

Clinical Outcomes Using Viora's PCR™ Technology: Patients' Safety and Treatment Efficacy

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ABSTRACT: Intense Pulsed Light technology was first commercially launched to the market for medical use in 1994 and similar to lasers, is based on the basic principle of photothermolysis. The combination of particular wavelengths, pulse durations, pulse intervals, and energy fluence, facilitates the treatment of a wide spectrum of skin conditions. The aim of this study was to investigate the safety and efficacy of Viora's new PulseConfiguRhythm technology. Seventy-six volunteers were treated as follows: 6 patients underwent 8 bi-weekly acne clearance treatments, 39 patients underwent 6-12 hair removal treatments, 7 patients were treated for general skin rejuvenation, 13 patients were treated for pigmentation lesions and 11 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. 5 of the 6 patients that were treated for acne clearance achieved significant reduction in acne appearance. The results represented in this study show without any doubt that Viora's new PCR™ technology presents a safe and effective method for most popular light-based esthetic procedures.

Introduction

Intense Pulsed Light (IPL) technology was first commercially launched to the market for medical use in 1994 [1]. Similar to lasers, IPL technology is based on the basic principle of photothermolysis, where the absorption of photons via endogenous or exogenous chromophores within the skin are transferred as light energy. This transfer generates heat and subsequently destructs the target tissue [2]. As selective photothermolysis aims to destruct 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 [2], 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 [3]. The combination of particular wavelengths, pulse durations, pulse intervals, and energy fluence, facilitates the treatment of a wide spectrum of skin conditions, such as unwanted hair growth, acne vulgaris, pigmented lesions, vascular lesions, and other symptoms of photoaged skin.

Viora's new PCR™ technology stands for Pulse ConfiguRhythm. The aim of this study was to investigate the safety and efficacy of this technology incorporated in the V-IPL handpiece.

Material and Methods

Case Study Group

A group of seventy-six volunteers (45 females and 31 males) participated in the current study, ranging in age from 15-70 years (average age, 38 years) with Fitzpatrick skin type I-VI.

Handpiece Description

Viora's IPL handpiece (V-IPL) utilizes the proprietary PCR™ technology. The main principle of PCR™ technology is to facilitate choosing between three diverse pulse configurations: Single, Multiple and Rapid. The Single pulse configuration represents a typical pulse structure, while the Multiple pulse configuration represents a pulse which is divided into three sub-pulses with two delays in-between. 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.) resulting in selective thermal damage (the principle of

thermokinetic selectivity) [4]. Consequently, this Multiple pulse configuration enables high fluence delivery to the skin, with an elevated safety treatment profile and deeper depth penetration, which allows using higher energy fluence for darker skin patients. The Rapid pulse configuration represents a train of short and low fluence pulses 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. In general, the lighter-medium skin types are treated with Single pulse configuration, medium skin colors with Multiple configuration and dark skin phototypes with Rapid pulse configuration

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

Treatment Regimen

Six (6) patients underwent a total of 8 bi-weekly acne clearance treatments with the 415nm cut-off filter. Thirty-nine (39) 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 (18 patients with 570nm and 21 patients with 630nm). Seven (7) patients were treated for general skin rejuvenation with the 580nm cut-off filter for 4 treatments with 2-4 week intervals in-between. Thirteen (13) patients were treated for pigmentation lesions, including solar lentigo, freckles and solar keratosis (8 patients with 530 nm and 5 patients with 580nm) for a total of 2-5 treatments with 3-4 week intervals. Finally, 11 patients were treated for vascular lesions, including small facial telangiectasias, facial and chest couperose and facial rosacea with 530nm cut-off filter, for 3-6 treatments with 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 6 months postoperatively, while skin rejuvenation, pigmented and vascular lesions were evaluated 4 weeks following their last treatment, and acne clearance 2 months following their last treatment. and acne clearance 2 months post last treatment.

Results

All 76 patients completed the treatment course according to the relevant indications, and visited the treatment clinic for at least one follow-up visit from 4 weeks (in the case of acne clearance) and up to 6 months (in the case of hair removal), following their final treatment. 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 39 patients treated for hair removal achieved significant hair clearance. The female axilla and pubic region responded the best with a notable change already post one treatment (Figure 1). Also female legs and male back areas responded well to the treatment, followed by female arms and male shoulders. 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, in where 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. A 45 year old female (Fitzpatrick III) before (left) and 8 weeks after 1 treatment session (right) with the 570nm cut-off filter, Single pulse structure, 40 msec pulse duration and 15 J/cm² energy fluence.

