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## Evaluation of Safety and Efficacy of Variable Pulsed Light (VPL™) for the Treatment of Excess Hair in over 100 Volunteers

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### **Background:**

Several studies on Hair Removal with IPL and Laser Sources have been performed but adequate data on long term follow up is scarce. The present study evaluated safety and long term efficacy of Variable Pulsed Light (VPL™) on hair removal for medical and/or cosmetic indications.

### **Study design/material and methods:**

The Variable Pulsed Light (VPL™) system (Energist Limited, UK) was used with indications on multiple body sites ranging from face, chest, extremities to other locations in 102 otherwise healthy volunteers. The minimum follow up time after the last treatment was 9 months.

### **Results:**

Over 50% of hair clearance was observed in 85% of treated areas.

Erythema and Leucotrichia were the most often associated side effects. Transient pigmentary changes were not reported.

### **Conclusion:**

The VPL™ System presents as an efficient and safe treatment alternative for long term removal of unwanted hair. It is particularly effective in fair-skinned patients with dark hair (Skin Types II-III-IV). Adverse effects are minimal and transient and in no patient significant enough to interrupt treatment.

## INTRODUCTION

Hypertrichosis is a common cosmetic problem for both women and men; mechanical and cosmetic amelioration for destruction of the unwanted hair includes electrolysis (although tedious and painful, with efficacy rates of between 15% – 50% in long term hair removal), laser epilation and chemical epilation e.g. Eflornithin. Hirsutism is defined as the presence of terminal hairs in females in a male-like pattern affecting 5% to 15% of women. The management of this condition is often a significant challenge in spite of the availability of numerous possibilities for hair removal; this is important due to the associated side effects, as well as lack of efficacy and short lived effects.

Pulsed light sources, commonly referred to as Intense Pulsed Light (IPL), are devices which emit high intensity polychromatic light. Their output is non-coherent in nature and delivers wavelengths across a broad spectrum from 400nm to 1200nm and has the possibility to adapt to different skin types and indications. By placing appropriate filters over the light source, the specific wavelength of choice (dependent upon different indications) can be selected.

The treatment is highly dependent on skin type and hair colour as well as hair coarseness. Cooling is achieved by a layer of transparent cooling gel.

The indication for use of refrigerated gel is to minimize unwanted epidermal injury, particularly in dark skin individuals, who have high melanin content and associated increased energy absorption transformed into heat. Its use thus reduces local unwanted damage and increases tolerance to treatment. Additionally, by utilising the high water content of the gel we can reduce the difference in refractive index, between air and tissue, and thus decrease the angle of refraction, so enabling more photons to penetrate the tissue.

The Variable Pulsed Light (VPL™) system utilises bursts of filtered visible light, in which each burst is made up of a series of narrower pulses. The unique properties of the VPL™ system are in its ability to change the number, width and delay between the micro pulses. These micro pulses of light ensure the target reaches its desired temperature with little effect on the surrounding tissue, thus reducing the incidence of unwanted side-effects. The VPL™ system utilises a glass filtering mechanism to allow output wavelengths in the range from 530nm to 950nm and 610nm to 950 nm and a secondary water jacket to eliminate any water absorbing wavelengths that may be present. This ensures that the treatment is more tolerable with much less non-specific thermal damage.



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The mechanism of hair removal by use of lasers, pulsed light and VPL™ is based on the principle of selective photothermolysis by targeting specific energy absorbing molecules and/or organelles called chromophores, e.g. such as melanin. The melanin-containing melanocytes within the hair follicles absorb light in a spectrum ranging from ultraviolet to infrared wavelengths and the energy absorbed by melanin is transformed into heat that is capable of damaging the surrounding germinative cells.

Hair in the anagen phase responds to laser and IPL™ or VPL™ because of an increased concentration of melanin within the hair follicles. Since hair follicles in the catagen and telogen phase lack melanin, the possibility of light (energy) absorption and subsequent heat generation is significantly reduced; the result is thus a reduced capability of follicular germinative cell damage with subsequent hair removal. Due to the lack of energy absorbing chromophores, lasers, pulsed light systems and VPL™ are not able to induce removal of white hairs. In some selected of patients there is reversible white/clear hair re-growth after application of pulsed light or VPL™ use for hair removal.

The aim of this study was to document our center's clinical experience with 102 patients treated with VPL™ for hair removal in different sites of body with different energies and number of treatments.

#### PATIENTS & METHODS

A total of 102 patients were included in the study. Of these 14 patients were lost to follow up and could not be evaluated for results. On the remaining 88 patients, 106 areas were treated for removal of unwanted hair and were evaluable for final statistical analysis (Table 1).

