Pulsed Light and Heat Energy in the Treatment of Pigmented Lesions

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Abstract: Removal of pigmented lesions by non-ablative Laser or Intense Pulsed Light (IPL) systems are gaining increasing popularity. To avoid thermal damage to the epidermis these systems require a skin cooling device. Radiancy's pulsed light and heat energy technology (LHE™) was found safe and effective for hair removal without the need for skin cooling. Therefore, LHE based systems are simple to operate, compact and cost-effective. In this study the efficacy and safety of the LHE based system, SkinStation™, for the removal of pigmented lesions was addressed. Thirty one areas with pigmented lesions, mostly lentigines, were treated with SkinStation. Photographs and measurements of the lesions were taken before the first treatment and after completion of treatments. An average of 3.72 treatments were applied every 2 to 4 weeks. After completing the treatment regimen lightening of lesions was observed in all treated areas except two. Reduction of lesion dimensions was seen in most treated areas and complete disappearance of lesions in five. Side effects were mild and resolved without specific care. No scars were observed. The results of this study show that the treatment of pigmented lesions by LHE is highly safe and effective.

Introduction

Pigmented lesions are a common aesthetic problem, especially in older populations. Ablative treatment solutions include dermabrasion, deep chemical peels and laser skin resurfacing. However, there is significant downtime associated with these methods and the post treatment complications can make the cure worse than the disease.

The demands of a modern life-style drive many patients to seek a safe and effective non-invasive solution, without down time. Therefore, since their introduction few years ago, non-ablative light based therapy methods are gaining increasing popularity [1-6]. Several reports have described the successful removal of pigmented lesions using either non-ablative Laser or Intense Pulsed Light (IPL) systems [6-9]. Light emitted by these systems selectively targets melanin in pigmented lesions subsequently causing heating of the lesions to the coagulation point of 70-75 ºC causing their disappearance [10]. Normal tissue contains much lower melanin concentration than the targeted lesions and is therefore not damaged. Most non-ablative Laser or IPL systems require large cooling devices to protect the epidermis from burn [11, 12]. This renders the systems too heavy to be portable. Additionally, the practitioner must be skilled in both operating the system and in use of the skin cooling device to ensure the treatment safety. Therefore, the development of compact systems that are simple to operate and safe was desired.

Light and Heat Energy (LHE) based technology has recently joined the arena of non-ablative light based systems used for skin rejuvenation. A new LHE system named SkinStation was introduced for the treatment of pigmented and superficial vascular lesions as well as for the treatment of fine lines. SkinStation is compact and portable (9.5kg). Its LUA (Light Unit Assembly) contains one flash lamp, which emits broad spectrum light of 400-1200 nm. In contrast to lasers and IPL systems that suppress the heat by using various cooling methods, LHE uses dual light and heat energy pathways, allowing a safe temperature margin on the skin without the need for skin cooling. This article addresses the treatment course of pigmented lesions by LHE technology and its results.

Materials and Methods

Patients: Twenty five patients with benign pigmented lesions and Fitzpatrick skin type I-IV participated in the study. Before enrollment each patient completed a medical history form and signed an informed consent form. Patients with suspicion of premalignant lesions or history of skin cancer in the treated area were excluded. In order to singly quantify the safety and efficacy of LHE photorejuvenation, the patients were not allowed to use any prescription skin product. Patients who had received photorejuvenation treatments in the treatment area or treated with retinoic acid derivative tablets (for example Accutane) in the past 6 months, or used photosensitizing drugs in the past 3 months were excluded from the study. Patients with known inflammatory skin diseases or any disease stimulated by light were excluded. Tanning was not allowed 3 weeks pre and post treatment.

Match Expectations: Each patient was informed about the basis of the technology. Typical temporary effects associated with treatment were described and patients were offered the option to use EMLA cream. Patients were also informed that typical post treatment after effects may include erythema, edema and temporary darkening of the lesions . The low risk of burn and pigmentary changes was also discussed. Pre and post treatment photos were presented according to patient request. In order to best maintain the treatment results patients were advised to either avoid sun or use a sun block in the future.

Lesion measurement and photography: The treatment area was measured and then photographed using a Nikon

coolpix 4300 digital camera, before treatment and one week, one month and two months following the last treatment. The zoom, distance and illumination conditions were kept constant.

Changes in color and dimension of the lesions were determined by comparing before and after photographs, and measurements of the lesions. Established end points were color diminution and reduction of lesion dimension.

Assessment of improvement: The pictures and the measurement of lesions at each follow up were compared to baseline and average (of all treated lesions) eradication of lesions (color and area diminution) was semi-quantitatively graded by the physician as: grade -1 for worsening more than -10%, 0 for -10% to 10% disappearance, grade 1 for 11%-39%, grade 2 for 40%-60%, grade 3 for 61%-89% and grade 4 for 90%-100%.

