Comparison of efficacy and safety of a novel 755-nm diode laser with conventional 755-nm alexandrite laser in reduction of axillary hairs

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Abstract

Purpose: The aim of this study was to compare the efficacy and safety of a novel diode system emitting 755 nm wavelength with conventional 755 nm alexandrite laser in skin types III and IV.
Methods: It was a randomized, right-left comparison, assessor-blind, clinical study. 16 female volunteers age 29.52 ± 9.52 were randomly assigned to receive 6 treatment sessions using 755 nm diode laser on one axilla and 755 nm alexandrite on the opposite axilla. Efficacy was assessed by counting of hairs per cm2, 6 months after the last treatment. Treatment outcome was also evaluated by blind reviewing of before and after pictures, using Physician Global Assessment scale (GAS). Subject satisfaction was assessed using visual analogue scale (VAS), pain level and adverse effects were recorded. Skin biophysical parameters (transepidermal water loss, skin sebum, and erythema index) were also measured.
Results: Significant reduction in hair count was observed, 6 months after last treatment session, for both devices (-33% for 755 nm diode and -35. % for 755 nm alexandrite; p value=0.85). The mean GAS score was 2.66 for alexandrite treated side vs. 2.00 for diode treated side (p-value= 0.036). No severe adverse events were reported. The subject satisfaction score was significantly higher after treatment with alexandrite laser. No significant changes were detected in none of skin biophysical parameters.
Conclusion: 755 nm diode laser is suitable for hair removal procedures, and it is as effective and safe as the 755 nm alexandrite laser in skin types III-IV.

Keywords: 755 nm, diode laser, Alexandrite. Laser, hair removal

Introduction

Unwanted hair is an exceedingly common concern for men and women and has profound effects on psychological well-being. Laser-assisted photo epilation or laser hair removal, as first reported in 1996, is accomplished through destruction of the follicular unit (1). During the past decade, laser hair removal has become an accepted and popular means of achieving hair reduction [2]. The ability to remove hair without damaging the surrounding skin is based on selective photothennolysis [3, 4]. Laser hair removal provides hair-free intervals of several weeks, which lengthen with repeated treatments, and the hair regrowth becomes sparser and finer [5-7].
The hair removal lasers range from the short end of light spectrum starting with the 694 nm ruby, to the middle, with the 755 nm alexandrite and the 800-810 nm diode, to the long end with the 1064 nm Nd:YAG [6,7]. In terms of efficacy and safety, Alexandrite laser and long pulsed diode laser are the most popular systems available and suitable for skin types I-IV [8].

A number of comparative studies have been conducted to ascertain which of the medium-wavelength lasers, namely the alexandrite and diode, is most effective and safe, but their results have been conflicting. Some of these studies reported equal efficacy [9], while others showed the alexandrite or diode lasers to be more effective [10-12]. However, in case of darker skin, there is some evidence that long pulse diode laser with high repetition rate and high average power is safer and more effective, since the use of traditional alexandrite 755nm laser may pose clinical challenge in dark skin due to its high peak power [13].
Furthermore, the traditional flash lamp pulsed alexandrite laser has some limitations including the need to exchange the flash lamps regularly, type of cooling, problems of fragile transmission systems and bulky scanner [14]. On the other hand, it has been shown that long pulse diode laser induces less pain and discomfort compared to the alexandrite laser [15]. Recently, a novel technical advancement has been developed as a high power diode laser emitting 755 nm wavelength. Accordingly, due to the highly selective 755 nm wavelength, even thinner and lighter hairs can be treated with the best results and the proven reliability of the diode technology assures the optimization of the treatment procedure (no time-consuming heating up and no running costs) [16].
The aim of this study was to compare the efficacy and side effects of novel diode emitted 755 nm laser with conventional 755 nm alexandrite laser for axillary hair removal in Iranian subjects with Fitzpatrick skin types III and IV.

Patients & methods

This randomized, parallel, right-left comparison, assessor-blind, clinical trial was performed from September 2016 to February 2018, in the Pharmaceutical, Cosmeceutical and Hygienic Evaluation Lab (DermaLab) at the Center for Research & Training in Skin Diseases & Leprosy, Tehran University of Medical Sciences (TUMS). The study was designed and conducted in accordance with the Declaration of Helsinki, and principles of Good Clinical Practice (GCP). The protocol and informed consent were reviewed and approved by the ethical committee of TUMS on June 4, 2016 (acceptance code: IR.TUMS.VCR.REC.1395.264) and was registered in Iranian Registry of Clinical Trial (IRCT) with the registration number: IRCT20 1 5010420514N2. All subjects were completely informed about the procedure and its side effects and written informed consent to participate in the study was obtained from the subjects at baseline.

Subject selection

A total of 20 healthy female volunteers with ages ranged between 18-50 years old and skin type III-IV were recruited for the study. The exclusion criteria included: any previous laser treatment to the study areas, endocrine disease, use of medication with androgenic effects and history of skin pigmentation disorders, photosensitivity, history of keloid scarring, active cutaneous infection, and cancerous or pre-cancerous lesions in the treatment area. The subject's axillae were randomly assigned to receive either diode laser or alexandrite laser. Randomization of hand piece type/ wavelength to each axilla was made by blinded card draw by the participant.

Patients & methods

The study participants were instructed to shave their axillary hairs two days before each laser treatment. Each subject received a total of 6 treatments at one month intervals. The treatment was done with the MeDioStar NeXTPRO with the ALX hand piece (manufactured by Asclepion Laser Technologies, Jena, Germany) and Elite (manufactured by Cynos ur e, USA). Table 1 shows a detailed description of the treatment' s parameter.
Each subject was randomly assigned to receive treatment with diode emitted 755 nm laser on one axilla (right or left) and the conventional 755 nm alexandrite on the opposite axilla. It was a simple randomization and

blinded card used to generate the random allocation sequence. The treatment was conducted on full area of both axillary areas. After baseline assessments and immediately prior to laser irradiation, the skin was cleansed with mild soap, rinsed with water and any hair was shaved. The participants' eyes were covered with suitable goggles. An ice compress was used before and after laser treatment to alleviate pain and reduce side effects. The participants were followed for 6 months after last treatment session.

