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# ALLEVIATING SKIN PIGMENTATION USING A UNIQUE APPLICATOR WITH 3D IPL MECHANISM – THE S-530 - A RETROSPECTIVE STUDY

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January 2021

# Alleviating Skin Pigmentation Using A Unique Applicator With 3D IPL Mechanism – The S-530 - A Retrospective Study

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*Ms. Talib is the owner of SkincosmediQ clinic. With more than 10 years of experience in the aesthetic field, Ms. Talib's clinic is a highly sought for multicenter dedicated to dermatologic procedures performed by herself, a team of skin therapists and physicians. All team skin therapists are affiliated with the Dutch Paramedics Quality Register and the Dutch Association for Skin Therapists*

**Abstract**

**Introduction:** Intense pulsed light (IPL), also known as pulsed light and broad band light, is a non-laser light source used to treat a variety of vascular and pigmented lesions, photo damage, active acne, and unwanted hair. This study sought to explore the effectiveness of a single 3D IPL treatment in reduction of pigmented lesions intensity.

**Patients and Methods:** 14 subjects who had pigmentation were treated. A single session of 3D IPL treatment was performed. The patients were photographed before treatment and at 1-month follow-up visit. The Post-inflammatory hyperpigmentation (PIH) severity scale was used to assess the pigmented lesions at baseline and follow-up. The scale includes the assessment of pigmentation intensity and affected area. Furthermore, the subjects' satisfaction of the treatment outcome was obtained using a 5-point Likert scale at 1-month follow-up visit.

**Results:** One month after the treatment, subjects displayed 73% & 80% reduction in pigmentation intensity and affected area, respectively. No side effects were noted due to treatment and subject satisfaction was high.

**Conclusion:** 3D IPL treatment was found to be an effective and safe treatment modality for reduction of pigmented lesions.

**Keywords:** Intense pulsed light (IPL), Pigmented lesions, 3D IPL, Hyperpigmentation, Solar Lentigos, and Melasma

## 1 | INTRODUCTION

Hyper-pigmentary problems, including post-inflammatory hyperpigmentation, solar lentigos, and melasma, occur widely in the human population and are thus of broad interest for control. Regardless of the nature of the problem, the general desire is for uniformity of skin color. Solar lentigines are a common manifestation of sun exposure and found in 90% of the white population aged > 60 years. Their incidence increases with advancing age [1]. Solar lentigines are 3 to 2-cm well-circumscribed, round, oval or irregularly shaped macules or patches that vary in color from tan to dark brown. They occur on sun-exposed areas, predominantly the dorsal aspects of hands and forearms, face, upper chest and back. Melasma is an acquired form of hyperpigmentation that is seen most on the face. It is a common disorder of hyperpigmentation affecting millions worldwide. It predominantly affects Fitzpatrick skin phototypes III and IV, [2] and at least 90% of those affected are women. The exact pathogenesis is unknown; however, it is hypothesized that rather than an increase in melanocytes, melasma may be caused by the presence of more biologically active melanocytes in the affected skin [2]. Exacerbating factors include pregnancy, hormonal therapy, such as oral contraceptives, and intense sun exposure. Sun exposure exacerbates melasma, probably because of the UV-induced upregulation of melanocyte-stimulating cytokines. Clinically, there are light to dark brown patches with irregular borders most commonly distributed symmetrically on the centrofacial, malar and mandibular regions and can also be on the forearms. Following exposure to UV irradiation, the melanocytes produce increased amounts of melanin compared with uninvolved skin.

IPL devices contain a powerful flashlamp that produces noncoherent, polychromatic light that can be tuned to provide a variety of wavelengths, fluences, and pulse durations. This light acts like a laser in causing selective photothermolysis and treatment of vascular and pigmented lesions, photo damage, acne, and unwanted hair. IPL technology delivers noncoherent light from about 420 nm to the midinfrared spectrum (Fig. 1). This light is tuned through cutoff filters that allow light only above a certain wavelength to be emitted. This spectral

adjustment is used to tailor the light to skin type and absorbing chromophore. The filter cuts off the emitted light, so that only wavelengths longer than the used filter value pass to the treated area.

