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ORIGINAL ARTICLE

Reduction of pain and side effects in the treatment of solar lentigines with pneumatic skin flattening (PSF)

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Abstract
Background: Energy densities utilized in the treatment of pigmented lesions such as solar lentigines with intense pulsed light systems are often limited by pain and post-treatment erythema and edema. The sensation of pain associated with the treatment is immediate and acute. Application of topical anesthesia is time-consuming, with only very moderate pain relief. *Objective*: (a) To test pain reduction as well as the reduction of post-treatment erythema and edema when using pneumatic skin flattening (PSF). This new technology utilizes an evacuation chamber to generate skin compression and activates tactile neural receptors in the skin. The result is an afferent inhibition of pain transmission in the dorsal horn (the 'gate theory'). (b) To test the efficacy of PSF. *Methods*: Twenty patients were treated for solar lentigines. The patients were treated by three different IPLs. The evaluation of acute pain and post-treatment erythema and edema was performed on all 20 patients: one to three sites per patient treated with PSF and the same number of control sites without PSF. Identical energies and IPL were applied to both sites on each patient. The pain evaluation was performed on a 10-level scale modified McGill Pain Questionnaire. The clinical response to treatment was also evaluated. *Results*: All 20 patients completed the study and preferred the PSF treatment side over the non-PSF side. Substantial pain reduction was observed in 19/20 patients (95%). The average reduction of pain was by two levels, from very painful to very mild pain. Erythema reductions were observed on 14/18 (77%) patients and edema reduction on 8/9 (88%) patients. Treatment efficacy on PSF sites was identical to that of non-PSF sites. *Conclusion*: The pneumatic skin flattening (PSF) technology considerably reduces pain, erythema and edema in the treatment of solar lentigines by IPLs. Treatment efficacy is preserved. The enhanced safety of PSF enables the increase of energy density and the acceleration of results.

Key words: *Lasers and light sources, pain relief, pneumatic skin flattening, vacuum device*

Introduction

The treatment of pigmented lesions such as lentigines with intense pulsed light (IPL) systems is often painful. The sensation of pain associated with the treatment is immediate and acute. Post-treatment erythema is intense when treatment energies are increased in order to enhance efficacy. The most common approach to the reduction of immediate acute pain is the application of topical anesthesia to the treated area of the skin. The disadvantage of this is that it is necessary to apply the analgesic cream some 30–60 minutes prior to the treatment session, thus causing the patient inconvenience with only very moderate pain relief. In most cases, both pain and post-treatment erythema leads to compromise of efficacy by reducing energy densities and increasing the number of treatments.

This article summarizes a controlled clinical study with a new pneumatic skin flattening (PSF) technology. This technology is already known to significantly reduce the level of acute pain generated by hair removal lasers (1). It utilizes a thin evacuation chamber, which creates a negative pressure on the surface of the skin, resulting in skin elevation and very tight flattening of the skin under a transparent sapphire window (Figure 1A and 1B).

The skin compression induces pressure on tactile and pressure neural receptors in the skin. The result is an afferent inhibition of pain transmission in the dorsal horn (Figure 2: the 'gate theory'). According to the gate theory, nerve impulses from nociceptors (pain inputs) and their sensory fibers (slower and thinner A-delta or C fibers) arrive at synapses in the spinal cord on their way to the brain. Larger diameter and faster myelinated sensory neurons (A-beta fibers) carrying pressure and tactile information from the surrounding skin site activate secondary neurons which secrete endogenous opioids into the pain synapse, thus suppressing the flow of pain