Clinical assessments

Digital photographs were taken at baseline, immediately after each treatment and in follow up visit using digital camera (DSC/F707; Sony Corporation, Tokyo, Japan). The photography was done using the fix standard setting (light, distance, etc.). The photographs were reviewed for efficacy by one blinded independent medical evaluator.

The Physician Global Assessment scale (GAS) was used to evaluate the outcomes as: gradel (poor improvement described as hair reduction: 0-25%), grade 2 (moderate improvement, described as hair reduction: 26-50%, grade 3 (marked improvement described as hair reduction: 51-75%), and grade 4 (significant improvement described as hair reduction: 76-100%).

Assessment of hair density

A circle with 1 cm diameter around a central spot marked with a white tattoo in each axilla was selected as the target area for hair counting and other assessments. The hairs, vere counted before the laser treatment and 6 months after the last session using the digital photog raphs. To calculate hair reduction, the difference between the hair count in target area before the first session and 6 months after the last treatment was divided by the hair count before the first session.

Table 1 Treatment parameters of 755-nm diode and 75-nm alexandrite lasers

Laser type	Fluence	Spot size	Mode	Pulse speed/duration
755 nm diode laser	Up to 35.24 J/cm^2	140 mm^2	Professional + smooth pulse	1 (professional)/6 (smooth pulse)
755 nm alexandrite laser	Up to 25 J/cm^2	177 mm^2	–	Up to 2 Hz

Skin biophysical properties

Transepidermal water loss (TEWL), skin surface sebum, and erythema index were determined and recorded before and right after first treatment session, as well as 6 months after the last treatment. These properties were measured with MPA 580 probes: TEWAmeter, Sebumeter, and Mexameter (Courage & Khazaka electronic GmbH, Cologne, Germany). The measurement room temperature was set to 21 ± 1 °C and the humidity level between 30 and 40%. Before the measurements, volunteers stayed in the test room for 30 min for adaptation of skin to room temperature and humidity.

Pain level and side effects

Right after each treatment session, the subjects were asked to rate the discomfort using the 10-grade visual analogue scale (VAS) that ranges from 0, for no sensation to 10 for unbearable pain. Treatment-related side effects were evaluated by subjects' reports and physician evaluation after each treatment and at follow-up sessions. Subject satisfaction was assessed 6 months after the last session using a 10-grade visual analogue scale (VAS) from 0 for complete dissatisfaction to 10 for complete satisfaction.

Pain level and side effects

Data was entered in a commercially available statistical software program (SPSS 18.0 for Windows; SPSS Inc., Chicago, Illinois). Continuous data was reported as means (SDs). Paired sample T test was used to examine the differences between two laser treatments. Only two-sided probability values of less than .05 were considered statistically significant.
The mean fluence of six treatment sessions with 755 nm diode laser and conventional alexandrite laser is given in Table 2. Both lasers showed significant reduction in number of hairs 6 months after last treatment session (Table 3). Figure 1 demonstrates sample photographs of left and right axillae of one selected patient treated with 755-nm diode laser and conventional alexandrite laser respectively, at baseline and 6 months post last treatment. The mean score for a blind physician assessment of before-after photos, using GAS, was 2.66 (hair reduction 51–75%) for alexandrite-treated side vs. 2.00 (hair reduction 26–50%) for diode treated side ($p = 0.036$, paired sample t test). During the study period, no severe adverse events, including blistering, secondary infection, and hypo/hyper pigmentation, were reported. No significant change was detected in skin biophysical parameters including TEWL, erythema index, and sebum production rate right after both treatments as well as 6-month follow-up (Table 4). The subjects' evaluation of the treatment-related pain, using a visual analog scale, did not show significant difference between755 nm diode vs. 755 nm alexandrite laser (Table 5). The subject satisfaction score was higher after treatment with alexandrite laser (7.42 compared to 5.07) and the difference was statistically significant (0.01).

Table 2 Mean fluence of treatment using 755-nm diode laser versus 755-nm alexandrite laser

Treatment session	755 nm diode laser	755 nm alexandrite laser
1	26.29 J/cm^2	18.00 J/cm^2
2	28.71 J/cm^2	19.22 J/cm^2
3	30.67 J/cm^2	18.35 J/cm^2
4	32.81 J/cm^2	20.82 J/cm^2
5	35.02 J/cm^2	20.66 J/cm^2
6	35.24 J/cm^2	20.75 J/cm^2

Discussion

Laser hair removal (LHR) is one of the most requested cosmetic procedures. Although a number of lasers and non-laser light sources have been developed for hair removal, the 755- nm alexandrite and 800–810-nm diode lasers remain common options for this purpose among individuals with Fitzpatrick skin types I–IV [15, 17]. Several clinical studies conducted to compare these two laser systems, indicated various benefits of each

system as well as their limitations [9–11]. Recently, high power laser diodes emitting at 755 nm, the same wavelength as alexandrite, are available and have made their way into new hair removal systems. In this randomized, right-left comparative trial on subjects with skin types III and IV, we showed that both diode-emitted 755-nm and alexandrite-emitted 755-nm lasers are safe and effective in reduction of axillary hair. Significant reduction
in hair count was observed, 6 months after treatment, for 755-nm diode laser as well as the traditional 755-nm alexandrite system (p = 0.026, p = 0.00, respectively). However, the improvement assessment, using GAS showed almost higher improvement after treatment with conventional 755-nm alexandrite laser (p value = 0.036). Safety and efficacy of a device using 755-nm laser diode module have been recently evaluated in a pilot

Table 3 Treatment results of the 755-nm diode vs. 755-nm alexandrite

Laser device	Hair count (mean ± SD)		*p* value (before vs. after)	Reduction in number of hairs	Median of improvement grade (GAS 0–4)	Patient satisfaction (VAS 0–10)
	Before	After 6 months				
755 nm diode	21.15 ± 10.33	14.30 ± 10.08	*0.026*	33%	2.00	5.07
755 nm alexandrite	26.76 ± 9.73	17.61 ± 9.25	*0.00*	35%	2.66	7.42
				p value = 0.85	p value = 0.036	*p* value = *0.01*

