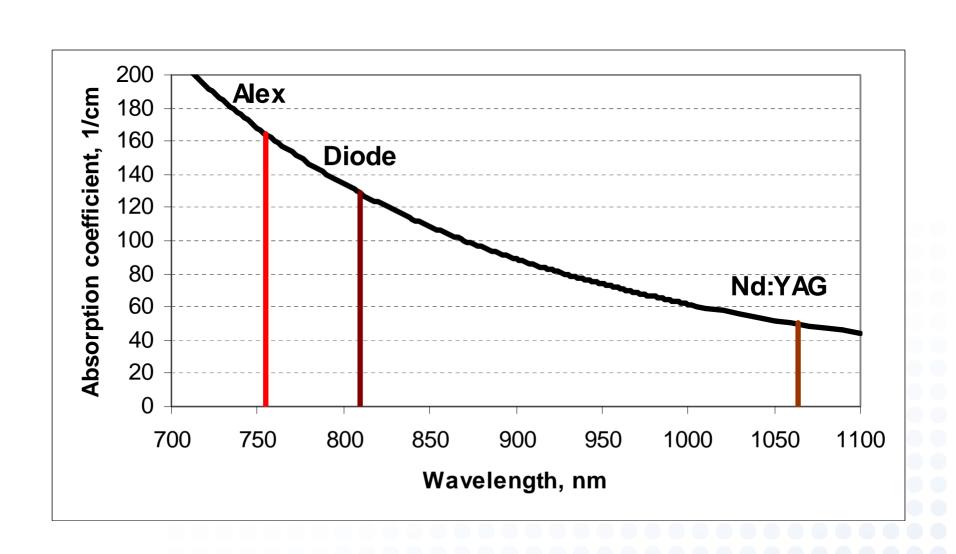
Melanin Absorption

CUNOGURE



Approx. pulse settings needed to achieve preset fluence for Lumenis



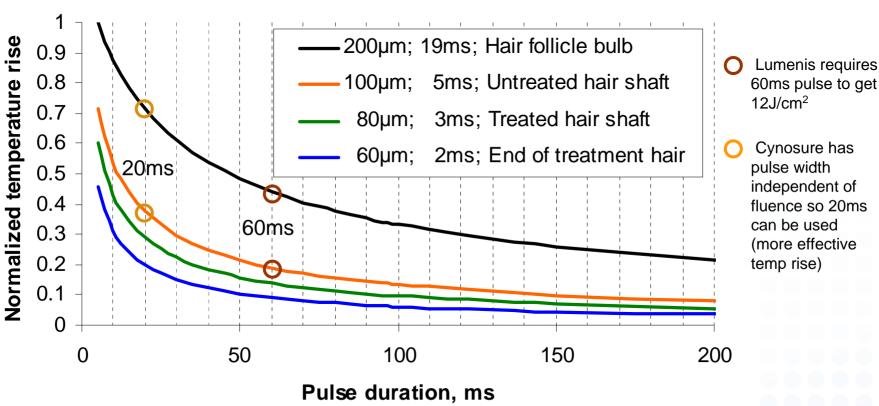
Peak power, kW 1.6 Spot size 2.2x3.5, cm²

Set fluence J/cm ²	Req. pulse, ms			
6	28.9			
8	38.5			
10	48.1			
12	<u>57.8</u>			
14	67.4			
16	77.0			
18	86.6			
20	96.3			

Calculations show that to achieve a fluence of 12J/cm2, the required pulse duration is 58ms

Hair follicle target temperatures

CANO(ABE



Example: 12J/cm², 60ms treatment has equivalent treatment efficacy to 6J/cm², 20ms in 100µm hair shaft OR 7.4J/cm², 20ms in 200µm bulb

>> 8J/cm², 20ms can be used with reduced pain and better efficacy

Clinical proof for Alex and Nd:YAG vs. Diode

Goldman et al Dermatol Surg 2008;34:665-671



- Greatest reduction seen with Alexandrite laser at 70.3% and combination of Alexandrite and Nd:YAG laser at 67.1%
- The long pulse diode laser was less efficacious at 59.7%

Comparative Evaluation of Long-Pulse Alexandrite and Long-Pulse Nd:YAG Laser Systems Used Individually and in Combination for Axillary Hair Removal

IANE G. KHOURY, MD.* RAMINDER SALUIA, MD.* AND MITCHEL P. GOLDMAN, MD*†

BACKGROUND. The 755-nm alexandrite and the 1.064-nm Nd:YAG lasers are both utilized for hair removal. Advances in laser technology have led to the development of dual-wavelength treatment for

OBJECTIVE The objective was to evaluate the safety and efficacy of combining 755- and 1,064-nm wavelengths for axillary hair removal.

