

Retrospective Analysis of Outcomes with a Unique IPL System

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Introduction: Intense Pulsed Light (IPL) technology is well accepted in the medical aesthetic field for the treatment of various skin lesions, including pigmented and vascular lesions. The light penetrates into the skin and is selectively absorbed by lesion chromophore. Absorbed energy is converted into heat, coagulating the lesion, which naturally fades following the treatment. The current article presents a retrospective efficacy evaluation of an IPL device with high peak power. Methods: Representative treatment results were collected from several clinics based on photographs taken at baseline and after treatments. Photos were evaluated and analyzed for aesthetic improvement of the various skin conditions in different facial and body areas. Results: Analysis included cases of pigmented and vascular lesions, textural lesions, and more specific conditions such as melasma and rosacea. The two evaluators' scoring demonstrated improvement in all cases according to the Global Aesthetic Improvement Scale (GAIS) scale. Conclusion: The vast experience gathered from the market in treating various skin lesions supports the safety and efficacy of the investigated IPL device. The device's particular specifications contribute to the successful results and ease of treatment for the practitioner and the patient.

Keywords

Intense Pulsed Light, IPL, Lumecca, Pigmented Lesions, Vascular Lesions, Peak Power Effect, Skin Rejuvenation

1. Introduction

Intense Pulsed Light (IPL) technology is based on principles of selective photothermolysis [1]. The light penetrates into the skin and is selectively absorbed by lesion chromophore (e.g., melanin or hemoglobin), having a darker color than surrounding tissue. Absorbed energy is converted into heat, coagulating the lesion which disintegrates and is eliminated by the immune system, thus fading during a few weeks following the treatment.

IPL systems are high-intensity light sources, which emit polychromatic light. Unlike laser systems, these flashlamps work with noncoherent light in a broad wavelength spectrum of 515 nm - 1200 nm. These properties allow for great variability in selecting individual treatment parameters and adapting to different skin types and indications. Various skin lesions, including benign vascular lesions and pigmented lesions, as well as rhytides, are improved by IPL treatment through a photo-rejuvenation process.

IPL is considered a gold standard treatment of a variety of vascular and pigmented lesions. The broad spectrum of IPL covers the visible and near infrared spectrum and can be easily adjusted for specific applications by using filters and optimizing pulse structure [2] [3].

According to the principles of selective photothermolysis, some treatment characteristics should be met for safe and effective treatment of vascular and pigmented lesions; the optical energy penetration depth should be high enough to reach the treatment target; the light absorption by the treatment target should be higher than that by the surrounding tissue, and the light should be delivered in pulses with pulse duration that is equal to or shorter than the Thermal Relaxation Time (TRT) of the treatment target.

The current retrospective results analysis is intended to demonstrate the safety and efficacy of the Lumecca IPL device for the treatment of pigmented, vascular and textural lesions, based on user experience.

2. Materials and Methods

The Lumecca IPL device (InMode Ltd., Yokneam, Israel) is used for treatment of vascular and pigmented lesions in clinics around the world since the year 2013.

Lumecca treatment instructions include the following information and guidelines: Two types of Lumecca handpieces are available: 515 nm (range 515 nm -1200 nm) recommended for treatment of pigmented and vascular lesions in Fitzpatrick skin types I-II and 580 nm (range 580 - 1200 nm) recommended for Fitzpatrick skin types III-IV. The use of the two filters may be customized. Thus, deeper lesions may benefit from the use of 580nm on skin types I-II, whereas light pigmented lesions on skin type III may be better treated by 515 nm. The Lumecca handpieces are suitable for treatment of superficial vascular and pigmented lesions on skin type I to IV.

The Lumecca handpiece with either 515 nm filter or 580 nm filter is shown in **Figure 1**.

Lumecca IPL exclusion criteria are similar to those of other IPL devices in the market, including current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles; pregnancy and nursing; impaired immune system due to immunosuppressive diseases, such as AIDS and HIV, or



Figure 1. Lumecca Handpiece.

use of immunosuppressive medications; severe concurrent conditions, such as cardiac disorders; sensory disturbances; any active condition in the treatment area, such as sores, psoriasis, eczema, and rash; history of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin; poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization; use of Isotretinoin (Accutane[®]) within 6 months prior to treatment; known skin photosensitivity or use of drugs increasing skin photosensitivity and diseases that may be stimulated by light, such as epilepsy, lupus and urticaria. Certain delay is recommended if other recent treatments such as light, laser or RF were performed on the treated area. Patients with a history of diseases stimulated by heat in the treatment area, such as recurrent Herpes Simplex, may be treated only following a prophylactic regimen.