Significant decrease in hair count, 6 months after hair removal treatment, using 755 nm diode laser and 755 nm alexandrite laser (p-value <0.05) are italicized

study in eight female subjects, with skin types III–V, on underarm and bikini areas. It resulted in satisfactory hair reduction with no serious adverse effects after four treatment sessions [18]. There is also a prospective study conducted by Royo J et al. in a group of 56 subjects who underwent four sessions of laser hair removal using 755-nm diode laser (with three different treatment methods), which all three tested options achieved a significant reduction in the number of hairs (P < 0.0001) [19]. The hair reduction rate of 755-nm diode laser in our study was comparable with the result of “stacking method” in Royo J et al. report, where the average clearance achieved was 41. 9%. However, Royo J et al. reported better hair reduction results using “conventional technique” and “in-motion technique” which led to 75.5%, and 70.1%, hair reduction, respectively [19]. It should also be noted that comparing hair reduction from different studies, using different subjects and laser settings, presents many limitations. The success rate of any laser treatment is related to many factors, such as the laser parameters (pulse duration, and fluence), the quantity and quality of hair, skin color, treatment interval, and the anatomic site [20].

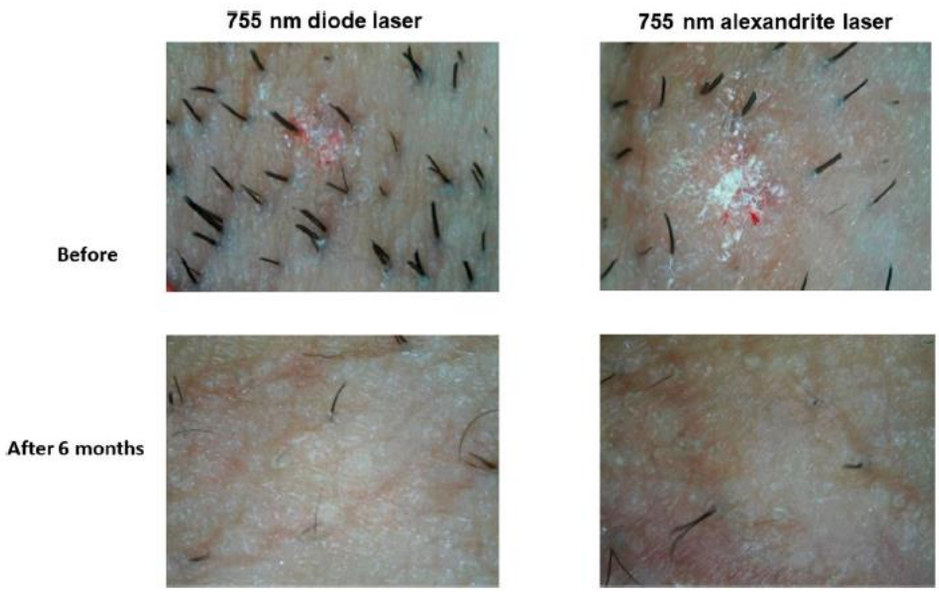

Fig. 1 A patient who was treated on left axilla with 755-nm diode laser and on right axilla with 755-nm alexandrite laser, before and 6 months after last treatment

To our knowledge, there is only one comparative study between 755 nm diode laser and conventional alexandrite laser conducted by Passch et al. [16]. This was a comparative single-case report on a 47-year-old male (Fitzpatrick skin type II). The subject received a total of four treatments at 4– 6 weeks intervals. During each treatment session, the right axilla was treated with the 755-nm diode laser, while the left axilla was treated with 755-nm alexandrite laser. Both systems showed proper efficacy in hair reduction (88.8% 755-nm diode laser vs. 77.7% 755 nm alexandrite laser). No severe adverse effects were reported during the study. Confirming Paasch et al. report, efficacy and pain level scores did not show significant difference between the two devices in our study; however, our subjects were more satisfied with alexandrite laser, and the difference was statistically significant ($p = 0.01$) which may be due to slight higher reduction in number of hairs in Alexander group compared with diode group (35% vs. 32%respectively). Moreover, according to the current guideline suggestions, we tested the efficacy of six treatment sessions, but previous studies often tested the efficacy of only three to four treatment sessions [16, 18, 19]. The hair reduction rate using alexandrite laser in our study was 35% which is comparable with Goldberg and Ahkami report. In this study, 14 subjects received three treatments with two different pulse duration 755-nm alexandrite lasers (a 2-ms and a 10-ms system). Subjects were evaluated 6 months after the last treatments. The authors reported average percentage of hair reduction of 33.1%for the 2-ms pulse duration and 33.9% for the 10-ms pulse duration. No cutaneous pigmentary changes or scarring was noted 6 months after the final treatment [21]. Also, in another retrospective study on 89 subjects with skin types I–V, long-termresults of laser hair removal by using 755-nm alexandrite laser were evaluated over a 15-month period. Each subject underwent a minimum of three treatment sessions spaced 4–6 weeks apart on the axillae, bikini, extremities, face, and trunk areas. The subjects experienced a mean of 74% hair reduction.

Table 4 Skin biophysical parameters after treatment with the 755-nm diode and 755-nm alexandrite

Skin parameter	Laser	Before mean ± SD	Right after mean ± SD	Month 6 mean ± SD	*p* value [1]	p value [2]
TEWL	755 nm diode	46.09 ± 12.81	48.63 ± 13.07	60.63 ± 22.79	0.52	0.08
	755 nm ALX	49.39 ± 12.69	47.54 ± 12.14	56.12 ± 23.44	0.61	0.59
Erythema	755 nm diode	305.66 ± 73.67	259.62 ± 98.69	309.42 ± 62.94	0.05	0.44
	755 nm ALX	287.32 ± 61.42	303.47 ± 54.48	326.26 ± 53.34	0.21	0.13
Sebum	755 nm diode	8.94 ± 6.52	3.73 ± 5.28	3.73 ± 5.28	0.29	0.81
	755 nm ALX	7.44 ± 7.08	9.13 ± 11.11	4.8 ± 11.42	0.59	0.25