METHODS Twenty patients received three treatments at 4- to 6-week intervals in four axillary quad rants. The left upper axilla was treated with the alexandrite laser, the left lower axilla with the Nd:YAG laser, the right upper axilla with combination alexandrite and Nd: YAG laser, and the right lower quadrant with the diode laser. At 1- and 2-month follow-up visits, subjects completed questionnaires and were assessed for percentage of hair reduction.

RESULTS Eighteen subjects completed the study. The greatest reduction was seen with the alexandrite efficacious at 59.7% and the Nd:YAG laser had the least improvement with 47.4% reduction. Subjects found the alexandrite and diode lasers to be the most tolerable and the Nd:YAG and combination treatment to be the most painful

CONCLUSION Combination treatment of alexandrite and Nd:YAG lasers provides no added benefit over

The Apogee Laser used in this study was loaned by Cynosure

aser hair removal is a well-established treatment __modality for the reduction of unwanted hair. Based on the theory of selective photothermolysis, several hair removal laser systems have been developed. Because of their wavelengths and extended pulse durations, the 755-nm alexandrite. 810-nm diode, and 1.064-nm Nd:YAG lasers have been shown to be effective in photoepilation,2-4 While many studies have been published that document the safety and efficacy of these laser systems, only two studies exist to date that directly compare these three hair and is more effective than the 1.064-nm wavewavelengths for laser-assisted hair removal. 5,6 Rao rotating these three wavelengths on improvement of 755/1,064-nm wavelengths simultaneously may inhair reduction. However, to the best of our knowledge no study to date has explored the benefit hair types.

of combining wavelengths for increased efficacy of laser hair removal.

Recently, the emerging trend of multiwavelength lasers has led several companies to offer a 755-nm alexandrite and a 1.064-nm Nd:YAG laser in one unit. The 1,064-nm Nd: YAG wavelength is better suited for removing hair from dark skin, but may not provide the most effective treatment for lighter hair. The 755-nm alexandrite wavelength can treat darker length in treating lighter hair but is not ideal for and Goldman⁶ in their study explored the benefit of darker skin. A new laser system capable of emitting crease efficacy in treating a wider variety of skin and

*Dermatology/Cosmetic Laser Associates; †La Jolla Spa MD, La Jolla, California

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Pili bigemini can be induced by intermediate doses of diode laser energy Kaniowska J Cosmetic Derm 2004 3 104-6

CANORE

- Pili bigemini appearance of two hairs coming from the same follicular opening
- The incidence of double hairs coming from a single follicle after two therapies may have been caused by the use of a too low fluence which induced hair follicles instead of destroying them
- Regrowing hairs were clearly thinner, lighter and fewer

Case Report

Pili bigemini complicating diode laser hair removal

E Kaniows

Polish Society for Aesthetic Demnatology, Wrocław, Poland

Summary

After two diode laser treatments for hair removal, a 39-year-old woman was noted to

Pili biggmini, the appearance of two hairs coming from the same follicular opening, can be induced by intermediate doses of laser energy. It follows sublethal damage to the hair follicule appearance.

Keiswords: laser hair removal, pili bigemini

Introduction

Excessive hair has been a problem of women for centuries. As far back as ancient times, neonle looked for an optimum method for hair removal. Until recently electrolysis and its later modifications seemed most effective. But lasers have ushered in a new era of enilation. Ruby, alexandrite, Nd: YAG and diode lasers are now used in hair removal, the latter currently regarded as the most efficient one. The diode laser is a semiconductor diode laser system with an actively cooled sapphire tin. 3,5,10,14 This modern cooling system that protects skin from burns increases therapy safety. However, despite all the security devices there may appear typical side-effects. such as erythema, cedema, epidermal crusting, blistering, temporary hyperpigmentation and hypopigmentation. The objective of this paper is to present a case of hair proliferation after diode laser treatment. So far, only one case of hair proliferation in some follicles after ruby and alexandrite laser treatment has been reported. This phenomenon was described as pili bigemini by Ye et al. in the article entitled 'Pili bigemini induced by low fluence therapy with hair removal alexandrite and ruby

