**Brief Report on the Novalight CPL Technology**

**Evaluation of a 3rd Generation Intense Pulsed Light System (IPL)**

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**General Introduction**

Intense pulsed light systems for aesthetic applications in medicine have become the devices of choice for the treatment of ‘photo-ageing’, for non-ablative rejuvenation, for hair removal, and for improving the skin condition related to ageing to an increasing extent. Pigmented lesions and small vascular disorders may also be treated successfully. Intense pulsed light systems are attractive for medical practitioners seeking equipment with a variety of treatment options.

Shorter wavelength selection is effective in targeting hair elimination, as well as vascular, and pigmentation changes associated with skin ageing. Longer wavelengths in the near infrared band are effective for skin rejuvenation – based on the effects obtained by dermal remodeling via collagen and elastic fiber stimulation.

A controlled pulsed light (CPL) device is now available with a new and interesting feature, which provides the possibility of selecting maximum light energy in the desired band of the visible or the infrared spectrum. Moreover, this Novalight CPL device which is small, light, readily portable and simple to operate is also capable of delivering energy in a single, double or triple pulse mode (Fig.1). The possibility of obtaining a controlled flash of light in the desired visible or infrared spectrum enhances the accuracy and efficiency in treating various skin conditions.

*Fig. 1: The Novalight system and filters used*
When lasers or intense pulsed light devices are used for hair removal, the question arises, as to what is defined as the principal target, in order to obtain the most successful treatment. Numerous studies suggest that if the heat is confined to the hair bulb, or thermal effects are transferred to the shaft, this is insufficient to achieve permanent hair elimination. Scientific rational and clinical follow-ups suggest that treatment should focus on all components of the hair structure, including adjacent vascular items and tissue. At the same time, protection and preservation of the epidermis is of mandatory importance.

To match these requirements and produce a consistently reliable course of treatment, both wavelength and a significant amount of energy should be transferred by means of a relatively long pulse, maintaining the prior condition of the epidermis. The Novalight CPL seems to offer an attractive solution to all these challenges. Presently, a number of trials have been initiated to demonstrate these capabilities for hair removal and other applications related to skin aging.

We have conducted an examination of the technical and clinical plan of Novalight CPL that was CE marked by the French organization GMED (CE No.3166).

I-Technical evaluation

Technical introduction

The system itself comprises a 15kg portable CPL, equipped with a single hand-piece. The lamp is a straight type with no need for pre-ignition; light is transmitted through quartz to a spot size of 7.65cm². It has three types of cap-shaped filters, for fair to dark skin phototype patients (Fig.1). An Ultrasound gel should be applied for optical coupling. The pulse durations range from 10ms to 240ms and the fluency settings range from 8 to 20 J/cm².

Materials and methods

A) Fluence measurement:
The CPL applicator (hand-piece) was tested on two different types of energy detectors and as a first step it was determined that the preset CPL display panel energy corresponded exactly with that recorded by the energy detectors. In addition to this, and based on 10 consecutive measurements, it was observed that the measured fluences were homogenous. For these trials, the fluence selected on the CPL display panel was 13 J/cm² at a pulse duration of 20ms, using the fair skin phototype filter.
B) Pain assessment:
At a second step the pain sensation level was determined on 10 patients, measuring it in terms of a visual analogical scale (VAS). Settings of 13 J/cm² and 20ms used in the axilla (armpit) region during depilation were all time homogenous. Dark or black haired patients of phototypes II to V with non-tanned axilla and variable hair densities were selected.

Results

A) It was found that with average fluences of 11.95 J/cm² for energy detector # I and 12.45 J/cm² for energy detector # II, the fluences measured were homogenous throughout the 10 measurements carried out.

B) The pain average was found to be 2.5cm on the 0 to 10cm VAS scale.

Discussion

Measured fluences were within the boundaries of 20% as stated by the manufacturer which is considered to be adequate for an IPL machine. Homogenous measurements mean that treatment results are reproducible from one area to another. The visual analogical scale shows a current relative homogeneity within the frame of reference related to pain.

The sensory nerve cells in the dorsal horn of spinal cord which relay cutaneous nociception to central nervous centers also posses the ability to perform both spatial and "temporal" summation of cutaneous afferent pain signals. The term spatial summation implies multiple sensory nerve inputs from a few nerve endings within smaller areas of treatment. Likewise, a series of shots delivered to adjacent skin areas with a rapid rate of repetition will cause the central nervous system to sum the pain from the individual shots.