P-value 1: comparison between baseline and right after treatment

P-value 2: comparison between baseline and 6 months after last treatment

The authors reported transient postinflammatory hyperpigmentation, burn, and postinflammatory hypopigmentation which resolved without permanent scarring [22]. Both the safety and efficacy of our study results using alexandrite laser are supported by these studies. No severe adverse effects were reported in our study right after the treatment with both devices, as well as 6 months later. In this study, we also measured skin biophysical parameters to determine the safety of interventions. During last two decades, non-invasive methods have been introduced as good options for safety assessment in human volunteers [23]. Effects of hair removal alexandrite laser on biometric parameters of the skin have been previously evaluated by Alavi et al. [24]. They reported that four sessions of treatment with alexandrite laser for hair removal had no significant effect on TEWL and erythema index of skin but could decrease melanin content and make the skin thinner and increase elasticity and density of the epidermis and dermis. Here, we also did not find any significant changes in TEWL, skin sebum, and erythema index after treatment with both devices. These noninvasive measurements permit us to evaluate the skin conditions objectively and the findings are reliable enough to judge about the safety of the tested procedures, especially in case of novel technology, 755-nm diode laser. In conclusion, the current study showed that the 755-nm diode laser is suitable for hair removal procedures, and it is as effective and safe as the conventional 755 -alexandrite laser in darker white and light brown skin types (skin types III–IV).

Table 5 Pain assessment after laser treatments (VAS 0–10)

	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6
755 nm diode	5.15	4	4.11	4.94	4.11	4
755 nm alexandrite	5.47	4.05	4.52	5.29	4.51	4.07
p value	0.50	0.90	0.42	0.59	0.42	0.90

The most notable characteristic of this laser is the high energy that can safely be applied to subjects with Fitzpatrick skin types III–IV. However, comparative trials with longer posttreatment follow-up period (1 year) are required between the 755-nm diode laser and 755-nm alexandrite laser in different cases in terms of anatomical areas, skin phototype, and hair characteristics.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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Monitoring study of permanent hair removal with high power diode laser MeDioStar NeXT carried out

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1 Summary

Over the period of May 2011 and June 2012, a total of 27 patients were treated with a new type of diode laser during 157 sessions on 1-3 areas of the body. A number of 17 patients had already undergone up to 11 treatments with other systems for permanent hair removal and were either dissatisfied with the result or the side effects – both of which led to the termination of the therapy. A total of 20 patients were very satisfied or satisfied with the results of the treatment series, among them were 13 patients with prior treatment. For most patients the new laser system provided a successful, reliable, fast and painless method of permanent hair removal with no side effects. The system meets its limits when treating dark skin types and light-coloured hair.

2 Introduction

The wide variety of systems and technologies for permanent hair removal available in the market poses a real challenge for consumers. Diode lasers with a wavelength of 810 nm however, have become established as the most effective system available. The system tested during this study is a diode laser with wavelengths of between 800 and 950 nm. Thanks to a maximum fluence of 44 J/cm2, a maximum pulse frequency of 12 Hz and a spot diameter of 14x10 mm, large areas of skin are treated as fast as can be expected of a state-of-the-art system. The MeDioStar NeXT is distinguished by its SmoothPulse, which emanates fluence rates of up to 12 J/cm2 at a frequency of up to 12 Hz. This so-called Multipass technology ensures that the same hairy section is treated several times over several sequences within only a few seconds. The resulting cumulative heating effect leads to the required thermal damage.

The treatments with the technology described above were intended to assess their therapeutic efficiency and to find out whether diode lasers would have an additional therapeutic effect on patients that had been treated and were not satisfied with other methods prior to this study. Moreover, the range of undesired side effects particularly on pre-treated patients was to be assessed in comparison to other technologies. Also, the therapeutic effect of the SmoothPulse function and potential side effects were to be analysed.

3 Material and method

Patients

Between May 2011 and June 2012, a total of 27 patients aged between 25 and 60 years of skin types II-IV (acc. to Fitzpatrick), 4 of which male, two transgender (male -> female) and 21 female were subjected to a total of 157 treatments on up to three body areas. The number of treatment sessions varied between 1 and 7, which was due to the limited duration of the study and the fact that the equipment was only available for a number of days. Body areas treated included the lower leg, thigh, bikini zone and female genital area, abdomen, mammary papillae, chest, back, arms, armpits and face.

A number of 17 patients, two of which male, 1 transgender and 14 females had already undergone prior treatments involving both IPL systems and diode lasers with or without bipolar radio frequency flow.
Technology

The MeDioStar NeXT diode laser manufactured by Asclepion Laser Technologies was operated either in professional mode or in SmoothPulse mode. Frequently both modi were used in combination, a minimum of two sessions was always applied. The fluence was set according to the local reaction up to 15 minutes after treatment of a test spot. The setting focused mainly on the perifollicular oedema and diffuse erythema with or without oedema, which were analysed in combination with the skin type according to Fitzpatrick, the hair colour and the hair shaft thickness.

Assessment

The patients were asked to assess the treatment efficiency after one, three and six sessions. The questionnaire provided four assessment options (very satisfied, satisfied, not fully satisfied, not satisfied). The same applied to the evaluation of unwanted side effects. The medical assistant or doctor carried out these assessments in parallel. A photo documentation was not possible for all cases, because some patients did not wish to be photographed or there were no follow-up photos made.

4 Results

A majority of the 17 patients with previous treatment experience described the new diode laser as either more efficient (n = 14/17 or 82%) as having less side effects (n = 12/17 or 71%) or both (n = 11/17 or 65%).

20 patients of a total of 27 (74%) were very satisfied or satisfied with the treatment.
Of those 10 patients with previous treatment experience, 7 (70%) were satisfied or very satisfied, 3 patients did not make any statement, as they only received one treatment after which they were unavailable. Of all patients treated, the medical staff rated the treatments of 21 (78%) patients as satisfied or very satisfied, 1 (4%) was not fully satisfied and 1 (4%) was not satisfied.

