Intense Pulsed Light Pulse Configuration Manipulation Can Resolve the Classic Conflict Between Safety and Efficacy

Inna Belenky PhD, Cruzy Tagger MD, and Andrea Bingham RE
Viora Ltd., Jersey City, NJ

ABSTRACT

The widely used intense pulse light (IPL) technology was first commercially launched to the medical market in 1994 and similar to lasers, is based on the basic principle of selective photothermolysis. The main conflict during treatments with light-based technologies is between safety and efficacy of the treatment. The aim of this study was to evaluate new IPL technology, which integrates three different pulse configurations, with specific attention on the safety and efficacy of the treatment. 101 volunteers (with Fitzpatrick skin types I-VI) were treated as follows: 9 patients underwent 8 bi-weekly acne clearance treatments, 51 patients underwent 6-12 hair removal treatments, 11 patients were treated for general skin rejuvenation, 15 patients were treated for pigmentation lesions, and 15 patients were treated for vascular lesions. No serious adverse events were recorded. All patients that were treated for hair removal achieved significant hair clearance. The patients with facial rosacea responded the fastest to the treatment. Eight of nine patients that were treated for acne clearance achieved significant reduction in acne appearance. The results represented in this study support the approach that when taking into consideration both efficacy of the treatment and safety of the patients, the system should be “flexible” enough to allow exact treatment settings profile for each patient, according to their skin type and the symptom’s biophysical characteristics.


INTRODUCTION

The widely used intense pulsed light (IPL) technology was first commercially launched to the market for medical use in 1994 and since then, many different devices and technology modifications have been introduced. Like in laser technology, IPL technology is based on the basic principle of selective photothermolysis, wherein the absorption of photons via endogenous or exogenous chromophores within the skin are transferred as light energy. This transfer generates heat and subsequently destroys the target tissue. The target chromophores in aesthetic applications are melanin, hemoglobin, water and porphyrin, which show broad light absorption spectrums. Since IPL technology emits a spectrum of wavelengths, these chromophores can be activated with one single light exposure, with convertible cut-off filters. On one hand, this versatility implies a reduced selectivity to the target chromophore, but the specific wavelength together with the precise pulse duration will increase the selectivity in the photothermolysis process. As selective photothermolysis aims to destroy the target tissue without harming the surrounding tissue, the specific cut-off filters (based on the target chromophore absorption profile) and the specific pulse duration (based on thermal relaxation time - TRT), should both be adjusted accordingly. In other words, the patient’s skin type and skin condition will determine the choice of suitable cut-off filter, while the biophysical characteristics of the target chromophore will influence the pulse duration. Pulse duration influences the optimum level of thermal absorption, but in order to prevent unselective damage to the surrounding tissue, the general rule of thumb is the pulse duration should be shorter or equal to the TRT of the target tissue. The combination of particular wavelengths, pulse durations, pulse intervals, and energy fluence, facilitates the treatment of a wide spectrum of skin conditions, such as unwated hair growth, acne vulgaris, pigmented lesions, vascular lesions, and other symptoms of photoaged skin.

However, the main conflict during treatments with light-based technologies is between safety and efficacy of the treatment. While high energy fluence may lead to higher thermal effect (more heat generation) and thus to more effective outcomes, the chance to accidentally cause side effects and complications also increases, especially for dark skin and Asian origin patients.

Hence, several manufacturers developed IPL technology with unique manipulations and changes in the pulse structure (or pulse configuration) with the safety profile of the treatment being the main consideration, while keeping a level of high performance.

The aim of this study was to evaluate new IPL technology, which integrates three different pulse configurations, with specific attention on the safety and efficacy of the treatment.

MATERIAL AND METHODS

Case Study Group
A group of 101 volunteers (57 females and 44 males) aged 15-70 years (average age, 39.6 years) with Fitzpatrick skin types I-VI participated in the study.
Device Description
A new IPL handpiece (Viola LTD, NJ) with PCR™ (Pulse ConfiguRhythm) technology using three integrated distinct pulse configurations, single, multiple, and rapid, was used in the study. The single-pulse configuration represents a typical square (smooth) pulse structure, while the multiple-pulse configuration represents a pulse that is divided into three sub-pulses with two delays between them. The delay allows the epidermal cells and smaller vessels to cool down between pulses while the heat is retained in the target tissue (vessels, hair follicles, etc.). This results in selective thermal damage (the principle of thermokinetic selectivity). Consequently, this multiple-pulse configuration enables high fluence delivery to the skin with elevated safety treatment profile and deeper depth penetration. The rapid-pulse configuration represents a train of short and low fluence pulses with several passes over the treatment area, which enables gradual heating of the target tissue while avoiding injury to the surrounding tissue. This pulse configuration is most suitable for darker skin patients who usually cannot be treated with typical IPLs. The determination of single-, multiple-, or rapid-pulse is dependent upon skin type (I-VI) and the symptom's depth.