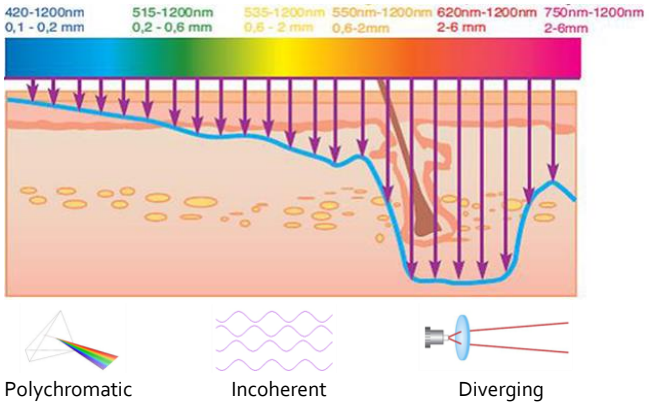


**Figure 1** IPL Spectrum

## 2 | PATIENTS & METHODS

This was a single center, retrospective, open-label clinical trial. All the participants signed an informed consent prior to treatment. Fourteen healthy adult subjects, 32-73 years of age with Fitzpatrick skin type II-V, presenting with light-colored, challenging, or resistant, age or sun-related flat and benign pigmentation were included in the study. Subjects were excluded if they: (i) had a history of pigmentary disorders, particularly a tendency for hyper-or hypo-pigmentation; (ii) had undergone treatment with a laser, light or other type of energy device; ablative resurfacing procedure; medium-depth or deeper chemical peels; dermabrasion; face lift; or any other significant surgical procedure in the expected treatment area within 6 months of the initial treatment or during the course of the study; (iii) were hypersensitive to light exposure or were actively taking photosensitive medication for which light exposure is contraindicated; (iv) had multiple dysplastic nevi in the treatment area; (v) were pregnant or breastfeeding; (vi) had sun exposer or artificial tanning 3 weeks prior to initial treatment; or (vii) had significant concurrent illness or any disease state that in the opinion of the Investigator would interfere with the treatment or healing process.

### 2.1 | Treatment Protocol

Prior to undergoing treatment, subjects underwent test spots to evaluate for skin reaction. Test spots were performed on photodamaged skin of the preauricular cheek, 20-30 min prior to the treatment. Subjects free of excessive skin reactions to test spots underwent 1 IPL treatment with 3D IPL system (Magma Spark Pro/Alpha; Formatk systems Ltd., Tirat Carmel, Israel – Figure 2). Follow-up evaluation was performed 1 months after the treatment session. Photographs were obtained at each visit. Subjects were required to remove makeup and/or any creams prior to photography.

**Figure 2** Magma Spark Pro/Alpha System

### 2.2 | Laser Procedure

The S-530 IPL handpiece operates at a spectrum of 530 - 1,100 nm. The IPL handpiece includes a rectangular (20 x 10 mm) sapphire cooled lightguide. The system controls the lightguide temperature, pulse mode, pulse duration and energy fluence. Fluence range was 22-24 J/cm$^2$ delivered via single pulse mode, pulse duration of 15-40 ms and lightguide temperature of 5°C.

### 2.3 | Assessment

The Post-inflammatory hyperpigmentation (PIH) severity scale (Table 1) [3] was used by the investigator and 1 blinded aesthetic expert not involved in the study to assess pigmentation improvement at 1-month follow-up visit. The primary efficacy endpoint was pigmentary intensity and area reduction of at least one level in the scale at the 1-month follow-up visit.

The subjects' overall satisfaction with the treatment outcome was recorded at the 1-month follow-up visit. This assessment utilized a 5-point satisfaction scale where, (-1) = very dissatisfied, 0 = dissatisfied, 1 = somewhat satisfied, 2 = satisfied, 3 = very satisfied.

**Table 1** PIH severity scale

| Grade | Pigmentary Intensity of Hyperpigmented Lesions | Area of Hyperpigmented Lesions |
|---|---|---|
| 0 | None | None |
| 1 | Trace (mild and localized) | Trace (1-10%) |
| 2 | Mild (mild and diffuse) | Mild (1-25%) |
| 3 | Moderate (moderate and diffuse) | Moderate (26-40%) |
| 4 | Marked (moderate and dense) | Marked (41-50%) |
| 5 | Severe (prominent and dense) | Severe (>50%) |

## 3 | RESULTS

Fourteen subjects (13 females and 1 male) with a mean age of 51±14 years and skin types II to V were included in the study (Table 2). All 14 subjects were treated for pigmentation around the face or neck. All study subjects completed the treatment and follow-up visit.