The number of recommended Lumecca treatment sessions typically varied from 1 - 5 sessions every 3 - 4 weeks. The treatment session usually lasts only a few minutes according to the size of the treatment area and depends on the number of pulses required. Pigmented lesions usually require less sessions than vascular lesions. Treatment fluence was ranging from 8 to 16 J/cm², employing lower fluence for darker skin types. Specific treatment protocol was adjusted to patient according to the skin type characteristics and the lesion condition.

A unique characteristic of the Lumecca IPL is related to the pulse shape of both spectra, 515 nm - 1200 nm and 580 nm - 1200 nm. The short pulse shape is narrower than in other IPL systems (laser-like) and creates a high peak-power in the spectrum range of 500 nm - 600 nm, which is well absorbed by melanin and hemoglobin.

Clinical evaluation of Lumecca treatment efficacy was based on photographs of treated areas taken at standard conditions at baseline, after the treatments and at follow-up visits in several clinics.

Clinical evaluation of treatment safety was performed during and after each treatment with specific attention to sensitive areas such as loose or thin skin areas. Side effects, if any, were documented and followed.

The photos were collected by the company (InMode Ltd.) from the clinics and were handed to the author who also provided ten cases to the pool of results. Evaluation of change was scored by two qualified evaluators. Before and after patients' photos were presented to the evaluators who scored skin appearance improvement, using the Global Aesthetic Improvement Scale (GAIS) below (Table 1).

3. Results

The current retrospective summary includes representative photographs, demonstrating Lumecca's treatment effects. The photos were taken at baseline and at follow-up time points of 54 subjects, gathered from 27 clinics. Nine cases were of Asian skin that were treated for pigmented lesions according to the general guidelines. Treatment procedures were conducted according to instructions in the Lumecca Operator Manual. Number of treatment sessions and parameters were adjusted according to individual conditions and needs. All cases included in this retrospective summary showed an improved appearance of pigmented, vascular and textural lesions, with no reported unexpected or significant side effects.

Results demonstrated that epidermal and junctional pigmented lesions are treated very effectively, often in one session. Deeper and multilayered pigmented lesions such as melasma are more difficult to treat and recommended regimen may include combination with bleaching agents and use of very low fluence. Regarding vascular lesions, papillary and upper reticular dermis vascular lesions are a challenge for treatment by IPL, as the safety margin is narrower than pigmented lesions. Nevertheless, Lumecca is able to treat these lesions in 1-3 sessions, due to its unique characteristics.

The results include 34 cases of pigmented lesions, 5 cases of vascular lesions, and 7 having a combination of skin lesions—pigmented, vascular and/or textural lesions. In addition, there are 3 cases of rosacea, 2 cases of melasma, 1 case of acne signs and 1 case of scar redness. All skin imperfections improved after Lumecca treatments on various face and body areas. Areas of treatment included face—34, décolleté—5, arms—3, hands—6, head/forehead—2, nose—3 and 1 test patch.

No unexpected or significant side effects were reported among the included patients.

| Score | Improvement | | | |
|-------|--------------------|--|--|--|
| 1 | Very much improved | | | |
| 2 | Much improved | | | |
| 3 | Improved | | | |
| 4 | No change | | | |
| 5 | Worse | | | |
| | | | | |

Table 1. Global Aesthetic Improvement Scale (GAIS).

Table 2 summarizes the evaluators GAIS scoring results.

Both evaluators scored all photos as 1 - 3 (Very much improved, much improved and improved, respectively) according to the GAIS scale. No cases were scored as "no change" or "worse".

Figures 2-10 demonstrate representative cases of treatment results of the various skin lesions in facial and other body areas. Informed consent was received by all patients to include their photos.

Table 2. Evaluators' scores according to GAIS scale. PL-Pigmented lesions, VL-Vascular lesions, TL-Textural lesions.

