Solar Lentigines Removal Using Ultra-Short Pulse 530nm Air Cooled IPL - A Retrospective Study
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Abstract

Background and Objectives
Solar Lentigines are one of the most common skin disorders, mainly in middle aged people, and in sun exposed areas such as the face, back of hands. There are different approaches to treat such lesions, including creams, lotions and energy-based devices. Intense Pulsed Light (IPL) has been the most common type of optical energy for this treatment, but it is mainly used using a long protocol of 4-8 sessions where pigment is gently and gradually being removed. This article discusses the results of a unique, short protocol for the reduction of the appearance of Solar Lentigines.

Materials and Methods
26 patients with Solar Lentigines were treated using a ultra-short pulse IPL head with an effective spectrum of 530nm-1100nm (Forma System, Formatk Systems Ltd., Israel). Patients underwent 1-2 sessions. Each Lentigo was targeted 2-5 times using a fluence of 21.8 J/cm² until its color was changed to dark grey. Patients' photos were taken at baseline and before each session. Results were evaluated by a blind reviewer and in addition, patient questionnaires were filled by the patients.

Results
Following the treatment, a localized crust was formed. Crusts were peeled spontaneously within up to 21 days. All patients experienced significant reduction in the appearance of pigment following one session, with a greater improvement after the second session (see graph #2).

Patients’ results were evaluated by a blind reviewer using patients’ photographs and graded according to a Percentage Improvement Scale (Graph #4). Results were classified into five scores, including: worse (-1), no change (0), improved (1), much improved (2), very much improved (3). 73% of the lesions improved after 1 Tx. (see graph #1), 27% of the lesions much improved after 1 Tx. (see Graph #1). 73% of lesions much improved, with a reduction in pigment greater than 75%, after Tx2 (see graph #3). An average final result of 81% of reported lesion reduction was collaborated with a blind review result of 87% (see graph #4).

Pain was evaluated with a reported average of 2.46 out of 10 (see graph #5). Average patient satisfaction of 91.5% from the treatment results was reported (see graph #6). No unexpected adverse events were documented.

Conclusions
This evaluation demonstrates the safety and effectiveness of a short duration, intensive protocol for the reduction in the appearance of Solar Lentigines using a ultra-short pulse air cooled IPL. This device and protocol enable to shorten the treatment period dramatically without compromising patients’ safety, effectiveness and discomfort.
Introduction

Optical energy sources, such as Laser and IPL technologies have been widely used for the last two decades to treat numerous types of indications and skin conditions such as vascular and pigmented lesions, removal of unwanted hair, Acne, skin rejuvenation, skin tightening and other skin conditions, based on two main principles – the first is the idea of conversion of optical energy into thermal energy while the other principle is the absorption of this optical energy in different chromophores, or types of tissues, depending on the specific wavelength used. These two principles are implemented through careful consideration of different patient related parameters such as medical condition and history, skin type and more. Fitzpatrick TB, described in his article the classification of skin types into 6 classes, I-VI. This classification is widely used today to determine treatment parameters, in order to maintain safety and effectiveness. In spite of the fact that there is some overlap between the use of IPL and Laser devices for the treatment of some indications, there is no one correct answer to the question which technology is preferable. Some indications are commonly treated by both technologies, while some skin conditions are conventionally treated by one of the two. IPL technology seems to be more common in some regions, mainly because of regulatory reasons and the perception of this technology to be safer for the patients compared with Laser technology. Each technology has its pros and cons. Some prefer the monochromatic, coherent nature of lasers while others prefer the polychromatic, diverging, IPL technology. The level of effectiveness of the two technologies varies in the literature. In addition to the common indications mentioned above, IPL has been proven to be effective for the treatment of scars, Rhytids and also capable of collagen proliferation. One of the most common treatment indications is the reduction of the appearance of pigmented lesions and specifically the reduction in the appearance of Solar Lentigines that are commonly called Age Spots or Liver Spots, and are widely spread, especially among people who tend to be over exposed to the sun ultraviolet radiation or mature people. According to literature, this indication can be treated by both Laser and IPL technology but the use of the latter is more common due to the high absorbance of low wavelength (500-700 nm) IPL in Melanin and the polychromatic nature of IPL. Kawada A, investigated the relation of sun exposure and formation of solar lentigines and Ephelides. He found IPL to be highly effective for this treatment. Solar lentigines may be small (less than one cm in diameter) or bigger and are usually flat in nature. In most cases these pigment deposits rest within the epidermis or upper parts of the papillary dermis. The majority of Solar Lentigines poses no medical threat and is merely an aesthetic problem. As these spots are correlated to sun exposure, they are mainly common on the face, back of hands and legs. Most treatment protocols found in literature and in commercial companies' user guidebooks recommend a series of 4-6 sessions that gradually reduce the appearance of the spots with varying results. Some studies demonstrate improvement after a single treatment but not always with high level of success.

This retrospective work demonstrates the safety and effectiveness of a unique treatment protocol that shortens the duration of the entire treatment to one or maximum 2 sessions, with very high level of success, tolerable treatment for the patients and virtually no adverse reaction.

Materials and Methods

Patients and Enrollment

26 Mediterranean patients 17 females and 9 males) at the ages of 33-82 (average 57.5) underwent a treatment for the reduction in appearance of Solar Lentigines. Patients
Fitzpatrick skin type varied between II-V. Patients had 1-2 sessions depending on success rate of the first session (7 patients had one session and 19 had 2 session). All patients signed an informed consent form before getting the treatment.