**Table 2** Characteristics of the study subjects

| Parameter | Study subjects *N* = 14 |
|---|---|
| Age, years | |
| Mean (SD) | 51.4 (14.1) |
| Min, max | 32.0, 73.0 |
| Gender, *n* (%) | |
| Female | 13 (92.9) |
| Male | 1 (7.1) |
| Skin type, *n* (%) | |
| II | 8.0 (57.0) |
| III | 2.0 (14.0) |
| IV | 3.0 (22.0) |
| V | 1.0 (7.0) |

### 3.1 | Treatment Responses

Significant improvements from baseline in pigmentation were noted at the follow-up visit for each subject according to investigator and blinded aesthetic expert assessments (Figures 3-13).

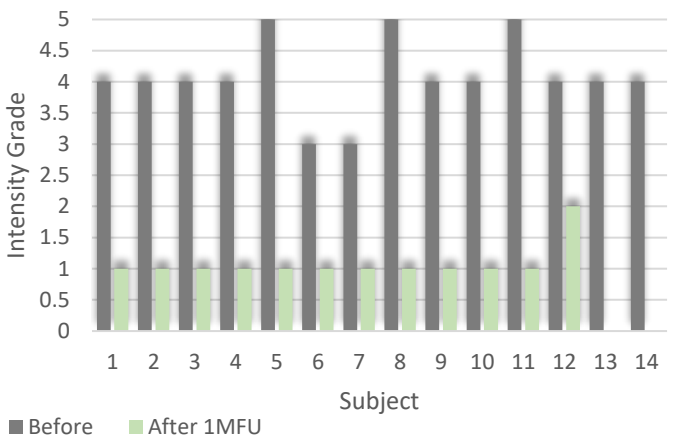


**Figure 3** Investigator assessment per subject - reduction in pigmentation intensity according to PIH severity scale

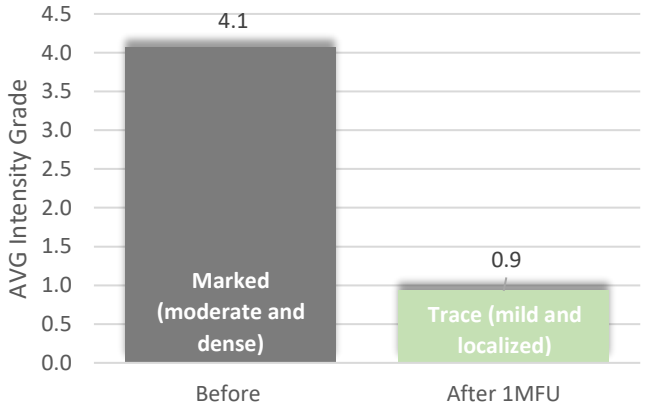


**Figure 4** Investigator assessment - average reduction in pigmentation intensity according to PIH severity scale

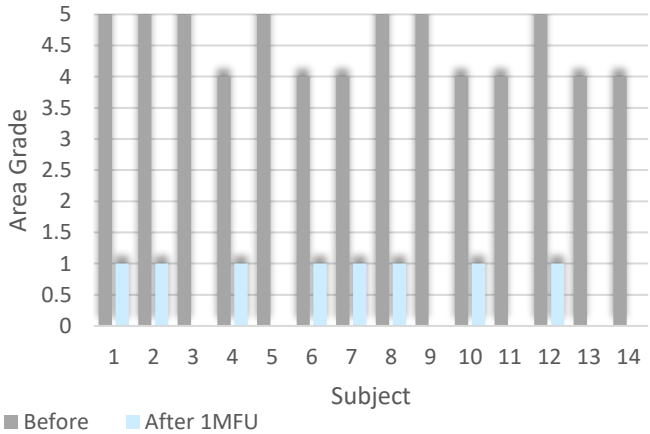


**Figure 5** Investigator assessment per subject - reduction in area of pigmented lesions according to PIH severity scale