| Patient No. | Condition | Evaluator 1 | Evaluator 2 | Patient No. | Condition | Evaluator 1 | Evaluator 2 |
|-------------|------------|-------------|-------------|-------------|---------------|-------------|-------------|
| 1 | Face PL&VL | 1 | 1 | 28 | Nose VL | 1 | 2 |
| 2 | Rosacea | 1 | 2 | 29 | Nose VL | 2 | 3 |
| 3 | Face PL | 1 | 2 | 30 | Chest PL | 2 | 2 |
| 4 | Face VL | 1 | 1 | 31 | Chest PL | 2 | 2 |
| 5 | Face PL&TL | 1 | 1 | 32 | Chest PL | 1 | 1 |
| 6 | Rosacea | 1 | 2 | 33 | Chest PL | 3 | 2 |
| 7 | Face PL&TL | 1 | 2 | 34 | Chest PL | 1 | 1 |
| 8 | Face PL | 1 | 1 | 35 | Arm Scar VL | 1 | 2 |
| 9 | Face PL | 1 | 1 | 36 | Arm PL | 1 | 1 |
| 10 | Face PL | 1 | 2 | 37 | Arm PL&TL | 2 | 2 |
| 11 | Melasma | 1 | 2 | 38 | Hand PL | 2 | 2 |
| 12 | Rosacea | 2 | 1 | 39 | Hand PL | 2 | 1 |
| 13 | Face PL | 1 | 1 | 40 | Hand PL | 2 | 1 |
| 14 | Face PL | 2 | 2 | 41 | Hand PL | 1 | 1 |
| 15 | Face VL | 2 | 2 | 42 | Hand PL | 1 | 1 |
| 16 | Face PL&VL | 2 | 2 | 43 | Hand PL | 1 | 2 |
| 17 | Face PL | 1 | 1 | 44 | Boldness PL | 1 | 1 |
| 18 | Face PL | 1 | 1 | 45 | Forehead PL | 1 | 2 |
| 19 | Melasma | 1 | 1 | 46 | Test patch PL | 2 | 1 |
| 20 | Face PL | 2 | 2 | 47 | Face PL | 2 | 2 |
| 21 | Face PL | 3 | 3 | 48 | Face PL | 1 | 2 |
| 22 | Acne | 2 | 2 | 49 | Face PL | 2 | 1 |
| 23 | Face PL | 2 | 3 | 50 | Face PL | 1 | 1 |
| 24 | Face PL&TL | 2 | 3 | 51 | Face PL | 2 | 2 |
| 25 | Face PL | 3 | 3 | 52 | Face PL | 2 | 2 |
| 26 | Face PL | 1 | 2 | 53 | Face PL | 2 | 3 |
| 27 | Nose VL | 1 | 2 | 54 | Face PL&TL | 1 | 1 |

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Figure 2. Patient 7. Facial sun spots and skin imperfections before (left) and after (right) treatments. Photos courtesy of Dr. Judith Hellman.



Figure 3. Patient 12. Melasma before (left) and after (right) treatments. Photos courtesy of Alena Kutaliya.



Figure 4. Patient 15. Facial vascular lesions and skin imperfections before (left) and after (right) treatments. Photos courtesy of Dr. Judith Hellman.



Figure 5. Patient 18. Face pigmentation/freckles before (left) and after (right) treatments. Photos courtesy of Dr. M Taylor.



Figure 6. Patient 32. Chest pigmentation before (left) and after (right) treatments. Photos courtesy of Dr. Judith Hellman.



Figure 7. Patient 34. Arm scar redness before (left) and after (right) treatments. Photos courtesy of Park Avenue Skin Solutions.



Figure 8. Patient 37. Arm sunspots and skin imperfections before (left) and after (right) treatments. Photos courtesy of Dr. R.Shukla.



Figure 9. Patient 40. Hand age spots pigmentation before (left) and after (right) treatments. Photos courtesy of Lux Skin Lab.



Figure 10. Patient 44. Bold head freckles before (left) and after (right) treatments. Photos courtesy of Lux Skin Lab.

4. Discussion

Photo-rejuvenation by IPL is a common procedure vastly used in aesthetic medicine for over 20 years, to treat pigmented, vascular and textural lesions, mainly on the face but also on the neck, chest, and back of hands [4] [5] [6] [7].

Despite the inclusive facial treatment regimens, there are specific characteristics for each indication that are described in detail: vascular lesions [8], textural lesions [9], and pigmented lesions [10]. In all of them, the wavelength can be customized according to lesion depth and skin type—the longer wavelength cut-off filter is used for the deeper lesions and for the darker skin.

More recent articles [11]-[16] published in 2012-2014 focus on the efficacy, safety and advantages of using IPL alone or in combination with steroids for the treatment of various aesthetic and medical dermatological indications. These publications are in line with the previously published experience and even expand it to special indications such as melasma, hand and chest rejuvenation, rosacea, keratosis, acne and more.