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Accepted for publication 13 August 2004

Case report

A 39-year-old woman of Fitznatrick skin type III requested laser hair removal in thigh and leg area. The patient decided on the therapy because of very dense, thick and dark hair. After the laser test the area was initially irradiated using the diode laser with fluences of 25-27 J/cm². After 10 weeks, the patient returned for another therapy with complete hair regrowth. The use of the same fluence in the second therapy was dictated by overreaction of epidermis (whitening, vesiculation) occurring at the attempt of fluence increase. After 4 months the national came in again. The examination showed that the regrowing hairs were clearly thinner lighter and fewer and that there were two hairs coming from a single follicle in numerous follicles on the skin of the thigh which had undergone the therapy (Fig. 1). The third treatment was carried out at fluence of 31 J/cm2. The follow-up after 5 months showed further remarkable hair reduction. The phenomenon of regrowing double hairs was not observed.

Discussion

Success of laser therapy is not fully predictable as a result of the influence of many factors determining hair regrowth, 7-8.1341 The light beam should be characterized by adequately high fluence and pulse duration as well as proper penetration into the skin in order to be efficitive. The dominant skin chromoshore is

Laser Hair Removal Review David Goldberg, MD Dermatol Clin 20(2009) 561-567

CUNOQURE

- Long term hair removal requires damage to one or more growth centers of hair
- New hairs may evolve from the dermal papilla, follicular matrix or the bulge (3-7mm deep in the skin)
- Due to this skin depth, significant energies must be applied for effective hair removal.
- Significant hair loss only at sites treated with the highest fluences
- With diode, clinically obvious long-term hair reduction usually required greater or equal to 30J/cm2
- Treatment with the diode laser also showed reduction in hair diameter (19.9% reduced diameter) and color (lighter and thinner).



Demastol Clin 20 (2002) 561-567

Current therapy

Laser hair remova

David J. Goldberg, MD

Later Research, Department of Dermatology: Mount Sinai School of Medicine, 5 East 98." St. New York, NY 10029, USA

Long-term hair removal requires that a laser or light source damage one or more growth centers of hair. To do so, an appropriate target or chromophere must be identified. The major hair growth center has always been thought to be the hair matrix. As has now been described, however, new hairs may evolve from the dermal papila, followlar matrix, or the bulge. Although the phropotential growth sales of the arrector political section of the control of the

greater depth of penetration. The pluripoterial cells of the bulge, dermal papilla, and hair matrix must be treated in the anagen oycle for effective hair removal. If the damage is not permanent during this cycle, folicides move into the telogen stage as hey fall cut. All of the folicides may become synchronized after the first laser treatment. The hair follicides hen return to the anagen phase during the natural hair cycle. This cycle varies denesting the natural hair cycle. This cycle varies derespond to the stage of the control of the stage of the control of the natural hair cycle. This cycle varies derespond no the anatural hair cycle.

Bruce H. Thiers. MD. Consulting Editor

photothermolysis is the concept of thermal relaxatio the limitation of thermal damage when a desired target that is equal or less than that target's thermal relaxa-tion time. With the right combination of wavelength. hair follicle precisely without causing injury to the injury to the hair follicle is by increasing the pulse duration of the laser exposure. The thermal relaxation time for hair follicles that are 200 to 300 um in diameter is approximately 40 to 100 millisecond. If nulse duration should lie between the thermal relays tion time for epidermis, which is approximately 3 to 10 millisecond, and the thermal relevation time to hair follicles. There are other factors, however, to consider. If a laser or light source delivers its energy through a large beam, an increase in skin penetration occurs. Greater depth of penetration provides a greate chance of reaching hair growth centers.