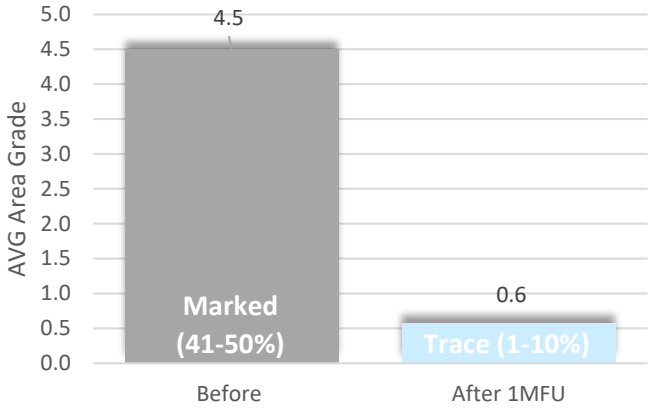


**Figure 6** Investigator assessment - average reduction in area of pigmented lesions according to PIH severity scale

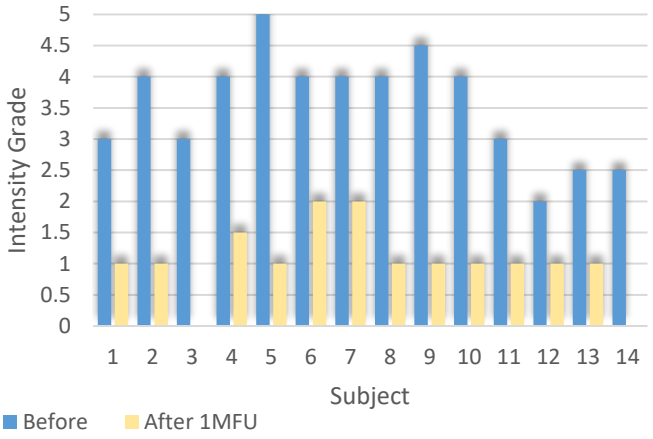


**Figure 7** Blinded aesthetic expert assessment per subject - reduction in pigmentation intensity according to PIH severity scale

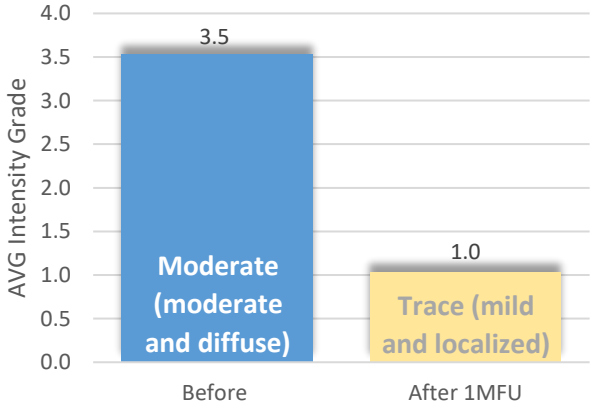


**Figure 8** Blinded aesthetic expert assessment - average reduction in pigmentation intensity according to PIH severity scale

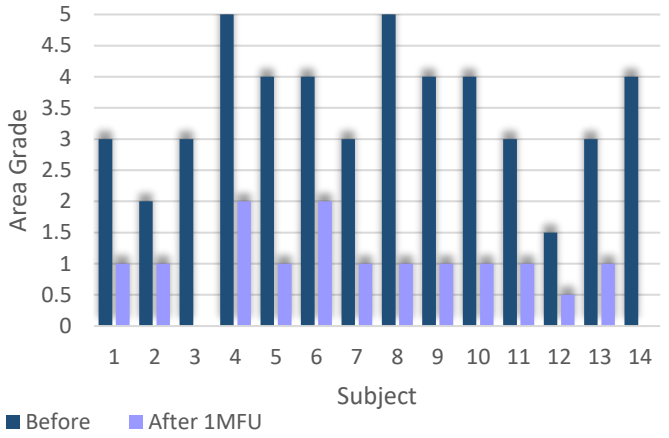


**Figure 9** Blinded aesthetic expert assessment per subject - reduction in area of pigmented lesions according to PIH severity scale

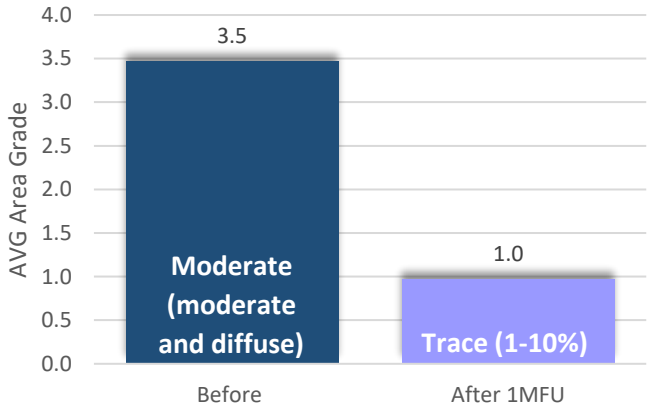


**Figure 10** Blinded aesthetic expert assessment - average reduction in area of pigmented lesions according to PIH severity scale

Figures 11-12 display side-by-side comparison between blinded aesthetic expert and investigator assessments. While average pigmentation intensity assessments at 1-month follow-up is basically the same for both blinded aesthetic expert and investigator, the average reduction in the "area of pigmented lesions" assessments are somewhat further apart. But still, both are around grade 1 of the PIH severity scale. The difference between assessments (including the "before" scores) can be attributed to the fact that the blinded expert was able to grade the intensity and area of the lesions only via photos while the investigator was able to judge the lesions condition in person. Additionally, there is a natural difference of opinions between the practitioners.