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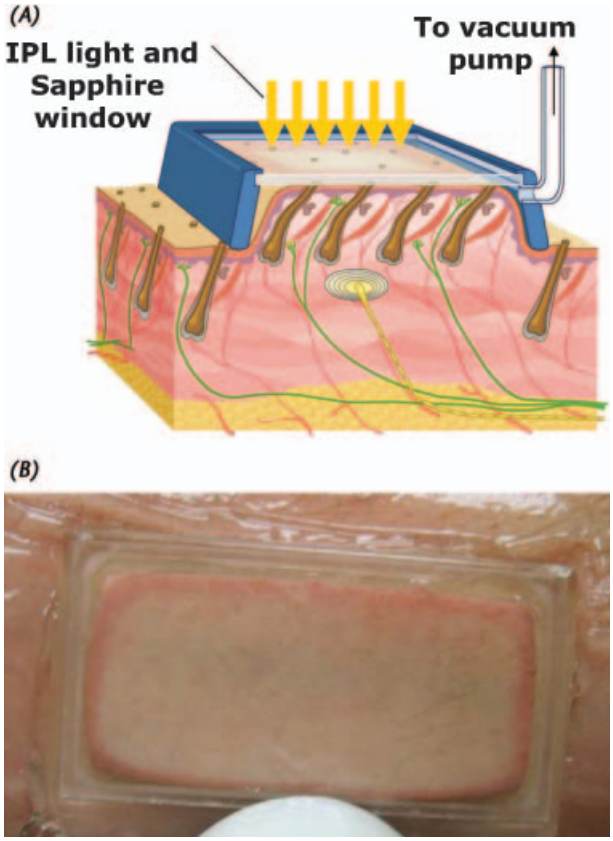

Figure 1. (A) Schematic presentation of a pneumatic skin flattening chamber. The IPL (not shown) is placed above the sapphire window. Upward skin compression expels blood from the beam pathway. (B) Skin compressed by a pneumatic skin flattening chamber.

information up to the brain. The gate theory of pain transmission is well confirmed and was first suggested by Wall and Melzack some 45 years ago (2–5). However, we test it here for the first time with vacuum-based skin compression.

Skin compression also expels blood from the treatment site, thereby considerably enhancing the spectral discrimination between melanin and hemoglobin chromophores. This enhances the safety of the treatment at higher energy densities since both chromophores strongly absorb light in the green/yellow part of the spectrum. The elimination of hemoglobin from the light path helps avoid post-treatment erythema and edema. We have compared the level of pain as well as post-treatment erythema and edema in the treatment of pigmented lesions with three different IPLs operated at 9–30 J/cm^2, with and without PSF.

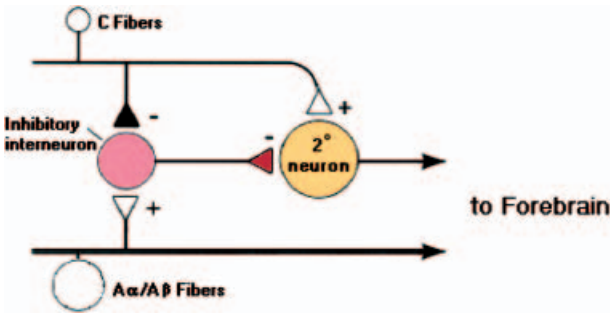

Figure 2. Operating principles of the 'gate theory'. Non-myelated C-type pain fibers and inhibitory interneurons activated by myelated pressure fibers are connected to synaptic gaps of a second neuron in the dorsal horn.

Materials and methods

Patients

Twenty patients, with a mean age of 60 years, all females, were treated for solar lentigines, with a total of 71 lesions. Skin types varied between Fitzpatrick types I–IV and Glogau III–IV. The number of treatment sites for PSF was 38 (group A) and the number of control sites was 33 (group B). The size of the treated lesions varied from 0.7 mm to 21 mm and the number of passes from one to three. The number of treatment sessions was one to three. The treated areas were face, neck, chest, hands, forearms, arms, and shoulders. All patients had undergone no previous treatments.

All patients had a complete file detailing age, sex, phototype, and Glogau type and had signed a consent form approved by an ethical committee. The number of treatment sites with PSF (group A) and the number of control sites without PSF (group B) were noted, and also the size of the treated lesions and the number of passes on the same lesion.

Equipment

IPL systems. Three different IPL systems were utilized to show that the clinical results with the PSF were not dependent on the IPL performing the treatment:

Prolite (Quantel Médical, France), 550–580 nm, operated at energy levels of 28–30 J/cm^2, 20 mm spot size, single pulse of 32–36 ms in duration, no cooling system.

Photosilk plus (Deka, Italy), 550 nm, operated at 9–11 J/cm^2, 45 mm spot size, double pulse with an interval of 10 ms in duration, contact cooling system integrated.

Harmony (Alma, Israel), 540 nm, operated at 13–18 J/cm^2, 30 mm spot size, 15 ms pulse duration.