In human skin, about 15% to 20% of incident ligh

large spot size, scattering of light in the dermis is lessened, leading to greater depth of penetration. In

addition, whenever a melanin-absorbing laser or light

source is used for hair removal, competing epidermal

melanin must be protected from damage. This is usually accomplished by cooling the skin surface. Currently popular cooling techniques include conta and cryogen cooling. Cold gel cooling, used exter

face and longer on the hody, varying between several

Selective photothermolysis describes the use of selected wavelengths to destroy particular targets in

DERMATOLOGIC

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Low fluences may induce terminal hair growth Bouzari and Firooz. Dermatol Surg 2006 32:460



- "Terminalization" is the conversion of vellus hairs to terminal hair (thick pigmented hairs)
- We observed "terminalization" mainly in patients who were treated with low fluences
- We hypothesize that produced heat is less than the temperature necessary for thermolysis of the hair follicle
- The heat shock may induce follicular stem cell differentiation and growth via increasing the level of heat shock proteins (HSP 27) in the tissue

Hair Growth Induced by Diode Laser Treatment Bernstein Dermatol Surg 2005;31:584-586

CYNOQURE

- Dramatic case of hair growth following treatment with 810nm diode laser
- Reduction in hair on posterior neck approx 25% post 3 TX
- Test spot on back had a dramatic increase in hair growth
- Three treatments cleared the area of hair growth but an annulus of hair appeared surrounding the treated area
- See images on next slide

Hair Growth Induced by Diode Laser Treatment

ERIC F. BERNSTEIN, M.

Laser Surgery and Cosmetic Dermatology Centers, Bryn Mawr, Pennsylvania

BACKGROUND. Although hair reduction by long-pulsed red and infrared lasers and light sources is generally quite effective, paradoxical hair growth has rarely been observed following treatment. OBJECTIVE: To operat case of thick hair growth following 810 nm diode laser treatment and its subsequent treatment.

METHODS. A 24-year-old man who had previously had laser hair reduction on his posterior neck was treated to a test area on his upper back. RESULTS. Thick terminal hair developed in the treated area subsequent to laser treatment. Further treatment of this area removed the terminal hair but resulted in terminal hair growth in an annular distribution surrounding the treatment site.

CONCLUSIONS. Diode laser treatment rarely stimulates terminal hair growth. This phenomenon should be studied to better understand hair growth cycles and to help develop more effective treatments for hair loss and hair growth.

ERIC F. BERNSTEIN, MD, SERVES AS A DIRECTOR FOR CANDELA CORPORATION AND IS ON THE SCIENTIFIC ADVISORY BOARD OF LUMENIS LTD.

LASER HAIR reduction uses pulsed red, or infrared, laser radiation to target melanin pigment in unwanted hair, stimulating its removal. 1-3 Most hair removal lasers and light sources use a cooling device to extract heat from the epidermis, providing relative protection to the melanincontaining surface epidermis, increasing the relative amount of heat delivered to the hair follicle versus the epidermis. The initial proposed mechanism of action of hair removal lasers is the induction of a prolonged telogen phase.1 Immediately following treatment, an urticarial papule develops around each hair follicle that contained a pigmented hair shaft. The fact that these papules develop individually throughout a much larger treatment area speaks to the selectivity of the treatment. Normal skin not containing a hair shaft is unaffected, demonstrating the principle of selective photothermolysis. 4 This urtication initiates a complex inflammatory response that appears to be integral to the overall effect of reducing terminal hair growth. Rarely, treatment with hair removal lasers and light sources does not remove the bair but instead paradoxically stimulates anagen hair growth, resulting in, at best, a surprised patient and physician.5-7 I report here a dramatic case of hair growth following treatment with the 810 nm diode laser.

Case Repor

A 24-year-old white male bodybuilder with Fitzpatrick type III skin presented for laser hair reduction on the pos-

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terior and lateral aspects of his neck. He was not tan at the time he presented. The 810 nm pulsed diode laser with a contact-cooling sapphire tip, cooled to 5°C, was used (LightSheer, Lumenis Ltd, Santa Clara, CA, USA). The first treatment was delivered using a fluence of 25 J/cm2 and a pulse duration of 30 milliseconds. The patient then returned 6 weeks later for a second treatment to his neck using a fluence of 28 Ucm2 and a pulse duration of 30 milliseconds and, finally, for a third treatment 6 weeks following that using a fluence of 32 J/cm2 and a 30-millisecond pulse duration. The reduction of hair on this patient's posterior neck was rated to be only approximately 25% following three treatments by the treating physician and slightly effective by the patient. This was less hair reduction than is typically seen following three treatments to this area in the average patient. Six weeks following his third treatment, he returned for a fourth treatment, and one was administered using a fluence of 32 [/cm2. Despite the slow improvement in clearance of his neck hair, this patient also decided that he wanted his back hair treated on the same visit. His hair growth on the back was relatively sparse, and the patient was informed that laser hair reduction might provide only a moderate change in the appearance in his back hair owing to its sparse covering to begin with. Nonetheless, he was extremely upset by the hair on his back and wished to pursue treatment in this area. Thus, it was agreed that a small test area would be performed on this patient's back to ascertain the amount of hair reduction that this patient could expect following laser treatment of his back. A square area approximately 6×6 cm in area was treated on the patient's back using a fluence of 32 J/cm2 and a pulse duration of 30 milliseconds. The patient's past medical history was noncontribu-