The majority of treated areas was in female patients (n=101, 95,28%, males: n=5, 4,72%). The Fitzpatrick skin types were distributed as follows: 19,81% (n=21) were skin type II, 43,40% (n=46) were skin type III, 33,02% (n=35) were skin type IV, 2,83% (n=3) were skin type V and 0,94% (n=1) skin type VI. Most areas treated for hair removal were located in the face (n=77, 72,64%), the rest on the trunk (n=20, 18,87%), in the axilla, the bikini zone (n=8, 7,55%) and legs (n=1, 0,94%).

A strict medical indication for hair removal was identified in 21 of all areas treated: pilonidal

sinus in 3 patients and recurrent folliculitis in 18 patients.

Prior to VPL™ treatment, sixteen (16) patients (17%) reported having undergone laser-hair removal with other systems such as the Ruby, Diode, Nd:YAG and Alexandrite lasers with no evidence of long term hair growth reduction. Patients with recent sun exposure and mild photosensitivity were not excluded. Informed consent was obtained from all patients.

**Table 1. Patients' characteristics**

<b>Patients</b>	<b>n=102</b>
<b>Total Number of Treatments</b>	<b>n=106</b>
Male patients	n=4 (4,72%)
Female patients	n=98 (95,28%)
<b>Fitzpatrick Skin Type</b>	
II	n=21 (19,81%)
III	n=46 (43,40%)
IV	n=35 (33,02%)
V	n=3 (2,83%)
VI	n=1 (0,94%)
<b>Treatment Areas</b>	
Face	n=77 (72,64%)
Trunk	n=20 (18,87%)
Axilla/bikini zone	n=8 (7,55%)
Legs	n=1 (0,94%)

Treatments were performed with a VPL™ System (Energist Limited, U. K.) with a 610 nm hand piece and 5cm x 1 cm spot size was used. Pre-cooled cooling gel was always applied generously before the treatments on the treatment area.

The initial treatment settings were adjusted according to skin type and hair thickness. In order to gauge individual patient pain tolerance the initial settings were set at the low range of known effective fluence.

Treatments were generally repeated until no re growth of hair in the treated area was observed at the following visit after 4 to 6 weeks. The mean number of treatments per patient was 6,76 (range: 2 to 18) treatments. The time interval between treatments was chosen depending on the known physiological growth characteristics of the hair at the specific location: Face: four to five weeks, axilla 8 weeks, legs 10 to 12 weeks. Patients were instructed to stop shaving or waxing prior to the following treatment.

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The long-term efficacy of the treatment was evaluated clinically and by photographic documentation using the teach screen-monitoring system (Foto-finder; Germany). After 9 months minimum follow-up hair clearance was analysed grading the response to treatment into four categories:

1. Very good (loss of treated hairs: 75 % or more)
2. Good (loss of treated hairs: 50– 75%)
3. Moderate (loss of treated hairs: 25–50%)
4. No response (loss of treated hairs: less than 25%).

The clinical grading was further substantiated by comparing pre- and post treatment photographs. Additionally side effects of the treatment, such as erythema, leucotrichia and hyper- and hypo pigmentation, were evaluated after each treatment by the investigators.

## RESULTS

Over 50% hair clearance was observed in 85% of the treated areas.

The overall treatment response after a follow up of a minimum of 9 months was as follows: Most of the patients yielded a very good (hair clearance >75%, n=36, 33,96%) or good (hair clearance 50-75%, n=54, 50,94%) long term treatment response. Moderate long term treatment response (hair clearance 25-50%) was observed in 12 cases (11,32%) and treatment failure in 4 cases (3,77%)

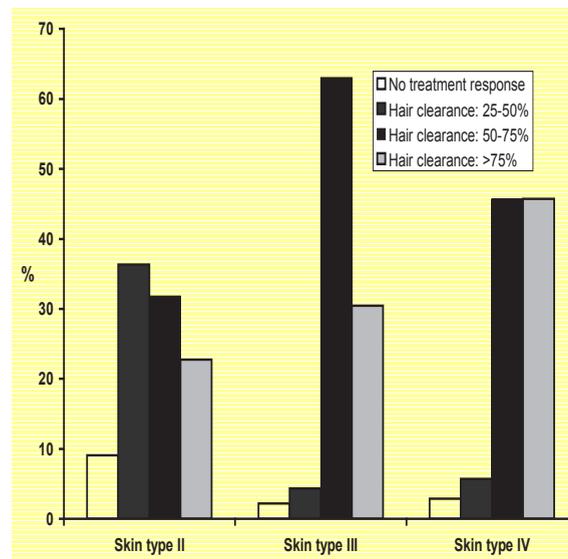
There was no significant difference ( $p>0,05$ ) in the energy fluence levels between patients who demonstrated very good response (mean:  $37,80 \pm 3,58$  J/cm<sup>2</sup>) and patients with moderate or no response (mean:  $40,23 \pm 3,66$  J/cm<sup>2</sup>)