Pneumatic skin flattening (PSF). PSF was linked to every IPL applied. The PSF vacuum chamber (Inolase, Candela Ltd) comprised of a vacuum chamber (lateral dimension: 26 × 52 mm; height: 7 mm) and a pump which automatically pumps air from the treatment site. It allows a negative pressure of 600 mmHg to be attained within less than 0.2 seconds following the placement of the handpiece on

Table I. Level of pain reduction and reduction of post treatment erythema and edema in treatments of solar lentigines by PSF.

Patient no.	Skin type	Treated site	Pain level without PSF (level 0–9)	Pain level with PSF (level 0–9)	Post-treatment erythema without PSF (level 1–4)	Post-treatment erythema with PSF (level 1–4)	Post-treatment edema without PSF (level 1–4)	Post-treatment edema with PSF (level 1–4)	Laser/IPL
1	2	Hands	3	0	1	1	1	1	Prolite (Quantel)
2	2	Chest	6	1	3	1	2	1	Prolite (Quantel)
3	2	Arms	4	2	3	2	2	2	Prolite (Quantel)
4	4	Forearms	5	0	3	1	4	1	Prolite (Quantel)
5	2	Face, neck, hands	3	1	2	1	2	1	Prolite (Quantel)
6	2	Shoulder	2	1	3	3	1	1	Prolite (Quantel)
7	4	Chest	2	1	3	3	1	1	Prolite (Quantel)
8	4	Forearms	5	0	1	1	1	1	Prolite (Quantel)
9	4	Chest	2	0	3	1	2	1	Photosilk (Deka)
10	4	Face	6	1	3	1	2	1	Photosilk (Deka)
11	2	Chest	4	0	3	1	1	1	Photosilk (Deka)
12	2	Hand, forearms	2	2	3	1	1	1	Photosilk (Deka)
13	2	Chest	4	2	3	1	2	1	Photosilk (Deka)
14	1	Chest, hands	5	1	2	2	1	1	Photosilk (Deka)
15	2	Face, arms	3	1	3	2	2	1	Photosilk (Deka)
16	2	Arms	3	0	2	1	1	1	Photosilk (Deka)
17	2	Arms	5	1	2	2	1	1	Photosilk (Deka)
18	3	Arms	6	2	2	1	1	1	Harmony (Alma)
19	3	Chest	7	2	3	2	3	1	Harmony (Alma)
20	3	Arms	6	2	2	1	1	1	Harmony (Alma)

the treatment site. A lubricant such as water spray or non-viscous gel is preferably applied to the skin to allow sealing and fast skin movement. Since the negative pressure is far above the capillary and blood pressure, blood is temporarily forced to the periphery around the treatment area, resulting in a more transparent treatment site. The vacuum chamber is covered with a sapphire window which can tolerate the high energy densities generated by the IPLs. Energy transmission of the window has been measured and found to be 95%. The IPL is placed over the PSF cover window. Once the negative pressure is high enough and the skin has been tightly compressed against the cover window, the IPL is activated and treats the lentigines through the window. The IPL is normally fired less than a second after the application of the vacuum. This is automatically followed by ventilation of the chamber, which takes place within less than 0.2 seconds, thereby releasing the vacuum to allow quick repositioning of the handpiece onto the next treatment spot.

The rational for applying negative pressure is the well-documented afferent inhibition of sensory nerves in the dorsal horn by activating tactile nerves in a sufficiently large surrounding area (2–5) (the 'gate theory'). The blood expulsion allows for better chromophore selectivity. That effect is particularly important with green/yellow lights which are utilized in the treatment of pigmented lesions.

The rational for applying a high vacuum level is the prerequisite of strong skin compression for the gating effect to take place. Lask et al. have shown that the compression level should be above 400 millibars (1).

Data collection

Pain evaluation was performed on all PSF-treated sites (group A) as well as on all control non-PSF sites (group B). The evaluation was based on a modified McGill Pain Questionnaire, which is commonly used in pain evaluation (6). Pain was graded according to a 10-level scale: 0–1 – patient barely feels the treatment pulse; 2–3 – the patient can feel the treatment pulses but there is no pain; 4–5 – mild and tolerable pain; 6–7 – acute but still tolerable pain; 8–9 – intolerable pain. Patients reported on the level of pain. Although patients were instantaneously aware of the utilization of PSF when being used (due to suction), we estimate that the effect of that knowledge did not affect the result since only 1 second separated suction and the treatment pulse. As a result the study can be considered close to randomized.