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Hair Growth Induced by Diode Laser Treatment Bernstein Dermatol Surg 2005;31:584-586

CANO(ABE.



Figure 1. Hair growth 14 weeks following an 810 nm diode laser treatment to a rectangular test patch on the upper back.



Figure 2. An annulus of hair growth surrounding the test patch shown in Figure 1 6 weeks following three diode laser treatments to this abnormal patch of hair growth.

Lumenis summary for Lightsheer Diode Laser System for the FDA Rox Anderson, Christine Dierickx et al. Wellman Labs



- Regrowing hair is typically thinner and lighter in color
- The efficacy for hair removal increases with increasing treatment fluence

TABLE 4. HAIR REDUCTION RESULTS								
Fluence	Number of Treatments	Percentage of Hair Reduction						
		1 mo.	3 mo.	6 mo.	9 mo.	12 mo.		
5 ms, 15 J/cm ²	1	65.4	21.5	17.9*	15.5*	26.6		
10 ms, 20 J/ cm ²	1	66.7	21.0	22.2	20.7	25.9		
15 ms, 30 J/ cm ²	1	70.8	30.2	28.7	30.6	29.4		
20 ms, 40 J/ cm ²	1	70.2	26.8	29.8	32.5	32.5		
20 ms, 40 J/ cm ²	2	69.3	51.5	37.1	42.3	46.6		
20 ms, 40 J/ cm ² 3x	2	71.1	51.9	36.8	41.4	46.2		
20 ms, 40 J/ cm ² 3x	1	68.9	30.8	32.3	32.4	38.5		
Control	0	17.3	10.5	10.8	6.3	5.5		

^{*}Percentage is not statistically significant.

Lumenis White Paper

CANO(ABE

- Just 5.5% of treatments were done with fluences <20 J/cm2
- The most frequently used fluence was between 25-29 J/cm2
- This requires use of the smaller
 9x9mm handpiece (the 22x35mm handpiece is limited to 12J/cm2)
- The 9x9mm hand piece utilizes contact cooling which requires frequent cleaning to remove contamination and debris

Use of the LightSheer™ Diode Laser System for Hair Reduction: Safety and Efficacy in a Large Series of Treatments

Rube J. Pardo, MD, Ph.D., Judy Fahey, RN
Coral Gables Dermatology and Laser Center
Department of Dermatology, University of Miami

Summary Provided by Lumenis Inc.

ABSTRACT. An 800 nm high-power, long-pulsed diode laser with contact cooling provides safe and effective reduction of pigmented hair in patients with a variety of skin types. This paper presents the safety and efficacy results of 800 treatments performed on 250 sites in 144 patients with Fitzpatrick skin types II.V.

Over 84% of sites showed a good or excellent response following the second and subsequent treatments. Treatment responses were similar for all skin types treated, with an excellent safety profile. Side effects were noted in only two of the 800 treatments and were transient in anture. Patients were extremely or moderately satisfied with over 96% of their treatments.

INTRODUCTION

SEMICONDUCTOR DIODE LASERS are considered the most efficient light sources available and are particularly well suited for clinical applications including hair reduction. This paper reports the use of the LightSheer diode laser system, a high-power, long-pulsed diode laser with a wavelength of 800nm, for laser hair reduction in a large population of patients with a variety of skin and hair types.

Laser hair reduction operates on the principle of selective photohermolyis. This process combines selective absorption of light energy by the melanin in hair follicles with suitable fluences and pulse durations'. In order to achieve maximum selectivity, the laser energy is applied in a pulse duration that approximately equals the thermal relaxation time of the target. In practice, the appropriate pulse duration maximizes the temperature rise of the hair follicle and minimizes the conduction of heat to the surrounding tissue, thus sparing adjacent structures from damage.