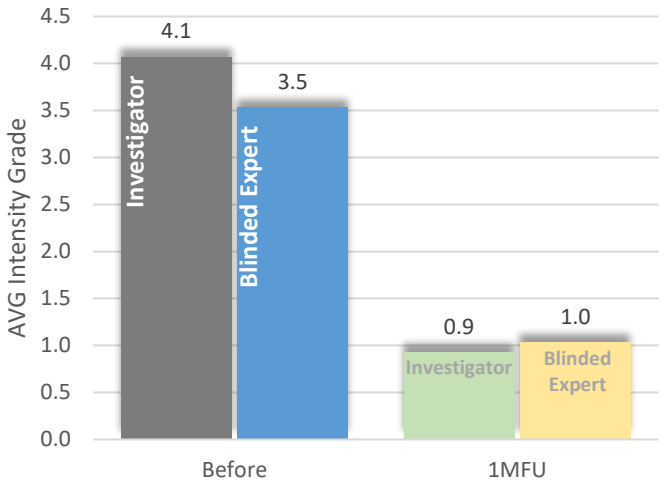


**Figure 11** Comparison of blinded aesthetic expert and investigator assessments - average reduction in pigmentation intensity according to PIH severity scale

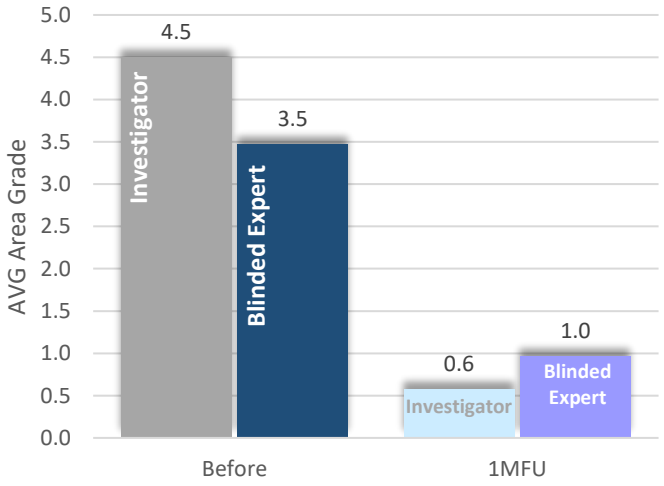


**Figure 12** Comparison of blinded aesthetic expert and investigator assessments - average reduction in area of pigmented lesions according to PIH severity scale

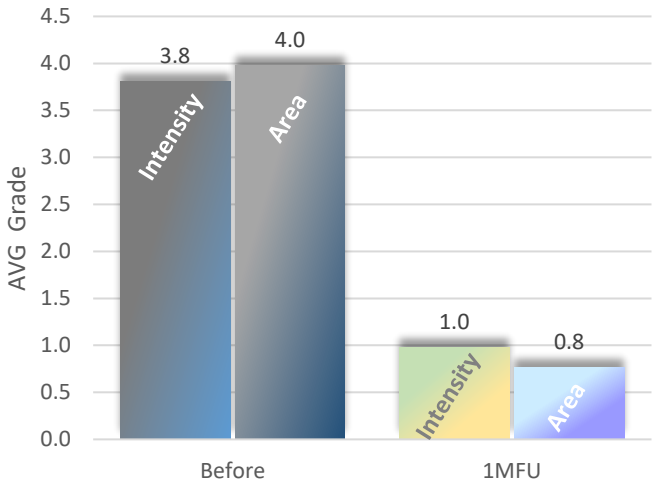


**Figure 13** Average score of investigator and blinded aesthetic expert - reduction of pigmentation intensity and area of pigmented lesions according to PIH severity scale

Figures 14 - 16 present an example of pigmentation clearance 1-month follow-up compared to baseline.