Treatment Protocol: First the treated area was carefully cleaned, cream and makeup were removed and the hair was trimmed where necessary. Following pre-treatment protocol, lesions were treated with SkinStation, an LHE based system, operated on a spectral window of 400-1200 nm, with a pulse width of 10 msec, and pulse light energy density of 5-10 J/cm² (SkinStation, Radiancy Inc, Orangeburg NY). Three quadrangular spot sizes, 11x11mm, 34x11mm, and 54x11mm, were used. The light density delivered by a single pulse was adjusted according to the patients skin types and nature of the lesions. For safety, the fluence was increased gradually as the treatment advanced. Treatments were applied every 2 to 4 weeks. In each treatment a few passes over the treatment area were performed until redness or darkening of the lesions appeared. Three minutes pause between the passes were maintained to allow the tissue cool.

Results

In total 31 areas in 25 patients were treated for pigmented lesions. Patients' mean age was 50.64 (range 33 to 68) and Fitzpatrick skin types were I-IV. Most lesions were defined as lentigines (23 areas). Some were pigmented keratosis (3 areas), nevi (4 areas), skin tags (1 area), melasma (1 area) and poikiloderma (1 area). Locations in decreasing order of frequency were face, arms, neck, chest, back, abdomen and scalp.

The treatment was usually accompanied by irritation and a mild burning sensation. However, all patients chose to avoid topical anesthesia. The burning sensation disappeared after a few minutes up to a few hours post treatment. In each treatment the lesions were passed a few times until they darkened or redness appeared around them. Following this guideline is important as the extent of redness and darkening was usually positively correlated with the effectiveness of treatment. In average, 3.32 passes (range 1 to 6) over the treatment area were performed. Treatment duration was 1 to 20 minutes depending on the dimensions of the treated area. Average number of treatment sessions was 3.72 (range 1 to 9).

Follow-up was up to 3 months. At completion the treatment regimen lightening of the treated lesions was observed in all treated areas except two. Reduction in the diameter of the lesions was observed in most treated areas up to complete elimination in five (Figs. 3-5).

Decrease in the dimensions of pigmented lesions could be seen a few days following the first treatment but its extent was usually related to the number of treatments applied. Total improvement of both color and reduction of area was assessed on a scale of -1 to 4 (as detailed in methods, where grade -1 was used for worsening more than -10%, grade 0 for -10% to 10% disappearance, grade 1 for 11%-39%, grade 2 for 40%-60%, grade 3 for 61%-89% and grade 4 for 90%-100%). Following up to 2 visits, average result was 1.63 and one month following last treatment average result was 2.22. The distribution of grades one month following last treatment is shown in Figure 1.

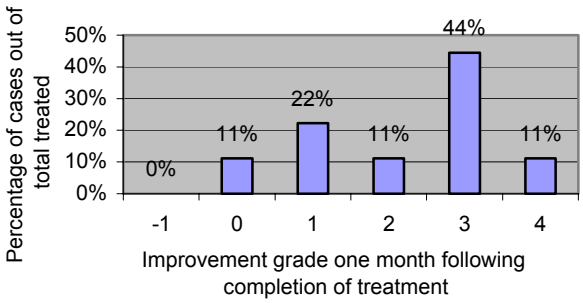

Figure 1 - Improvement grade distribution one month following treatment completion.

Side effects commonly included edema which lasted up to a few hours post treatment, erythema which lasted up to 2 days post treatment, and a thin crust formation on the treated lesion which exfoliated within a few days. In 4 cases, transparent discharge was seen around the crust and fade away within a few days without specific care. Hyperpigmentation appeared in one patient, lasted 2 months and disappeared following treatment with hydroquinone 4% cream. This patient was treated with higher light fluence compared to other patients in this study with similar skin type (Fitzpatrick IV). Partial clearance of hair in the treated areas occurred in a few patients and persisted for 3 months post treatment. No scars or other adverse effects occurred.

Discussion and Conclusions

Treatment of pigmented lesions resulted in lightening of lesions in all but two patients. One of these patients had melasma that is usually considered resistant to light based therapy [13], and the second had lentigines. Additionally, the treatment reduced the dimensions of pigmented lesions. The average efficacy of treatment was good (2.2 on a scale of -1 to 4), more than 60%

improvement (refer to Figure 1). Similar results were achieved by IPL: out of 17 patients that completed 5 IPL treatments at Sadick center 47% achieved more than 50% improvement in colorimetry [7] and Negishi reported that out of 97 Asian patients treated by IPL 90% had good elimination of pigmentation [6]. Several treatments of lentigines by Nd-Yag laser resulted in lightening of most lesions by at least 50% [13].