The handpiece incorporates changeable cut-off filters, including skin rejuvenation (580nm), vascular and pigmented lesions (530nm), acne clearance (415nm), and long-term hair removal (570 and 630nm). In addition, the handpiece enables the application of pulses at a maximum energy fluence of 35J/cm², with a 10-205 msec pulse duration range and two spot sizes, 6.4 and 2.4 cm². It also integrates TEC contact cooling, which is customizable per application, meaning that the contact temperature changes according to the cut-off filter.

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Treatment Regimen
Nine (9) patients underwent a total of 8 bi-weekly acne clearance treatments with the 415nm cut-off filter. Fifty-one (51) patients underwent 6-12 hair removal treatments with 4-12 week intervals (depending on the treatment area) using the 570 or 630nm cut-off filters (25 patients with 570nm and 26 patients with 630nm). Eleven (11) patients were treated for general skin rejuvenation with the 580nm cut-off filter for 4 treatments with 2-4 week intervals in-between. Fifteen (15) patients were treated for pigmentation lesions, including solar lentigo, freckles, and solar keratosis (10 patients with 530 nm and 5 patients with 580nm) for a total of 2-5 treatments of 3-4 week intervals. Finally, fifteen (15) patients were treated for vascular lesions, including small facial telangiectasias, facial and chest couperose, and facial rosacea (11 patients with 530 nm and 4 patient with 580nm) for 3-6 treatments at 3-6 week intervals.

Clinical Assessment
Clinical photographic assessments were recorded in two phases: (1) at baseline prior to the first treatment and (2) four weeks after the final treatment of the treatment course. Additionally, the treating practitioners were asked to record, and immediately report, any adverse or unexpected side effects.

The hair removal efficacy was assessed as short-term efficacy up to 12 months postoperatively, while skin rejuvenation, pigmented and vascular lesions were evaluated 4-8 weeks post final treatments and acne clearance 8 weeks post final treatment.

RESULTS
All 101 patients completed the treatment course according to the relevant indications, and visited the treatment center for at least one follow-up visit after 4 weeks (in the case of acne clearance) up to 12 months (in the case of hair removal).

The side effects were limited to slight erythema and edema, which is considered a positive end-point for most of the applications. No serious adverse events were recorded.

Hair Removal
All 51 patients that were treated for hair removal achieved moderate to significant hair clearance, depends on the hair type, color, and Fitzpatrick skin type. The female axilla and pubic region, as well as deep dark hair responded the best with notable change already post one treatment. Also female legs and male back areas responded moderately well to the treatment, depending on the hair color. The moderate response was mostly seen on very light hair, female arms, and male shoulders (Figure 1). Body areas with thick and dark hair and deep hair follicles were treated with the 630nm cut-off filter. The skin phototype influenced the pulse configuration, wherein the lighter-medium skin types (Fitzpatrick I-IV) were treated with single-pulse configuration, medium skin colors (Fitzpatrick III-V) with multiple configuration, while dark skin phototypes (Fitzpatrick VI) were treated with rapid-pulse configuration (Figure 1).

Vascular Lesions
The 15 patients that were treated for vascular lesions were mostly treated with the 530nm cut-off filter, while the 580nm filter was used for deeper vascular lesions, such as deep facial
FIGURE 1. A 65-year-old male (Fitzpatrick IV) before (left) and 4 weeks after 1 treatment session (right) with the 630nm cut-off filter, multiple pulse structure, 40 msec pulse duration and 12 J/cm² energy fluence.

FIGURE 2. A 55-year-old female (Fitzpatrick II) before (left) and 2 weeks after 4 treatment sessions (right) with a 530nm cut-off filter, single pulse structure, 12 msec pulse duration and 16 J/cm² energy fluence.

Spider veins. The patients with facial rosacea responded the fastest to the treatment with significant clearance as soon as post 2 treatments (Figure 2). The blood vessel depth and patient’s skin prototype influenced the pulse configuration, whereas the shallow vessels and lighter-medium skin types were treated with single pulse configuration, medium skin colors with multiple pulse configuration.

Pigmented Lesions

All 15 patients that were treated for pigmentation lesions exhibited immediate darkening of brown pigment followed with crusting during the next several days. Light and more superficial pigment lesions were treated with the shorter cut-off filter of 530nm, while deep (junctional and dermal) lesions were treated with the 580nm cut-off filter and, in most cases, with multiple pulse structure. While treating more difficult body areas such as hands and décolleté, the treatment outcomes were mostly surprising due to the ability to get to the “fine tuning” of the treatment settings (Figure 3). The skin prototype also influenced the pulse configuration, in which the lighter-medium skin types were treated with single-pulse configuration, medium skin colors with multiple-pulse configuration and dark skin phototypes with rapid-pulse configuration.
FIGURE 3. A 64-year-old male (Fitzpatrick III) before (left) and 4 weeks after 1 treatment session (right) with the 530nm cut-off filter. Single pulse structure, 15 msec pulse duration and 16 J/cm² energy fluence.