**Figure 14** Melasma on the forehead at baseline versus 1 month following 1 treatment. HP: S-530 | Fluence: 23 J/cm² Single Mode, Pulse width: 30-40ms, Rate: 0.5Hz Tip Tmp: 5°C | 1 pass over area | Home Skin care: Only SPF

**Figure 15** Poikiloderma of Civatte at baseline versus 1 month following 1 treatment. HP: S-530 | Fluence: 24 J/cm² Single Mode, Pulse width: 15ms, Rate: 0.5Hz Tip Tmp: 5°C | 1 pass over the area & additional pulses over specific spots |

**Figure 16** Solar lentigines at baseline versus 1 month following 1 treatment. HP: S-530 | Fluence: 24 J/cm² Single Mode, Pulse width: 30-40ms, Rate: 0.5Hz Tip Tmp: 5°C | 1 pass over the area & 2 additional pulses over specific spots |

### 3.2 | Safety

No subject experienced excessive erythema or edema from test spots performed prior to the treatment. Post-treatment erythema was short-lived and was always self-resolving. There were no reports of posttreatment edema or purpura. Subjects felt comfortable to go out in public within a day and mentioned that pain levels during the treatment were tolerable.

### 3.3 | Subject Satisfaction

At the 1-month follow up, 50% and 50% of subjects were satisfied or very satisfied with treatment outcomes, respectively (Figure 17).


**Figure 17** Subject satisfaction. A 5-point Likert scale at 1-month follow-up visit was used to assess subject satisfaction.

## 4 | DISCUSSION

This study aimed to evaluate the reduction of skin pigmentation lesions intensity after a single IPL session at one month follow up time frame. Results were extremely encouraging as significant improvements from baseline in pigmentation were noted at the follow-up visit. Pain sensation during treatment was not retrospectively assessed but according to subjects feedback it was mild. 100% of subjects were satisfied or very satisfied with treatment outcome.

The removal of pigmented lesions is commonly requested by affected individuals. Systematic use of high SPF sunscreens, avoidance of sun exposure during high-irradiation hours, regular skin cleansing and epidermal barrier properly protective care can prevent the onset of new pigmented lesions and may lead to spontaneous regression of some pre-existing ones. Therapeutic options of pigmented lesions are photochemical treatments including cryotherapy, laser, intense pulsed light, and chemical peels [4] [5] [6] [7]. Topical application of specific active materials aims at inhibition of melanin production, blockage of melanocyte biostimulation and suppression of melanin delivery to final acceptor cells, not without possible side-effects [8] [9]. Studies have demonstrated that **laser/IPL approaches are significantly more effective than topical treatments** or liquid nitrogen for treating pigmented lesions [10]. Long pulsed light systems, such as 595 nm PDL or 755-nm lasers, and IPLs work on the principle of extended theory of selective photothermolysis, micro-amplifying collateral photothermal effects to non-photo-absorptive biological structures [11] [12]. IPLs provide a valuable option for successful treatment of superficial pigmented lesions. Its effect is broad causing a gradual uniform epidermal injury while sparing deeper layers. Low intensity pulses should be used to prevent unwanted non-specific epidermal damage. If these measures are followed, one could achieve a significant reduction in pigment without side-effects [13].

The Magma Spark Pro/Alpha system allows for control over contact cooling intensity. Most IPL systems available in today's market offer contact cooling of 4-5°C without the option to control cooling intensity. Lowering the lightguide temperature is very effective in protecting the epidermis from thermal damage but it also means that fluence/energy levels need to be elevated to cause the destruction of the target chromophore. Controlling cooling intensity increases treatment effectiveness without compromising safety or comfort. For example, it is very effective to increase lightguide temperature from the standard 5°C cooling to 15°C when treating vascular lesions as over-cooling may lead to vasoconstriction and reduction in treatment effectiveness. In this study, cooling temperature was set to 5°C. For future studies on pigmentation lesions, the author hopes to further investigate and create treatment protocols which utilize the option to elevate lightguide temperature thus enabling to decrease fluence/energy levels. This increases the safety profile of the procedure and can be highly beneficial when treating darker skin types, where heating technique should be gradual, and gentle compared to lighter skin types.

## 5 | CONCLUSION

A single 3D IPL treatment produced significant reduction in the investigator-rated pigmentation intensity and area of hyperpigmented lesions. Similar scores were rated by a blinded aesthetic expert. The treatment was well-tolerated and showed high subject satisfaction scores.

**** I would like to thank Ms. Veronica Joshua, owner of NOBILITY cosmetics clinic, Israel, for providing pigmentation assessments as a blinded aesthetic expert.***

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