This CPL treatment causes minimal pain only. It has to be recognized, however, that there are slight individual variations, depending on the differences of hair densities. The result is strictly comparable with that produced by other IPL’s with a small perifollicular edema.

Conclusion of the technical evaluation

The long-term testing fluence reproducibility as determined by an external energy detector and the homogeneity of its repetition within the skin contact zone confirmed that the Novalight CPL can be used under maximum safety conditions. The low pain level registered in a group of test patients during depilation of the axilla provides undisputed evidence of a comfort advantage.
II-Preliminary Clinical Observations on Hair Removal

Technical laboratory trials
We have implemented various basic trials as shown in the protocol of study (Fig. 2) based on visual control of tissue reaction and biopsy outcome

- The program selection has been represented graphically with a view to better appreciation of the relationship between pulse shooting and heat build-up in tissue (Fig. 3a & 3b)
- Ten volunteer patients were administered comparative treatment with the DYE 585 pulse laser – using parameters recommended for skin rejuvenation, in order to determine the tolerance to the delivered energy and the side effects developed immediately after treatment (Fig. 4).

Fig. 2: Protocol of study
Fig. 3a: Relationship between pulse shooting and heat build-up in tissue during treatment of ageing skin: the whole bell shape corresponds to a single pulse.
Fig. 3b: Relationship between pulse shooting and heat build-up in tissue during hair removal.
Fig. 4: Comparative treatments with the DYE 585 pulse laser
Clinical Trials

- Ten patients were selected whose characteristics are detailed (Table 1).

![Table 1: Patient selection]

For these trials, energy mode #5 was selected, as well as option 1 with short pulse duration. These settings correspond to the maximum of the spectrum emitted between 570 and 880nm, and with an effective energy work time of 20ms. The prolonged duration of energy activity is obtained by a single pulse which progressively builds up heat in the target for sustainable therapeutic effects in hair elimination (Table 2).

![Table 2: Sustainable therapeutic effects in hair elimination by a single pulse (upper graph)]

Progressively built up heat for maintained energetic action in non-ablative resurfacing (lower graph)
Preliminary tests were conducted to observe the effectiveness of hair removal with Novalight CPL, both macroscopic (short-term) and histological for the purpose of evaluating immediate effects (Fig. 5, 6 & 7).

**Fig. 5:** Skin, He/Eo x 100, prior to Novalight CPL treatment. Epidermis and dermis appear normal, showing hair structures with standard characteristics in all its components.

**Fig. 6:** Skin, He/Eo x 100, immediately after Novalight CPL treatment for hair removal. Epidermis appears normal, with contracted dermis and eosinophilic staining of collagen fibers. Lymphocytic inflammatory infiltration was noted, particularly at perifollicular locations.

**Fig. 7:** Skin, Masson Trichromic x 400
Examination of hair folliculi at larger magnification shows collagen fiber separation, corresponding to an edema phenomenon.

Histological, perifollicular edema and inflammatory infiltration were observed immediately after using Novalight CPL for hair removal. This demonstrates preferential absorption of the energy pulse delivered according to the aforementioned parameters. At the same time, the edema appeared to separate the collagen fibers, as a reaction to the thermal diffusion affecting the surrounding hair structure. These observations may be interpreted as a source of beneficial results, from the therapeutic point of view, indicating the potential effectiveness of Novalight CPL for hair elimination.
At clinical level, it was noticed one month after treatment that in contrast to regular razor shaved areas there was no hair re-growth, in areas such as the legs, where patients had been treated with Novalight CPL (Fig. 8 & 9).

Fig. 8: A large area of the leg was selected for testing the treatment effectiveness of hair removal by Novalight CPL versus regular razor shaved areas. Areas I & II were regularly shaved to the same extent but Novalight CPL was only used in area I (Option 1, energy mode 5, high energy pulse).

Fig. 9: One month after treatment hair is seen re-growing in the shaven area II but not in area I (where Novalight CPL was used).

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Figure 2: Protocol of study

Figure 3: Relationship between pulse shooting and heat build-up in tissue

Figure 4: Comparative treatments with the DYE 585 pulse laser

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Figure 7: Skin, Masson Trichromic x 400 Examination of hair folliculi at larger magnification shows collagen fibre separation, corresponding to an edema phenomenon (Fig.7 & 9).

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Table captions for tables 1 to 2

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