During the Multipass approach, the SmoothPulse passed over the same area up to ten times. A total of 9 patients underwent treatment with conventional single and double-pulse methods as well as with the SmoothPulse technique. As expected, all patients experienced the SmoothPulse as clearly more pleasant, as it is virtually painless. The therapeutic efficiency was rated as comparable by patients and users alike.

One salient aspect of the assessment of unwanted side effects was the virtual painlessness, particularly of the Multipass technique. Only one patient had persisting confluent urticaria in the treatment area of chest and back, which was observed for three days and did not have any residues. However, similar side effects also occurred for seven days during previous treatment with ELOS technology.

5 Discussion

This monitoring study was intended to assess the therapeutic efficiency and the treatment window of a new diode laser for permanent hair removal. It included patients with various previous treatment experiences as well as previously untreated patients. Special focus was on the application of the not yet established Multipass technique with low fluence to larger areas.

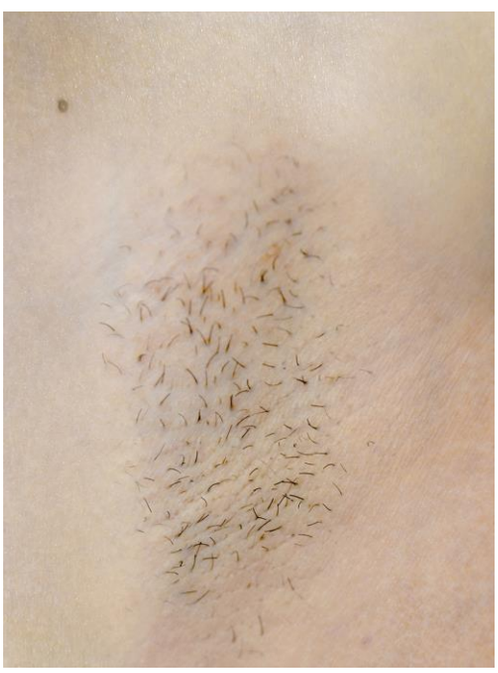
The reliable and permanent effect of a variety of epilation methods is undisputed.

For users and patients, benchmarking these technologies involves the therapeutic efficiency, as represented by the number of required sessions, the speed of the equipment and the duration of the individual sessions as well as the side effects. Moreover, the equipment is expected to be effective for a wide variety of skin types and epilation techniques.

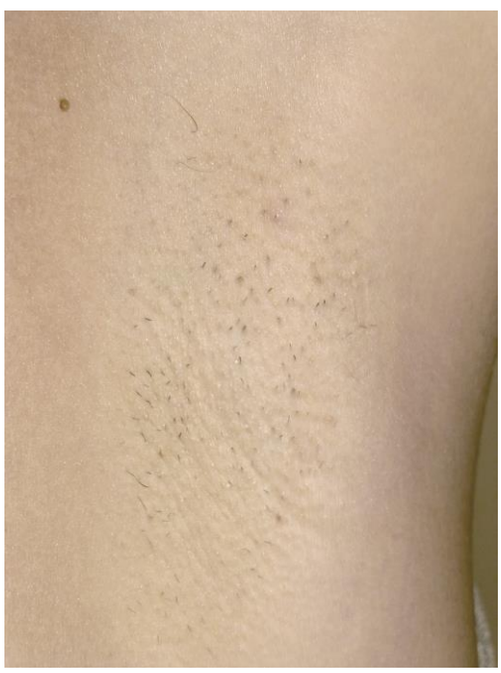
The medical experts themselves will also consider the investment and potential energy and material consumption costs as a critical factor for their decision.

In this study, the Multipass technique was proven as a very effective approach with a comparable response rate to conventional systems, high speed and virtually insignificant side effects, i.e. cursory erythema and short-term perifollicular oedema.

The MeDioStar NeXT diode laser has proven itself as a substantial enhancement of the range of epilation systems for permanent hair removal.



before treatment



after 4 treatments

Diode Laser Hair Removal: a Study with a new high power system

André Steps, Jena, Germany

The following paper reports a placebo controlled single blind prospective study, done to evaluate efficacy and safety of hair removal treatments performed by a dual wavelength high power diode laser of 800-950nm. The subjects treated were Fitzpatrick I-III of both genders in an age of 18 – 66 years.
Laser hair removal is based on the theory of selective Photothermolysis.[1] Firstly mentioned by Goldman in 1963, pulsed Ruby lasers were observed to remove hair in 1996. [2] After further trials have been made, longer wavelengths and pulse durations were found to be more efficient, such as Alexandrite (755nm), Diode (810nm) and Nd:YAG lasers (1064nm). Using an IPL represents the same method, but the wavelength is spread mainly into a broadband between 600 – 1200nm. Compared to Diode and Nd:YAG lasers, fluencies, IPLs are able to emit, are significantly reduced in most cases. Since the very beginning of hair removal some major problems had to be faced: How to distinguish the targeted chromophore Melanin in the hair and not to be treated epidermal Melanin? How saving the epidermis by applying a lethal dose to deeper localized hair reproducing tissues such as keratinocytes, stem cells and melanocytes inside the follicle? How to achieve an appropriate depth of penetration? Last but not least how to avoid any risk of paradoxical hair (re-)growth? Summarized, all influencing factors of the outcome of a hair removal treatment are wavelength (=depth of penetration, absorption), spot size, fluence, pulse duration, repetition, number of treatments and interval.[3] The authors of the study are convinced in using a high power diode of a wavelength λ=800-950nm is to be an appropriate tool for a save and efficient hair removal even in darker skin types.

Patients
This patients monitoring started with 33 subjects, dropout rate was 13.8% (n=4), 29 patients left, they were mostly female (n=18, 62%), 11 males (38%) underwent themselves the trial. Subjects were in an age of 22 - 68 (⌀=39.4years), treated three times within 18 weeks. The final results were observed 4 weeks after the third and last treatment. All of them were treated in axilla in both of the sides. Axillae were divided in five treatment zones and randomly treated.