The mean number of treatments was slightly, but not significantly, higher ( $p>0,05$ ) in patients in the group of very good treatment response ( $7,50 \pm 3,24$ ) in comparison to patients with moderate or no treatment response ( $6,97 \pm 3,77$ ). Concerning patients' characteristics we observed that patients who showed a very good long term treatment response were predominantly skin type III (n=14, 38,89%,  $p<0,05$ ) and skin type IV (n=16, 44,43%,  $p<0,$ ), in comparison to patients with skin type II who prevailed in the groups with moderate long term treatment response (n=8, 80,00%) or long term treatment failure (n=3, 66,67%) (Figure 1.).

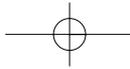
Patients yielding a very good treatment response were also significantly ( $p<0,05$ ) younger ( $33,3 \pm 6,05$ ) compared to patients with moderate or no treatment response ( $40,53 \pm 6,52$ ). A significant relationship between anatomic location of excessive body hair and treatment success could not be observed.

As for the adverse effects, no scarring or pigmentary changes of the skin were observed after treatment with the VPL™ System. However, 10 patients developed reversible leucotrichia. Reversible leucotrichia presented itself as clear hairs in the face area, which all regained their natural colour after about 10 weeks. One patient also reported multiple follicular small blisters in the abdomen area one day after the treatment. Since these lesions resolved without any medication after a few of days, they could not be identified by the investigators. Erythema was seen often immediately post treatment, but resolved within a few hours.

The adverse effects were minimal and transient and in no case presented an indication for cessation of treatment.

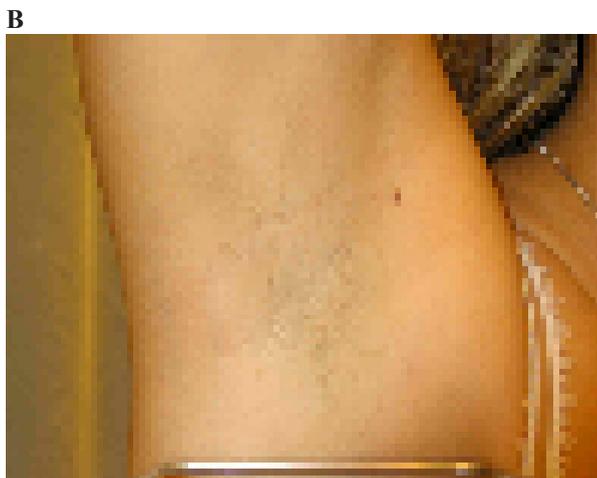


**Figure 1.** Relative distribution of treatment results according to Fitzpatrick skin types II, III and IV: Patients with skin type III and IV generally demonstrated a better treatment response than patients with skin type II



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**Figure 2.** Depilation of hair in the axilla with VPL:  
Before treatment (A) and  
9 months after the last treatment (B)

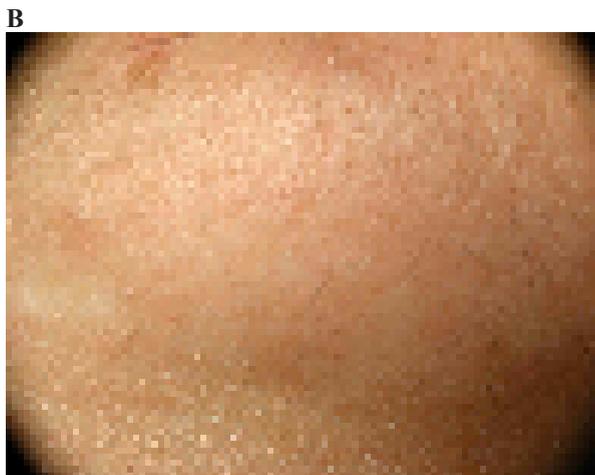


**Figure 3.** Removal of facial hair with VPL:  
Before treatment (A) and  
11 months after the last treatment (B)



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**Figure 4.** Detail view of facial skin treated with VPL:  
Before treatment (A) and  
10 months after the last treatment (B)



## DISCUSSION

The concept of hair removal has recently been defined as a delay in hair growth, which usually lasts for 1-3 months, consistent with the induction of telogen hairs. Permanent hair reduction refers to a significant reduction in the number of terminal hairs after a given treatment, which is stable for a period of time longer than the complete growth cycle of hair follicles at the given body site. Recently it has been suggested to add 6 months to this post treatment observation time.