In order to achieve permanent hair reduction, sufficient light energy must be absorbed by the hair follick. The melanin in the hair follicke absorbs 3-4 times more energy at 800 mm (the wavelength used in the LightSheer) than at 1064 nm (the wavelength of NdYAG lasers). This increased absorption means that the LightSheer laser can be used at significantly lower fluences to achieve hair

reduction in contrast to the much higher fluences required for a 1064 nm laser.

The effectiveness of laser hair reduction depends on the patient's skin type. Laser hair reduction is typically more effective in lighter-skinned people (Fitzpatrick skin types I-III). The challenge associated with laser treatment for darker-skinned patients is to avoid surface skin (epidermal and upper dermal) injury due to absorption of light in the pigmented epidermis, while still causing selective destruction of the underlying pigmented hair follicles. This study will examine almost equal numbers of treatments of light and dark skin types.

Recent clinical studies have shown that longer pulse durations combined with aggressive skin cooling provide a greater margin of safety when treating darker skin by allowing higher fluences and fewer side effects. Models of skin optics and heat transfer suggest that the entire hair follicle, including the outermost follicular structures (where the stem cells are located) can be selectively damaged with longer pulse widths than those typically employed (20-40 ms). The LightSheer can deliver pulse durations up to 100 ms. The thermal relaxation time for the hair follicle is dependent on its diameter; thus longer pulse durations are theoretically best suited for the treatment of medium to thick hairs. These longer pulse durations can be safely used with higher fluences when combined with aggressive with aggressive with aggressive with aggressive with aggressive.

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Spot size

CYNO(URE

- Efficacy of hair removal has been shown to be superior with a 12mm spot size vs. 8mm spot size
- No improvement seen at sizes beyond 12mm

Reference: Different Spot Sizes for Hair Removal, Bäumler et al, Dermatol Surg 28:2 February 2002

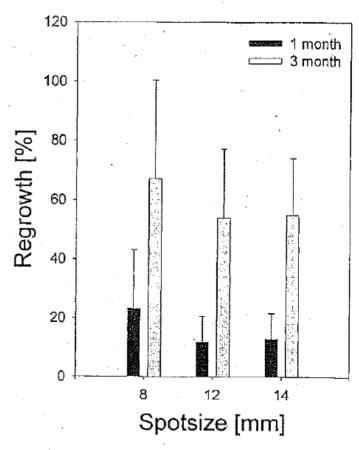


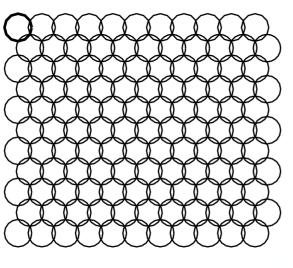
Figure 3. The regrowth of hairs 1 month (black bars) and 3 months after treatment (gray bars). The values are the mean \pm standard deviation of the mean regarding the regrowth of the 20 volunteers. One month after the laser treatment the growth delay was significantly different when using a spot size of 8 mm or 12 mm (P < .01).

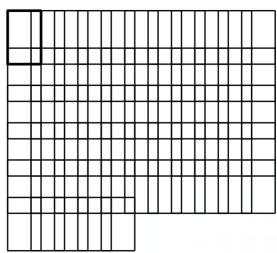
Coverage comparison 1 minute treatment

(VNO)URE

Elite 18mm Handpiece

Lumenis 22x35mm Handpiece





18mm spot

10% overlap

265 cm² covered

2Hz

22x35mm spot

30% overlap

255cm² covered

1Hz (time required for pneumatic action)

Example: 5'9" male back area of 2628cm² would take 10 minutes with Elite and 10.3 minutes with Lightsheer