Parameters
As an established[4] benchmark we used MeDioStar miXT (λ=810 + 940 nm, 10 – 500ms), spotsize of ⌀= 12mm. We compared with MeDioStar NeXT (spotsize 1 x 1.4cm), both of them manufactured by Asclepion Laser Technologies GmbH, Jena, Germany. Generally two different modes were applied: conventional high power single impulse mode (Professional) and a low fluence and high repetition rate mode (Smooth Pulse Mode).
Some approved parameters of MeDioStar miXT in Fitzpatrick skin type I/II represented benchmarks: 35 J/cm^2, 111ms (shortest possible pulse duration) at 1,5 Hz.[5] The same fluence was applied with the new model (MeDioStar NeXT) at pulse duration as short as possible of 82ms at 1,5 Hz, too. Additionally to those two modes we compared the new sublethal mode[6] (SmoothPulse Mode) with the setting of fluence = 10 J/cm^2, with a pulse duration of 20ms at 9,3 Hz. One of two randomized control areas was treated with 635nm diode, 0.5 J/cm^2, (xxx), single pulses with a pulse duration of 100ms.

[1] Anderson RR, Parish JA. Selective photothermolysis: precise microsurgery by selective absorption of pulsed radiation. Science 1983; 220:524-7.
[2] Goldman L, Blaney DJ, Kindel DJ, Frinke EK. Effect of the laser beam on the skin. *J Invest Dermatol* 1963;40:121-123.
[3] Nachweis fehlt
[4] Nemeth/ MSM
[5] McCoy papers
[6] Xxx alma soprano SHR mode

In Fitzpatrick skin type III following preset parameters were applied: benchmarking MeDioStar miXT with 30 J/cm^2, 95ms, 1.5 Hz and compared MeDioStar NeXT 30 J/cm^2, 70ms, 1.5 Hz. All the parameters for Smooth Pulse Mode and placebo treated area were exactly the same like those mentioned above.
During preparation it's been found that in using SmoothPulse Mode most influencing is the speed of moving the hand piece across the skin. Due to the high frequency one increases the applied fluence rapidly in moving the hand piece slowly, which is distributing more impulses in a certain area. In order to apply a comparable fluence of 35 J/cm^2 the hand piece in SmoothPulse Mode was moved forward with an average speed of 2cm/sec, accordingly to 4 impulses per area or a fluence of 40 J/cm^2.

Methods
Patients randomly matched three different modes (miXT professional, NeXT professional, NeXT SmoothPulse) and two control areas (untreated, but shaved, placebo treated and shaved). Those five randomized areas were photographically observed. For quantifying the results we applied a Trychodensometer (Neidel), which is a standardized mask with a measuring area of A=2cm^2, in which all the visible terminal hairs were counted before each session and finally 4 weeks after the last one. In order to evaluate the safety of the systems, all the zones were photographed 24h post op.

Results

Fitzpatrick I/II, conservative mode
After evaluating the hair reduction rate of visible terminal hair on the epidermis in axillae, treated by conventional modes of both of the machines, we found significant differences: In MeDioStar NeXT we measured 4 weeks after three treatments an average hair reduction of 64.3% (Median = 61.2%, spread: 29.8% - 90.9% reduction in visible terminal hair) using the NeXT Professional Mode with 35 J/cm^2, 82ms in 20 patients ($n_{♂}$= 8, $n_{♀}$=12) with Fitzpatrick I and II, subjects of both of the genders did not show significant differences in efficacy: 63.9% of the hairs in females were reduced, 65.2% of hair in males.
Hair reduction rates in axilla zones treated with MeDioStar miXT (35 J/cm^2, 111 ms) in Fitzpatrick I and II showed following results: average hair reduction of 50.1% (Median = 51.1%, spread: 17.2% - 85.7%), this method did not show significant gender related differences in efficacy (♂= 49.5%, ♀=52.6%).

Fitzpatrick III, conservative mode
Lower fluencies were used on remaining 9 subjects (31%, $n_{♂}$= 3, $n_{♀}$=6) with darker skin type (Fitzpatrick III), in both of the cases 30 J/cm^2 within 92ms (miXT) and 70ms (NeXT).
Results for 70ms-setting four weeks after the third treatment: the average hair reduction of all subjects was 65.1%, males improved 70.2%, females 62.6%, Median 63.8%. The authors reading of the significant difference between both of the genders are possibly caused by a very small number of subjects in the male cohort. Further trials are to be conducted.
Using the High power Diode with a pulse duration of t = 92ms the results of 9 individuals with Fitzpatrick III did not significantly differ to those treated by the short pulsed Diode: Average percentage of hair loss was 61.6% (Median 60.4%), in males 66.9%, females improved by 59.0%.

Fitzpatrick I-III, high frequency mode
In smooth pulse mode, subjects of all kind of skin types were treated with the same parameters, which were 10 J/cm^2 at 9.3 Hz repetition rate. The treatments were performed with a motion forward of an average speed of 2cm/sec. The combined factors were added to a total fluence of ~ 40 J/cm^2. The results for all the individuals were an average hair reduction of 67.1% (Median: 67.9), in female skin the results were not significantly increased than in male: ♂= 68.6%, ♀=64.6%.

Discussion

Once more, the high power diode laser proved to be an effective tool in the treatment of unwanted hair. We could see its efficacy both in the classical treatment procedure – established as pulse per pulse treatment – as well as in a relative new method, the smooth pulse mode. Side effects were low, and never exceeded a level of short time erythema. The MeDioStar NeXT is a safe and effective system for hair removal.

810-nm Diode Laser Offers 'Impressive' Results

Damian McNamar, Miami Bureau
Skin & Allergy News, June 2002, Volume 33, Number 6

ATLANTA — Researchers found no differences in hair removal efficiency or patient comfort when patients were treated on one side for 6 milliseconds and on the other for 40 milliseconds with an 810-nm diode laser, according to a study presented at the annual meeting of the American Society for Laser Medicine and Surgery.

In a double-blind study, 75 participants with unwanted hair were treated with the Asclepion MeDioStar 810-nm power-pulsed diode laser. The laser featured a 12-mm, sapphire-cooled tip and fluences of 10-40 J/cm2. All participants received a minimum of three treatments (range three-eight), and 84% were Fitzpatrick skin types II and III.