Evidence of the safe and effective use of IPL in Asian skin is also provided [6] [10] [17]-[23], with some articles focusing specifically on Chinese skin. Negishi et al. [6] demonstrated initial experience in Asian patients with photodamaged skin of full-face photo-rejuvenation by IPL with integrated contact cooling. Results were expressed in a scale of 5 gradings: >80% of patients had overall improvement of >60%. Histological results showed stimulation in collagen remodeling. Additional publications demonstrate improvements of various skin conditions in Asian patients such as facial freckles [10] [19], hand rejouvenation [18], rosacea [19] and melisma [19] [20] [21]. In an article from 2010 [23], a split-face study of IPL treatment effect on photoaging skin in Chinese population was investigated. Twenty-four Chinese women with photoaging were enrolled in this study. Patients were randomized to receive four IPL treatments at 3- to 4-week intervals on one side of face, with the other side spared as control. Changes of photoaging were evaluated by a few methods, using a global evaluation, an overall self-assessment, a Mexameter and a Corneometer. Skin biopsies were taken after four sessions of treatment on one side of face. Melanocyte density and melanin content, as well as collagen and elastic fibers density and organization were used following staining to evaluate the improvement on dyschromia and other signs of photoaging. Results demonstrated that the global scores of photoaging on treated side decreased significantly from 3.02 to 1.22, while remaining unchanged on the untreated side. Twenty-one of 24 patients (87.5%) rated their improvement as excellent or good. The difference in the values of melanin index and erythema index on treated side was significantly larger than those on untreated side after the 1st session, the 4th session and at 3-month follow-up (P < 0.05). The melanin content was significantly decreased and the collagen fibers were clearly increased only on treated side (P < 0.05). Adverse effects of treated side were limited to mild pain and transient erythema. It was concluded that using this split-face module, IPL treatment was proven both clinically and histologically to be effective in treating photoaging skin in Chinese population.

Another review on IPL [24] summarizes success of IPL use but elaborates the need of combination therapies to enhance results.

Two previously published articles on Lumecca [25] [26], demonstrate the safety and efficacy of Lumecca alone [25] or in combination with RF technologies [26].

In the first study, the Lumecca system IPL was tested to determine the correlation between a high peak-power short pulse and the successful treatment of pigmented and vascular lesions. Short pulse duration in the millisecond range and high peak-power of 3.3 kW/cm² enabled selective and effective destruction, not only of pigments but also of vessels in a comparable manner to the gold-standard, pulsed dye laser. Only one treatment session at a low fluence (8 - 16 J/cm²) was sufficient to achieve the desired results.

The objective of the second Lumecca study was to evaluate the safety and efficacy of combination facial treatment by 3 technologies: Lumecca IPL, Fractora fractional RF and Forma continuous RF (all by InMode Ltd.). Eleven patients completed the clinical trial that consisted of three sessions with Lumecca alternated with 3 sessions with Forma + Fractora, 3 weeks apart. Follow-up visits were made at 6 and 12 weeks following the last treatment. Lesions were evaluated by photographs taken at baseline and at follow-up time points according to a predetermined scale.

Results showed statistically significant improvement in wrinkling (24% after 6 weeks and 33% after 12 weeks), pigmentation (38% after 6 weeks and 62% after 12 weeks), vascular lesions (29% after 6 weeks and 67% after 12 weeks), and laxity (37% after 6 weeks and 40% after 12 weeks). It was concluded that combination facial treatment by IPL, with continuous and fractional RF is safe and enables the treatment of a variety of facial lesions, taking advantage of accessible applicators for different clinical indications on the same device. Thus, comprehensive facial skin rejuvenation has become feasible.

The Lumecca features common IPL principles and characteristics similarly to other IPL devices available in the market, such as the Quantum [6], VascuLight [10] [20], Lumenis One [19] [21] [22] [23] (Lumenis, Yokneam, Israel).

The Lumecca IPL device is designed to provide advantages over other IPL de-

vices. These include short pulse with high peak-power, large spot size, versatile spectrum, 515 nm and 580 nm cut-off filters, strong sapphire cooling, high repetition rate at all settings, and custom low pressure Xenon lamp. Still, there is flexibility to choose short or long pulse according to the lesion chromophore intensity, size and depth. Likewise, the efficient cooling may be controlled and reduced when treating superficial vascular lesion.

The Lumecca IPL high peak-power allows for the following potential treatment benefits: coagulation temperature in the target can be reached at a lower fluence, higher selectivity and ability to safely treat small targets. This results in effective treatment with fewer sessions, as compared with other IPL systems.

In summary, the current retrospective analysis demonstrates successful results of pigmented, vascular and textural lesions treatment, using the Lumecca IPL device. The vast experience gathered from the market in treating the various skin lesions supports the safety and efficacy of the Lumecca IPL. The simultaneous treatment of pigmented, vascular and textural lesions makes the Lumecca an effective tool for photo-rejuvenation, resulting in an overall appearance improvement.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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