Vascular lesions

The 11 patients treated for vascular lesions were treated only with the 530nm cut-off filter, although the 580nm filter can be used for deeper vascular lesions, such as hemangioma. 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 phototype influenced the pulse configuration, whereas the shallow vessels and lighter-medium skin types were treated with Single pulse configuration, medium skin colors with Multiple, and dark skin phototypes with Rapid.



Figure 2. 55 year old female (Fitzpatrick II) before (left) and 2 weeks after 2 treatment sessions (right) with a 530nm cut-off filter, Single pulse structure, 12 msec pulse duration and 18 J/cm² energy fluence.

Pigmented lesions

All 13 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 (Figure 3 and 4) and usually with multiple pulse structure.



Figure 3. A 52 year old female (Fitzpatrick II) before (left) and 4 weeks after 1 treatment session (right) with the 580nm cut-off filter, Single pulse structure, 10 msec pulse duration and 17 J/cm² energy fluence



Before

After

Figure 4. A 48 year old female (Fitzpatrick II) before (left) and after 3 treatment sessions (right) with the 580nm cut-off filter, Single pulse structure, 16 msec pulse duration and 16 J/cm² energy fluence.

Skin rejuvenation

All 7 patient treated for general skin rejuvenation, fine line reduction and improvement in 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 5).



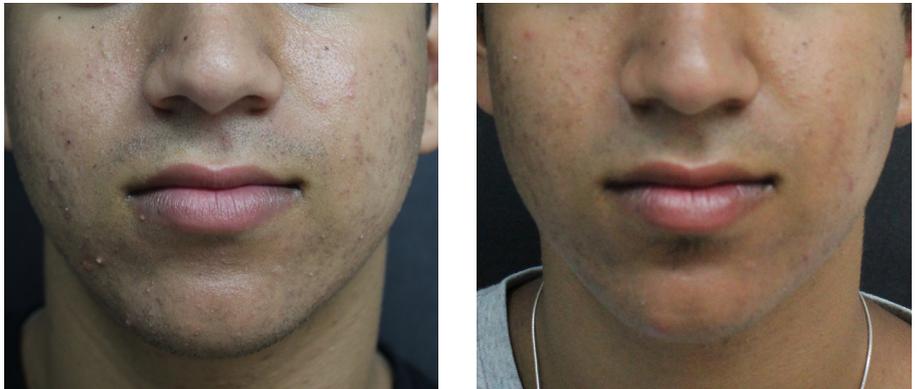
Before

After

Figure 5. 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

Five of six patients treated for acne clearance achieved a significant reduction in acne appearance (Figure 6 and 7) 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 or Rapid pulse configuration and longer pulse duration).



Before

After

Figure 6. A 15 year old male (Fitzpatrick V) before (left) and 4 weeks after 8 treatment sessions (right) with 415nm cut-off filter, Multiple pulse structure and 7 J/cm² energy fluence.



Before

After

Figure 7. A 22 year old male (Fitzpatrick III) before (left) and after 10 treatment sessions (right) with 415nm cut-off filter, Multiple pulse structure with range of 7-8 J/cm² energy fluence.

DISCUSSION & CONCLUSIONS

Numerous trials show the effectiveness and compatibility of using IPL devices in a variety of skin conditions. Most trials attest to comparative effectiveness of these devices to lasers; in some studies, IPL devices seem to be even more effective in the treatment of vascular malformations or hypertrichiosis [2]. The results represented in this study show without any doubt that Viora's new PCR™ technology presents a safe and effective method for most popular light-based esthetic procedures. The high safety profile of the treatment achieved in this study is based on a combination of different factors, including strong contact cooling, pre-set treatment parameters and a customized range of energy fluence, pulse configuration and pulse duration 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 [2]. Having very strong contact cooling in Viora's IPL system, together with different pulse configurations and adjustable range of treatment parameters, make the PCR™ technology as safe and comfortable for the patient, as possible.

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 [5] 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 of 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 crusting are signs of over-fluenced treatment [2]. These side effects can be mostly prevented by adjusting wavelengths and energy fluences to the patient's skin type and treatment area. In Viora's PCR™ technology, the energy fluence range is customized according to the chosen skin type, which limits the practitioner to the maximum energy fluence deemed safe for the chosen skin type. But energy fluence has also major influence on the efficacy of the treatment. Therefore, when in specific cases a high fluence is required, but safety issues limit the practitioner, the pulse configuration is designed to resolve this conflict. Changing the 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 a longer pulse duration. Also the relative depth of the symptom influences the pulse duration selection, as shorter pulse durations penetrate more superficially, compared to longer pulses.

Hence, the Viora's new PCR™ technology puts all these tools into the hand of a practitioner and, as demonstrated by the study, proves to be effective and, no less important, safe.

References

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