We have observed our patients for at least 8 months and seen differences in the time for hair to regrow. In some patients we have observed after 1 year the same picture as after the last treatment, and in some patients hair regrowth after only 2 months was observed for reasons and interpretations unknown. However, the hairs that re-grew were thinner and lighter, and we

were able to achieve better results with additional treatment in longer intervals.

In contrast to the usual pulsed light system used at our, and other institutions, we have observed a significantly higher safety profile for the VPL™ system. Increases in energy density of up to 45 J/cm<sup>2</sup> (maximum) without adverse effects of note were easily achieved. It thus appears, that the VPL™ system used is extremely safe because the temperature rise in the hair follicle and surrounding tissue is slow (the bursts of light ensure the target reaches its desired temperature with little damaging effect on the surrounding tissue). The OFF Delay (the time between each micro-pulse) was chosen between 1ms and 20 ms and, so it could be used on patients with darker or sensitive skin, such as patients who also suffered from atopic dermatitis.

## CONCLUSION

The VPL™ system presents itself as a highly efficient and safe method for long term hair removal. Additionally, the VPL™ system was highly effective in a group of patients which also included those who had previously failed other forms of treatment.

The associated side effects were minimal, so that none of the patients had to interrupt treatment. Additional long term observations and controls, as well as application of repeat treatments at pre-determined time intervals have shown a long term efficacy of long lasting hair removal in this subset of patients.

## REFERENCE

1. Wagner R. F., **Physical methods for the management of hirsutismus.** *Cutis* 1990; 45:319-326
2. Hatch R., Rosenfield R. L., Kim M. H. and Tredway D.; **Hirsutism: Implications, etiology and management.** *Am J. Obstet Gynecol.* 140(1981) pp. 815-830
3. Dierickx C.C., **Hair removal by Lasers and intense pulsed light sources** *Dermatol. Clin.* 2002 Jan; 20(1):135-146
4. Raulin C., Greve B., Grema H., **IPL technology: a review** *Lasers Surg. Med.* 2003;32(2):78-87
5. Altman D.J., Huber F., Schrode K., et al, **Randomized double blind, Vehicle controlled safety and efficacy evaluation of eflornithine 15% cream in the treatment of women** Poster presented at

Submitted for publication 26<sup>th</sup> July 2006

- the 58<sup>th</sup> Annual meeting of the AAD. USA; March 10-15/2000, San Francisco
6. Dierickx C.C., Grossmann M.C., **Laser hair removal in: D.J. Goldberg Laser and Lights Volume2.** USA:2005 Elsevier Saunders 61-76
  7. Nanni C.A., Alster T.S., **Laser-assisted hair removal: Side effects of Q-switched Nd:Yag, Long-pulsed ruby and alexandrite Lasers** JAAD 1999;41:165-171
  8. Tanzi E.L., Lupton J.R., Alster T.S., **Lasers in dermatology: Four decades of progress** JAAD 2003;49:1-31
  9. Goldberg D.J. **Laser Hair Removal** UK:2000, Martin Dunitz Ltd.
  10. Dierickx C.C. **Hair removal by Lasers and intense pulsed light sources in: R.E. Fitzpatrick, M.P. Goldman Cosmetic Laser Surgery** USA: 2000 Mosby 176-197
  11. Weiss R.A., Weiss M.A., Marwaha S., Harrington A.C. **Hair removal with a non-coherent filtered flashlamp intense pulsed light source** Laser Surg.Med.1999;24: 128-32
  12. Sadick N.S., Shea C.R., Burchette J.L., Prieto V.G. **High-intensity Flashlamp Photoepilation: a clinical, histological and mechanistic study in human skin.** Arch. Dermatol. 1999;135: 668-76
  13. Sadick N.S., Weiss R.A., Shea C.R., Nagel H., Nicholson J., Prieto V.G. **Long-term Photoepilation using a broad-spectrum intense pulsed light source** Arch. Dermatol. 2000;136:1336-40

**Keywords:** *hair removal; VPL; variable pulsed light; hypertrichosis; selective photothermolysis; pulsed light*