The study was a "real-world situation" because it included both patients who had previously had laser hair removal and those who had not, said Dr. Albert J. Nemeth, medical director of the Advanced Specialized Laser Center in Clearwater, Fla.

"We found impressive hair removal on both sides," he said. "Both 6 milliseconds and 40 milliseconds were equally highly efficacious." Results were the same for 69 out of 70 participants; the other participant experienced 20% more hair removal on the side treated for 6 milliseconds.

Hair removal efficiency improved after one, two, and three treatments in naive participants—an average of 26%, 45%, and 63%, respectively.

"This laser is very effective, but there is slower clearing in axillae and extremities," said Dr. Nemeth, also of the University of South Florida, Tampa. The most notable hair removal to date in this ongoing study is on the lip, chin, neck, bikini area, pubic area, beard, abdomen, back, shoulders, buttocks, and upper arms. All these areas had effective and rapid clearing. There was a fair response in the glabella region and the toes and a poor response on the ears. There were no significant differences in patient comfort. "Only three patients (4%) consistently found the 6-millisecond laser more comfortable," Dr. Nemeth said.

Adverse effects were rare. For example, only 4 of 619 total treatment sessions resulted in occasional crusting. No participant experienced scarring or permanent sequelae.

In another study presented at the meeting, Dr. Neil S. Sadick removed unwanted hair in 24 women using the Zeiss-Meditech 810-nm diode laser. The mean age of participants was 33 years; all received three monthly treatments with follow-up at 6 months. Patients had Fitzpatrick skin types II-IV, with light to dark brown hair. Dr. Sadick used a 12-mm spot size, pulse duration of 50 milliseconds, and a fluence of 25-35 J/cm2 to treat the face, bikini region, and axillae.

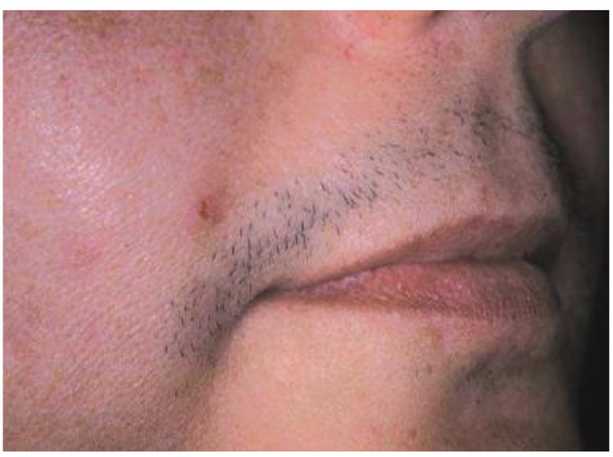
Handheld magnifiers were used to count hairs at baseline, after each treatment, and at follow-up. Two independent observers also performed hair counts using digital photography.

Adverse effects were rare: Two patients had transient hyperpigmentation, said Dr. Sadick of Cornell University, New York. At 3 months, there was a 74% mean hair removal efficiency, which was largely maintained at 6 months. Best results were attained in patients with type III skin who were treated for bikini-area hair.

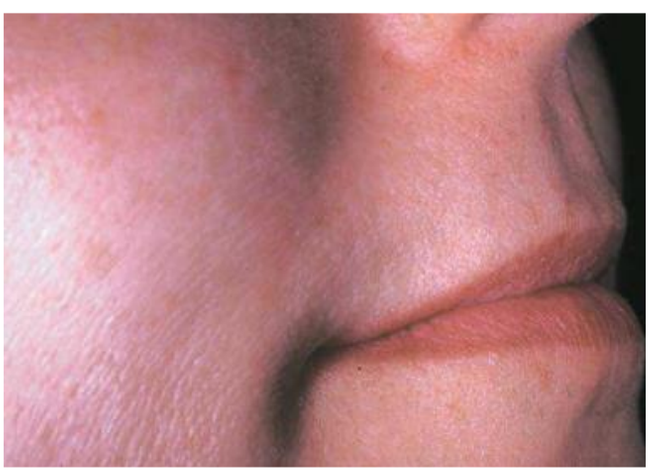
Five participants had biopsies at baseline, 1 month, and 3 months to assess histologic changes. There was vacuolar degeneration of the pilosebaceous outer root sheath, Dr. Sadick said. Biopsy results also showed multinucleated shaft cells.

Dr. Sadick disclosed that he received equipment and a research grant from Asclepion. Dr. Nemeth disclosed that he purchased one laser and a second was provided by the company for the comparative study.

This patient is shown before five treatments with the 810-nm laser with fluences of 29-32 J/cm2. Treatments were 6 weeks to 3 months apart.



Two months after treatment was completed, the patient's upper lip is still clear of unwanted hair.
Photos Courtesy Dr. Albert J. Nemeth



Study of Very Long-Pulsed (100 ms) High-Powered Diode Laser for Hair Reduction on All Skin Types

Eliot F. Battle, Jr., MD; R. Rox Anderson, MD
Wellman Laboratories of Photomedicine,Department of Dermatology,Harvard Medical School, Boston, MA -not published in a journal-Long-term, prospective study

Objective:
safety and effectiveness of long pulsed diode laser in permanent reduction of coarse pigmented hair in darker skinned subjects; Comparison of 30ms and 100ms in effectivity

Parameters:
Fluence: 15 – 100 J/cm²
Pulse duration: 30ms and 100ms
22 test sites, 6 for 100ms, 4 for 30ms, 1 control
11 for other fluence/pulse duration combinations

Patients: 40, 25 females, 15 males, All skin types

Evaluation of effectivity:
Hair counts by video camera an software
Before, 1, 2, 3 and 6 month after treatments

Side effects evaluated visually: pigment changes, erythema, edema, textural changes using a scale

Results:
Long pulsed diode laser provides effective, long-term reduction of medium to coarse pigmented hair, even in darker-skinned subjects.

Details:
- Long-term hair loss is strongly correlated with fluence level
- Hair regrowth after a single treatment is about 50-72% for high fluences
- the fluence levels for the 100ms pulse width can be increased to improve efficacy without compromising safety.