Similar to lasers and IPL systems [12], the principal of targeting melanin by light resulting in specific heating of the lesion also applies for LHE based SkinStation. However, in contrast to lasers and IPL systems, which rely on high light fluences and usually suppress the heat by using various cooling methods, LHE uses dual light and heat energy pathways, allowing safe temperature margins on the skin without the need for cooling means. When the light is on, most of the energy is light energy but when the light is off the light unit assembly (LUA) continues to emit heat. The light is specifically absorbed in the melanin in the lesion and its energy is transformed to heat. The rise in temperature will be proportional to the concentration of melanin in the tissue, so normal skin, where concentration of melanin is relatively low, will not be substantially heated. Theoretically, when the light is off the heat energy combines with the light energy that was absorbed in the lesion, and cumulatively raises the temperature of the lesion to the required coagulation point of 70-75 ºC. This leads to coagulation necrosis of the pigmented lesion with subsequent sloughing. Conversely, in normal skin where the first pathway of heating through specific light absorption was not effective, the use of heat pathway alone does not cause damage (Fig. 2). The safety of SkinStation is related to the use of low fluence light, and the addition of controlled heat energy makes the system highly effective. Safety is further related to the pulse duration setting of 10 msec, which is above the 3-7 msec thermal relaxation time of the epidermis [14] (Fig. 2).

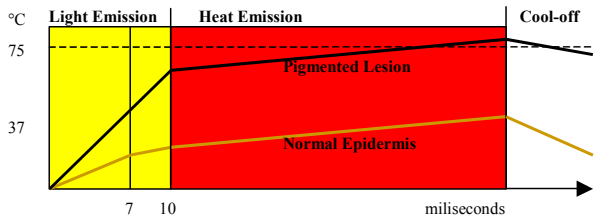

Figure 2 - A diagram describing the heating process of a pigmented lesion and normal epidermis during an LHE treatment (Due to the temperature gap of both tissues predicted by different light absorption and thermal relaxation, although their rate of heat absorption in the second phase is similar, the pigmented lesion reaches the coagulation point, whereas the normal epidermis does not).

Side effects were minimal and temporary. Partial clearance of hair in the treated areas occurred in a few patients and persisted for 3 months post treatment.

Therefore, before treatment patients should be advised that the hair in the treated area might be reduced. Temporary hyperpigmentation, the most serious adverse effect seen in this study occurred in less than 5%, compared with 10% to 50% reported after treatment with laser [13] or 0% to 16% after treatment with IPL [6, 15]. Scar formation did not occur after photorejuvenation by LHE, although it occasionally follows non-ablative photorejuvenation by lasers [12,13,16] and treatment by IPL [15]. This is probably related to optimizing the balance of light and heat in LHE technology, allowing safe temperature margin on the skin.

It is concluded that SkinStation offers a safe and effective treatment of pigmented lesions for those seeking a non-ablative approach. In comparison to laser or IPL it appears to be that the safety of the treatment is higher with similar efficacy.

Figure 3a

Figure 3b

Figure 3 - Lightening of pigmented lesion color following treatments with LHE, as shown in Figure 3a (before) and Figure 3b (after).

Figure 4a

Figure 4b

Figure 4 - One week following first treatment with LHE, the diameter of the lentigo was reduced to half, as shown in Figure 4a (before) and Figure 4b (after).

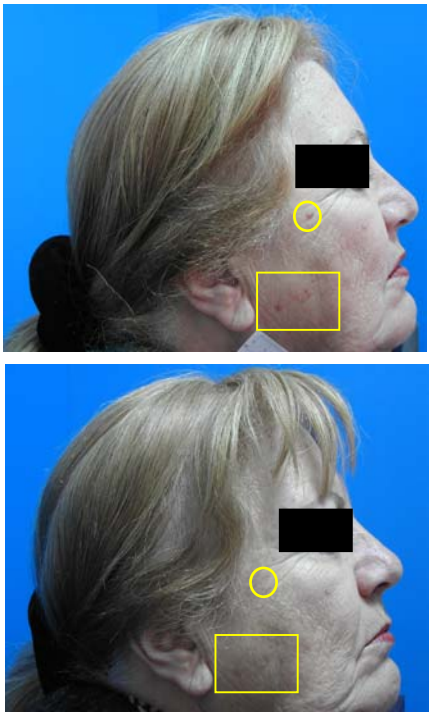

Figure 5a

Figure 5b

Figure 5 - Disappearance of pigmented nevus (upper cheek), lightening of pigmented lesions and lightening of lentigines (lower cheek) following 3 treatments with LHE, as shown in Figure 5a (before) and Figure 5b (after).

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