Skin Rejuvenation
All 11 patients that were treated for general skin improvement; fine line reduction and smoothening of skin texture were treated with the 580nm cut-off filter aimed at all skin chromophores to induce general dermal cell renewal. As with any general skin rejuvenation procedure, the evaluation results are more subjective and lack a specific evaluation tool. Nevertheless, in the close-up of the “before” and “after” pictures the general skin improvement is notable (Figure 4).

FIGURE 4. A 64-year-old male (Fitzpatrick II) before (left) and 6 weeks after 2 treatment sessions (right) with the 580nm cut-off filter. Single pulse structure, 20 msec pulse duration and 20 J/cm² energy fluence.
Acne clearance

Eight of nine patients that were treated for acne clearance achieved significant reduction in acne appearance (Figure 5) and one patient showed a poor-medium response. All patients were treated with a 415nm cut-off filter and the pulse configuration was based on the skin phototype of the patient. Moderate acne type (grade IV on Burton Scale) were treated with more aggressive settings, while mild types (grade I-III on Burton Scale) were treated with more moderate treatment settings (multiple-pulse configuration and longer pulse duration).

DISCUSSION AND CONCLUSIONS

The results represented in this study shows without any doubt that PCR technology presents a safe and effective method for IPL-based treatments.

Numerous trials show the effectiveness and compatibility of using IPL devices in a variety of skin conditions. Most trials attest to IPLs comparative effectiveness to lasers; in some studies, IPL devices seem to be even more effective in the treatment of vascular malformations or hypertrichosis. However, from past experience, the most effective results with IPL technology were usually observed in light skin patients, since Fitzpatrick skin types I-III can be safely treated with relatively high energy fluency. In many cases, while treating patients with skin type IV and those of Mediterranean or Asian origin, the results were limited due to use of mild settings. Moreover, treatment of patients with deep-pigmented skin, such as Fitzpatrick skin type V and VI were limited to other technologies such as long pulse Nd:YAG laser or electroepilation for hair removal purposes. The high safety profile of the treatment achieved with the subject handpiece is based on a combination of different factors, including strong contact cooling, pre-set treatment parameters, customized range of energy fluence for each skin type and pulse duration, and most importantly, the ability to choose between three pulse configurations according to the Fitzpatrick skin type and symptom's characteristics (such as hair color and thickness). An almost constant side effect of IPL treatment is the sense of pain during treatment. However, cooling (during or after treatment or both) can produce relief in most patients. When choosing the most suitable parameters for the treatment, one must consider safety concerns while not minimizing the efficacy of the treatment. This may be tricky in many cases. The skin type of the patient has to be documented according to the Fitzpatrick scale because photophysical parameters need to be adjusted depending on the individual patient's skin type. For example, when treating patients for hair removal, first a decision between using a shorter or longer cut-off filter must be made. The shorter wavelengths are more aggressive (more melanin absorption) and therefore the Fitzpatrick skin type may most influence this decision. On the other hand, if the patient is a light phototype, the filter length consideration will be influenced by the hair type. The shorter wavelengths have more superficial penetration; hence the hair follicle depth will dictate the appropriate cut-off filter.

Common side effects, which may last for a few days after treatment, are swelling and erythema. Blistering and crust are signs of over-fluenced treatment. These side effects can be mostly prevented by adjusting wavelengths, energy fluences and pulse configuration to the patient's skin type and treatment area. As mentioned before, in PCR™ technology, the energy fluence range is customized according to the chosen skin type, which limits the practitioner to the maximum energy fluence...
safe for the patient. But energy fluence has also a major influence on the efficacy of the treatment. Therefore, when in a specific case, high fluence is required, but safety issues limit the practitioner, the pulse configuration is designed to resolve this conflict. Changing from single pulse configuration, for example, to the multiple pulse configuration, will allow the use of a relatively high-energy fluence with a much higher safety profile.

Finally, the pulse duration also has a major role in efficacy and safety of the treatment. The shorter pulse duration is more aggressive and will be suitable for difficult-to-treat symptoms (such as relatively light hair colors). However, the target size will most influence the chosen duration. Based on the principle of the TRT (thermal relaxation time), larger targets (such as thick hair or blood vessels) will be most effectively treated with longer pulse duration. Also the relative depth of the symptom influences the pulse duration selection, when shorter pulse durations penetrate more superficially, compared to longer pulses.

In conclusion, the IPL-based treatment can enable the practitioner to perform wide range of different esthetical treatments in one system. However, when taking into consideration both efficacy of the treatment and safety of the patients, the system should be “flexible” enough to allow exact treatment settings profile for each patient, according to its skin type and symptom’s biophysical characteristics.

DISCLOSURES
All named authors are employees in Viora Ltd. But have no additional financial interests such as, stock ownership, honoraria, paid expert testimony, as well as any personal relationships, academic competition, and intellectual passion which may inappropriately influence the clinical data. All funding sources supporting the work and all institutional or corporate affiliations of mine are acknowledged within the paper.

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