Other considerations



- Elite MPX offers clinically proven epidermal protection using air cooling (no contact). The Lightsheer Duet offers contact cooling (requires frequent cleaning) or vacuum suction (will not work well with bony/small areas limited to back of legs and back)
- Elite MPX is a multiple application workstation leg veins, facial veins, pigmented lesions (with IPL), laser facial
- Lightweight and ergonomic handpieces that allow full view of treatment area. The Lightsheer Duet has a heavy and bulky handpiece. Vision of the treatment site is not possible
- The diode array is within the Lightsheer handpiece so if the handpiece is dropped this can be extremely expensive to replace
- Elite MPX offers multiple handpieces which are very quickly changed over (3, 5, 7, 10, 12, 15 and 18mm) enabling treatment of smaller areas (on face) and larger areas (back) to everything in between. The Lightsheer Duet offers just 2 options 9x9 (lengthens procedure time considerably for legs/backs or 22x35mm (too large for face/bikini area and limited to just 12J/cm2)
- Elite MPX 15 and 18mm spot sizes provide for a very quick procedure. The Lightsheer handpiece requires 30% overlap in one direction and 50% in the other. Combined with the constant need to clean the suction plate, the handpiece is not as efficient as the size would suggest.



Blinded, Bilateral Hair Removal Study Comparing the Alexandrite Laser with MPX Mode Preliminary Results

6 subject subset

Investigator: E. Bernstein

Hair Removal Study Clinical Comparison of Preliminary Results

CVNOSURE

Elite MPX

- 76% 79% reduction 1 month post 2 TX
 - Average reduction by Alex: 76%
 - Average reduction by Alex/YAG: 78%
 - Average reduction by YAG/Alex: 76%
- Alexandrite laser (Cynosure 510k data)
 - 76% reduction post 15 months, post 3-5 TX
- Nd:YAG (Alster/Tanzi, Derm Surg, 2004)
 - 58%-69% reduction post 1 month post 3 TX
 - 41% -53% reduction post 6 months post 3TX

Industry standard to determine clearance or reduction of hair follicles is:

6 months post last TX

CYNOSURE



CANORE

Alex/YAG



Alex



After just 2 treatments





CYNOSURE



CANO(RE.

Alex/YAG

Alex





After just 2 treatments





CYNOSURE

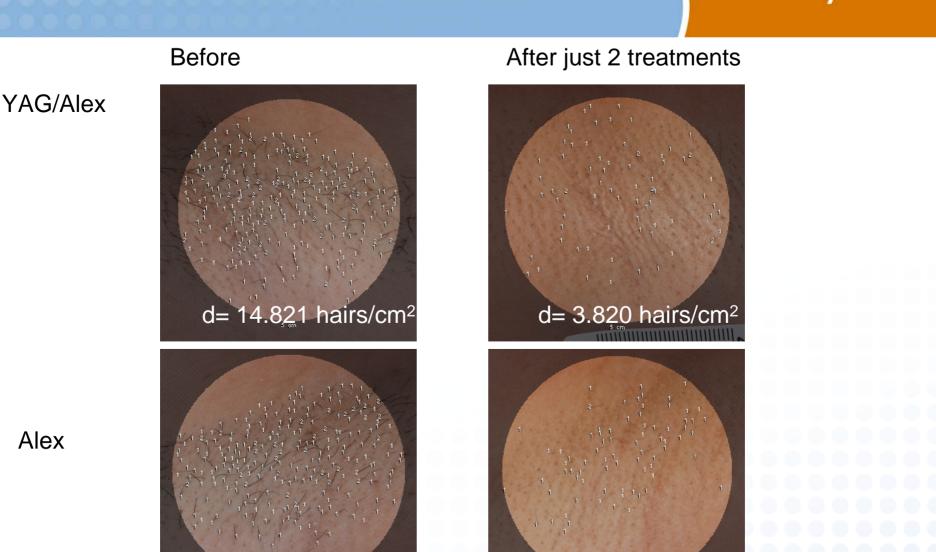


CANORE





CANORE



d= 3.769 hairs/cm²

d= 13.700 hairs/cm²

Hair Removal Study Clinical Comparison of Results

CANORE

- Elite MPX
 - 76% 79% reduction 1 month post 2 TX
 - Average reduction by Alex: 76%
 - Average reduction by Alex/YAG: 78%
 - Average reduction by YAG/Alex: 76%
- Alexandrite laser (Cynosure 510k data)
 - 76% reduction post 15 months, post 3-5 TX
- Nd:YAG (Alster/Tanzi, Derm Surg, 2004)
 - 58%-69% reduction post 1 month post 3 TX
 - 41% -53% reduction post 6 months post 3TX

Industry standard to determine clearance or reduction of hair follicles is:

6 months post last TX