Post-treatment erythema and edema were evaluated 20 minutes after treatment. Pictures of the site were taken before treatment, immediately after treatment and 20 minutes later. Erythema and edema were graded according to four levels: 1 – none, 2 – light, 3 – medium, 4 – severe.

Treatment efficacy was compared on a 1–3 treatment basis by comparing the darkening of the treated lesions 5 minutes after the treatment and the clearing at the 1-month follow-up. The immediate darkening considered as an endpoint was graded by four levels. Since energy density was not diminished, efficacy was expected to be unaltered. Presence of scar and hypochromia were noted 1 month after treatment.

Table II. Success rate of PSF in reducing pain, erythema and edema when the problem is present (when the non-PSF level is above zero).

	Pain reduction	Reduction of erythema	Reduction of edema
YES with PSF	19	14	8
NO with PSF	1	4	1

Table III. Quantitative summary of side effects and their improvements by PSF.

Side effects after treatment (all patients)	With PSF	Without PSF
Pain (1–10)	0.82	3.76
Erythema (1–4)	1.47	2.52
Edema (1–4)	1.05	1.58
Darkening (1–4)	2.23	2.29
Scarring 1 month after	0	0
Dyschromia 1 month after	0	0

Results

Quantitative results of the study are presented in Tables I–III.

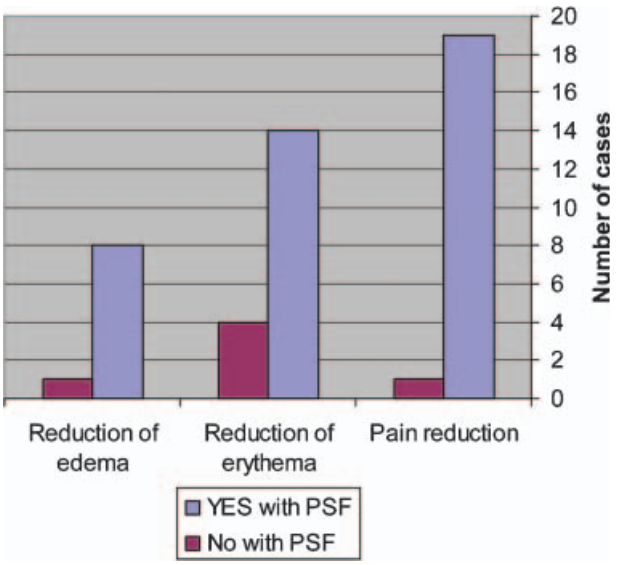

Figure 3. Summary of reduction of side effects by PSF.

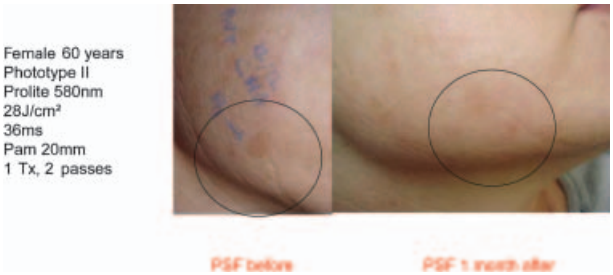

Figure 4. One-month follow-up of lentigine treatment with and without PSF. Results are visible after one treatment due to high energy density which was made possible by skin flattening.

Pain

The capability of PSF to reduce pain in the treatment of solar lentigines is presented in Table I. Substantial pain reduction was observed in 19/20 patients (95%). The average reduction of pain was by two levels. All substantially painful cases without PSF turned into no pain or very mild pain when PSF was added.

Post-treatment erythema

Table I presents the results of post-treatment erythema and edema on PSF sides (group A) and non-PSF control sides (group B). While not taking into account cases where erythema or edema were not present at all regardless of technology, the reduction of erythema by PSF was observed on 14/18 patients (77%) and edema on 8/9 (88%) – see Table II and Figure 3. The average reduction of post-treatment erythema and edema is respectively by 1 and ½ a level. We must emphasize that the reduction of post-treatment erythema and edema are more pronounced and of higher significance when higher energy densities are applied, as in the case presented in Figure 4. We have not observed any scaring or hypochromia on any patients during the follow-up.