**Inclusion and Exclusion Criteria**

Before enrolling for the treatment, patients had a consultation session to verify their eligibility for the treatment. All patients in this retrospective evaluation fulfill the main inclusion criteria – above 18 years of age, with visible Solar lentigines that they wished to remove, understand the course of the treatment and risks and were able to understand and sign an informed consent form. Exclusion criteria included irregular or suspected spot, epilepsy, current or history of cancer, auto-immune diseases, pregnancy or nursing, current anticoagulant therapy, recurrent Herpes, drug-induced photosensitivity, severe diabetes and any other medical condition as per physician discretion.

**Device and Treatment Protocol**

The device used for this evaluation is the Forma system (Formatk Systems Ltd., Tirat Hacarmel, Israel). This platform offers a variety of 13 IPL applicators, Radio Frequency applicators, Ultrasound and Diamond microdermabrasion technologies, that can be combined for enhanced results. The IPL used for this evaluation was the F-SR applicator, with wavelength range of 530nm-1100nm. The 530nm cut off is an optimal filter as it combines high absorbance in melanin together with good penetration depth to target the epidermis and upper papillary dermis (Figure #2 Absorbance chart).

![Figure 2: Absorbance chart](image)

Treatment areas include the common sun exposed areas, where Solar lentigines mainly appear face, décolleté, back of hand and arms. Patients were photographed at baseline, before the second treatment and at follow-up: 6 weeks post last treatment. Photography was done according to standard and consistent Before & After photography methods.

Before treatment patients had their face cleaned using a facial soap and then dried completely. After cleaning, patients had a session of 6 minutes with the PLG Diamond dermabrasion applicator in order to remove unwanted dead cells from the Stratum corneum. This enables to reduce loss of energy on the surface, what enables greater penetration of the optical energy which leads to less superficial heating and higher efficacy.

Before applying the IPL optical energy to the lentigines, each lentigo was first confined using a white stencil (Figure 3) to prevent the energy from penetrating into the surrounding tissue. This way, when applying the IPL applicator on the lentigo and delivering a pulse of energy, the only area that is affected is the lentigo itself, leaving the surrounding tissue intact.
After confining the lentigines, a thin layer of 1-2 mm of colorless ultrasound gel was applied on the treatment area (Aquasonic Clear 03-08 Parker gel, Parker Laboratories, New Jersey, USA) to enable optimal penetration of the energy and assist in reducing superficial heating. 2-3 IPL pulses were applied on each lentigo using the maximal energy (21.8 J/cm²) with a ultra-short pulse width of 6 mSec/pulse. The endpoint for the treatment was moderate darkening of the lentigines. Post treatment soothing cream (Biafin) was applied on the treatment area in order to soothe the area. Unlike conventional protocols where multiple sessions are done with no downtime, this unique protocol aims for a more aggressive approach, what enables to reduce dramatically the number of sessions needed and at the same time generate remarkable results. Because of this intended monitored injury the area becomes susceptible to UV radiation. In order to prevent the risk of Post-Inflammatory Hyperpigmentation (PIH), patients were advised to reduce sun exposure to minimum and to use high potency sunscreen for 4 weeks. Where needed, this procedure repeated itself with another treatment session 4 weeks after the first one.

Results
Immediately after the treatment a noticeable darkening of the lentigines was noted, with no effect on surrounding tissue. The darkening effect was increased during the next 24 hours. 1-2 days following the treatment, thin crusts were formed over the lentigines. The crusts pilled spontaneously after 14-26 days).

As a consequence of the intense heat that is generated by the IPL pulses, the melanin which is organized in clusters of melanosomes is burnt and being pushed up towards the surface for clearance using the natural clearance mechanism of the body20. After the 1st treatment, 61% of patients have reported an improvement of average 74% in the appearance of the lesions (Graph #1).

![Graph 1: Improvement Results after 1 treatment](Image)

Graph 1: Improvement Results after 1 treatment

20 patients (from 26) underwent a 2nd treatment, with a reported improvement of average 79% (Graph #2).

![Graph 2: Improvement Results after 2nd Treatment](Image)

Graph 2: Improvement Results after 2nd Treatment

With a final average of 81% improvement score in lesion reduction/appearance improvement.

73% of the patients have reported an improvement in lesion appearance of more than 75% (Graph #3).
Patients’ results were evaluated by a blind reviewer using patients’ photographs and graded according to a Percentage Improvement Scale (Graph #4).

<table>
<thead>
<tr>
<th>Score</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Very much improved</td>
</tr>
<tr>
<td>2</td>
<td>Much improved</td>
</tr>
<tr>
<td>1</td>
<td>Improved</td>
</tr>
<tr>
<td>0</td>
<td>No change</td>
</tr>
<tr>
<td>-1</td>
<td>Worse</td>
</tr>
</tbody>
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**Figure 4: Blind Review Improvement scale**

With an average result of 2.61 out of 3, or 87.2% average improvement from the blind review.

**Figure 5: Before (1 treatment) After**

**Figure 6: Before (2 treatments) After**
During the IPL treatment, patients felt mild heat sensation which was accompanied by a very low discomfort level (Figure #8). Pain level distribution (shown in graph #5) with an average of 2.46.

Customer satisfaction was evaluated with a scale of 1-5 were 5=very satisfied and 1=very dissatisfied.

With an average score of 4.58 or 91.5% satisfaction score.

**Conclusion**

The results described here clearly demonstrate the high level of safety and effectiveness of this unique, short duration protocol for the reduction in the appearance of Solar Lentigines using a ultra-short pulse, air cooled IPL. We conclude that this protocol is more beneficial for the patients compared to traditional protocol, in the way that it gives instant significant results, while maintaining high level of safety.
References