Safety:
Very long pulse widths allow for all skin types to tolerate substantially higher fluences, and thus darker skin types can be safely and effectively treated.

side effects
- transient pigment change was most common
- With 100ms a fluence of 30J/cm² could be safely used at all skin types besides type VI
- All patients with skin type VI had side effects, the test should be done with 10J/cm²
- Side effects increased with higher fluence, but at any given fluence they were significantly reduced with longer pulse durations.

Effects of the 810-nm diode laser on hair and on the biophys. properties of skin.

T. Ilknur et al.: Lasers Med Sci 2010, Oct.
Prospective, randomized, right – left comparison study

Objective: study was designed to investigate the effects of 810-nm diode laser treatment on hair and on the biophysical properties of the skin by using various non-invasive techniques on various parameters, including hair analysis, surface color changes, integrity of skin barrier, sebum production rate and pH level.

Parameter: MeDioStar HC, mode Basic and Professional, 810nm, 25 – 30J/cm², variable pulse up to 100ms, Spot size 12mm, Pre-cooling of skin by cold Aluminium probe

Patients: 31 women, 1 treatment of axilla, 4 patients with skin type II, 22 x III, 5 x IV

Evaluation of effectivity:
- before and 2, 4, 6 weeks after treatment treated area versus control area
- Hair analysis: hair density and thickness using photographs with digital microscope (zoom 30) and visual counting of the enlarged area
- Biophysical measurements:
  erythema index, melanin index (by Mexameter)
  transepidermal water loss (Texameter)
  capacity of stratum corneum hydration (Corneom.)
  Sebum secretion (Sebumeter)
  pH analysis (Skin-pH-meter)

Statistics (ANOVA, Bonferroni correction)

Results: Hair density and thicknesses statistically significantly decreased after the first post-treatment evaluation and remained during follow up.

Details: short-term changes of hair growth in our study was determined as:
49.68% in 2 weeks,
46.01% in 4 weeks,
and 48.15% in 6 weeks

Safety: The diode laser can perform a significant reduction in the hair amount without signifi cant epidermal damage, at least for a short period.

Details:
- erythema response with the diode laser can continue up to the second week.
- no difference in the Melanin index with the diode laser, although pigment changes are a common side effect of laser treatments in general
- no changes in the biophys. properties of skin, including transepidermal water loss, capacity of stratum corneum hydration, sebum and pH level

Epilation of 143 cases with diode laser

Yu Lin, Wang Min, Zhang Qiujie
Tianjin Changzheng Hospital , China, Dermatology Department

Prospective study

Objective:
To evaluate efficacy and adverse effect of diode laser assisted epilation

Parameter:
MeDioStar HC, 810nm, 20 - 29J/cm² dependent on skin type and area

Patients:
143 patients, 115 females, 28 males
treatment of lip, axilla, upper limb, lower limb, chest
3 – 5 treatments
4 patients with skin type II, 22 x III, 5 x IV

Evaluation of effectivity:
- photographs were taken before and 6 months after all treatments
- Hair counts in an area of 1 cm²
- clinical response was assessed according to the following criteria:
  cure (hair reduction≥80%),
  effective (hair reduction around 60%),
  poor (hair reduction<30%)
  side effects were documented

Results:
Diode laser assisted epilation is effective.

Details:
different anatomic sites exhibited different clinical response:
- Effect of hair removal for axilla is the best, that of upper lip, upper limbs, lower limbs and chest ranks behind in sequence.

Response is also different according to different skin type: Type III exhibiting the best effect and type V the poorest

Safety:
Diode laser assisted epilation is safe.

Details:
- Skill of operation and choice of treatment parameters are important factors, otherwise adverse effect such as blisters and hyperpigmentation is likely to occur.
- The adverse effect seen in 7 patients is not only caused by the above 2 factors, but is also due to too high fluence used in areas with dense hair and
- failure to remove hair adhering to handpiece during treatment

The Effect of Different Spot Sizes on the Efficacy of Hair Removal Using a Long-Pulsed Diode Laser.

Bäumler W, Scherer K, Abels C, Neff S, Landthaler M, Szeimies RM. Dermatol Surg 2002;28:118-121

Study design:
20 patients, skin type I-III, MeDioStar, 3 treatments only Fluence: 44J/cm² with 8mm spot size, 40J/cm² with 12mm spot size, 33J/cm² with 14mm spot size

Results:
3 month after 3 treatments regrowth was: 67% with 8mm spot size,
54% resp. 55% with 12 resp. 14mm. 15 month after 3 treatments regrowth was (for 12mm spot size): sparse in 4 volunteers, moderate in 5 volunteers, full in 7 volunteers , when evaluating 16 of 20 volunteers

Hair Removal with Long Pulsed Diode Lasers: A Comparison Between Two Systems With Different Pulse Structures.

Fiskerstrand EJ, Svaasand LO, Nelson JS. Lasers Surg Med 2003;32:399-404

Study design:
29 patients, skin type II-IV, 3 treatments only, upper lip
MeDioStarHC: PRO1, 12mm, Fluence 35J/cm²
LightSheer: 9x9mm, fluence 35J/cm²

Results:
MeDioStar: 49% hair reduction
LightSheer/Lumenis: 48% hair reduction
Side effects: no scarring or pigmentary changes
Less erythema and burned hair with MeDioStar

The Use of a New Diode Laser for Hair Removal.

Sadick NS, Prieto VD. Dermatol Surg 2003;29:30-34

Study design:
24 patients, skin type II-IV, MeDioStar, 3 treatments only Spot size 12mm,
fluence 25-35J/cm²

Results:
74% resp. 70% clinical hair removal efficacy at 3 resp. 6 months after 3 treatments; no serious side effect, 1 patient with transient hyperpigmentation for 2 weeks

Impressive laser hair removal with an 810 nm powerpulsed diode laser: safety and efficacy.

Nemeth AJ. EADV 2004

Study design:
200 patients, 978 treatments, MeDioStar, skin type I – VI fluence 10 – 36 J/cm², spot size 12mm

Results:
Hair reduction after 1. treatment: 26%, after 2. treatment 47%, after 3. treatment 64%; -
only 0,5% (5 treatments) transient hyperpigmentation