Efficacy

The post-treatment (5 minutes) darkening of treated lesions is a common indication of the efficacy of the treatment by an IPL. We have compared the darkening of the treated lesions with and without PSF (levels 1–4). Results show identical results with and without PSF. That result is not surprising since the energy transmission of the PSF window is 95%, resulting in essentially identical efficacy of the PSF treatment and the regular non-PSF treatment. The 1-month follow-up shows an essentially identical clearing level of the pigmented lesions in group A and group B (Figures 4 and 5).

Satisfaction

All patients (20/20) expressed higher satisfaction from PSF-assisted treatments compared with regular treatments.

Discussion

The PSF technology considerably reduces pain in the treatment of pigmented lesions with IPL systems. Pain reduction is attributed to the 'gate theory' of pain transmission. PSF also reduces

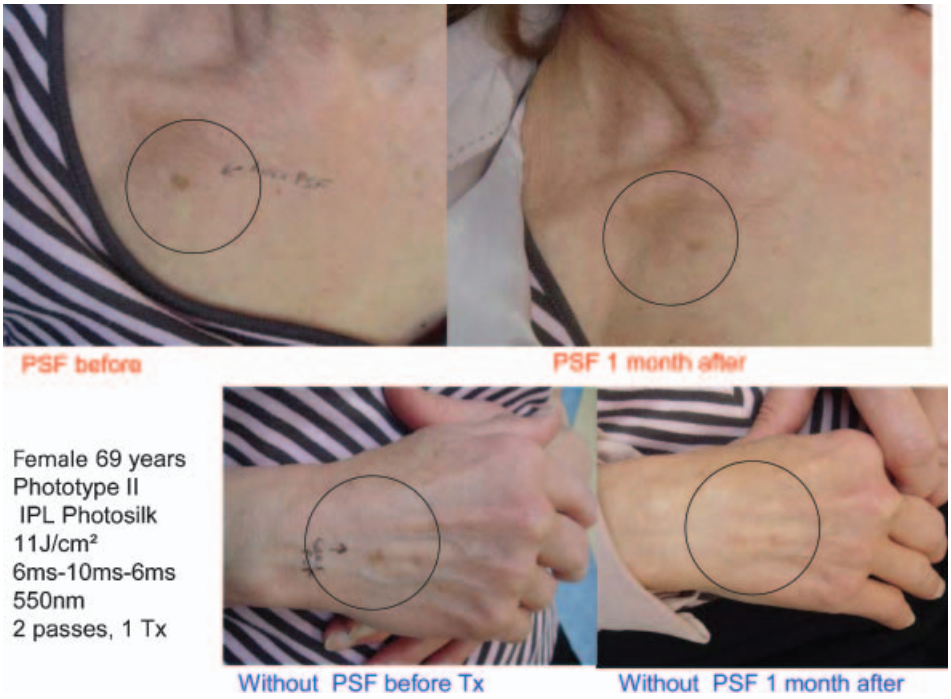

Figure 5. One-month follow-up of lentigine treatment with and without PSF. Clearance with and without PSF is identical.

post-treatment erythema and edema, thereby enhancing the safety and comfort of treatments. The reduction of post-treatment erythema with PSF is attributed to blood expulsion from the beam pathway by the skin flattening effect, resulting in higher spectral selectivity (since both hemoglobin and melanin strongly absorb green and yellow light). This is done automatically and consistently by the skin flattening vacuum chamber.

Our results also show that the treatment efficacy of PSF is identical to regular treatments. That conclusion is based on the blackening level of lesions and a 1–3-month follow-up of lesion clearing. We have utilized relatively high energy densities in our study.

We would like to emphasize that our approach is different to that described in Childers et al. (7,8) who have recently studied the changes in tissue morphology that affect underlying laser–tissue interactions by video-imaging and reflectance spectroscopy with a completely different suction device. They have utilized a vacuum device which does not flatten the skin – its upper cover is not in contact with the skin.

Conclusion

PSF is a new technology which considerably reduces pain and immediate post-treatment side effects in the treatment of lentigines with IPLs. Since efficacy is preserved, it may enable the increase of energy densities with less pain and fewer sides effects, thereby achieving faster results.

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