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ORIGINAL ARTICLE

Pneumatic skin flattening (PSF): A novel technology for marked pain reduction in hair removal with high energy density lasers and IPLs

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Abstract

Background: Intense pulsed light (IPL) aesthetic treatment, such as hair removal from large areas, is often very painful. The problems of pain and discomfort can be divided into two different phases: immediate acute pain and the long-term, milder, post-treatment discomfort also associated with erythema. The immediate acute pain is felt during each treatment pulse and can accumulate to an intolerable sensation after a few shots, resulting in the necessity of either using topical analgesic creams which have several limitations or else to considerably slow down the process and/or apply less efficient low-energy densities. The immediate pain is created by the stimulation of sensory nerves located near the basal layer of the epidermis and adjacent to the treated hair follicles. There is an interest in a technology which would significantly reduce acute pain and post-treatment erythema, without the necessity of lowering the energy density or speed of treatments. *Objectives*: To examine the advantages of pneumatic skin flattening (PSF) with negative pressure: (i) for the reduction or elimination of pain, without chilling the skin, during hair removal with high energy density IPLs and pulsed lasers; (ii) for the reduction of post-treatment erythema; and (iii) for the enhancement of hair removal. *Materials and methods*: We have removed hair from large areas such as legs and backs with a high-energy (42 J/cm^2) pulsed diode laser and an IPL (15–20 J/cm^2). Room temperature gel was applied to the skin before treatment. In all cases but one, skin was not chilled by external cooling devices. We utilized a vacuum chamber and a transparent sapphire window to generate deep negative pressure in the treatment site and flatten the skin against the window. The level of applied vacuum was in the 200–600 mmHg range. We have compared the level of pain (I–V according to a modified McGill Pain Questionnaire) and the efficacy of hair removal on a total of 40 treatment sites The results of the vacuum-assisted treatment sites were compared with the results on adjacent control areas, obtained without the application of vacuum. Post-treatment erythema was also compared. *Results and conclusions*: PSF significantly reduces pain in all patients, even when higher (+30%) treatment energy levels are applied. Skin is well protected thermally by the conductive sapphire window. Post erythema and edema is considerably reduced, as well. Hair removal efficacy is preserved or enhanced. Treatment is faster and is uninterrupted by pain, without the necessity to apply topical anesthetic over a large area. Blood expulsion resulting from flattening the skin has also enabled the treatment of thin hair in light-skinned patients, using yellow and green wavelengths (540 nm cut-off filter) and short pulse durations with a higher efficacy than with the 650 nm cut-off filter.

Introduction

Intense pulsed light-based aesthetic treatment, such as hair removal, is often very painful. This is particularly true for the removal of thick dark hair from large skin areas or sensitive areas such as bikini lines. Pain is felt with almost all types of intense pulsed light-based devices for hair removal, including broadband, intense pulsed light sources (IPL), as well as monochromatic pulsed lasers.

The sensations of pain associated with treatment are: immediate acute pain and post-treatment milder discomfort. The immediate acute pain is felt during each treatment pulse and can accumulate to an intolerable sensation after a few shots requiring a pause before continuing the treatment session. Occasionally, patients may elect not to continue the treatment. The immediate pain is caused by the rapid transfer of heat (>70°C) from the hair follicle to the sensory nerves located near the basal layer of the epidermis and to the deeper nerves adjacent to the treated hair follicles. Indeed, firing a laser pulse at a hairless zone is generally not painful. Excessive heating of the entire skin creates a much milder post-treatment discomfort. This heat is generated by

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light scattered and absorbed by collagen and blood vessels in the skin, which elevates the average skin temperature by a few degrees. This may induce redness and edema causing some discomfort. The application of a cold gauze immediately after the treatment usually helps avoid post-treatment erythema.

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 main disadvantage of such an approach is the necessity to apply the analgesic cream some 30–60 minutes prior to beginning the treatment session, thus causing the patient inconvenience. The application of topical analgesic cream over large areas also entails safety issues. Skin chilling only helps to reduce pain to a certain degree. The alternative approach of reducing energy density is generally not recommended since it may compromise hair removal efficacy.

The present article describes a pneumatic skin flattening (PSF) technology which significantly reduces the level of acute pain generated by hair removal IPLs or pulsed laser systems without reducing the treatment energy density, thereby preserving hair removal efficacy without actively chilling the skin. Moreover, the level of acute pain is considerably reduced, even if treatment energy density is increased by 10–30%. It also reduces post-treatment erythema. The PSF technology enables fast treatment of very large areas, even when covered with thick dark hair, without any necessity to pause due to acute pain. (After gel has been applied to a treatment area, the handpiece of the device is placed on the treatment area automatically generating a negative pressure on the surface of the skin. This vacuum flattens the skin tightly against a transparent sapphire window.)

The pressure created on the nerves of the skin by the vacuum-induced flattening is great enough to reduce pain and expel blood from the treatment area. The pulsed light source of the treatment is then fired and the vacuum is released at the end of the treatment pulse. This enables fast repositioning of the handpiece to a new treatment spot. The technology, which does not require a chiller, is adaptable to any IPL or pulsed laser system and works with standard transparent gel commonly used with hair removal devices.

Materials and methods

Patients

Hair was removed from 27 sites, on seven patients, with PSF using a vacuum chamber covered by a sapphire window (Inolase Ltd, Israel) and from 18 adjacent control sites treated without PSF. The selected sites were on the back, leg, arm, chest, bikini line and armpit. Skin types ranged from 2 to 5. We also conducted several treatments of five entire backs and legs with PSF technology and examined hair reduction results. In all cases, standard type transparent gel made from Carbomer 940 was applied to the skin before treatment.

Equipment

The following treatment light sources were utilized:

1. Lasers
   LightSheer (Lumenis, USA) operated at a wavelength of 810 nm and 30 ms pulse duration at an energy density E=26–42 J/cm^2.
   Alexandrite (Candela, USA) operated at a wavelength of 755 nm and 3 ms pulse duration at an energy density E=20–26 J/cm^2.
2. IPL
   Harmony (Alma Lasers, Israel) operated on 19 sites at a wavelength of 650–950 nm and 30–40 ms pulse duration at 15–20 J/cm^2 energy densities, and on 16 sites at a wavelength of 540–950 nm and 10–15 ms pulse duration at 15–17 J/cm^2 energy density on light skin. The rational for utilizing a 540 nm handpiece was the much deeper expected penetration of green and yellow light into the skin due to the blood expulsion effect combined with better absorption of these wavelengths by the hair shafts.
   Photosilk (Deka, Italy) operated at a wavelength of 550 nm and 12 J/cm^2.

The PSF vacuum chamber (Inolase Ltd) comprised 26 × 52 mm lateral sizes, a 7 mm height vacuum chamber and an extremely low friction miniature rotary pump which automatically pumps both compressible air and non-compressible gel from the treatment site and attains a negative pressure of 600 mmHg within less than 0.5 s following the placement of the handpiece on the treatment site. 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 transparent sapphire window on which the skin is compressed as a result of the negative pressure (Figure 1). The high thermal conductivity of the sapphire window, which is in excellent thermal contact with the skin, ensures immediate (approximately 2 ms) diffusion of heat from the epidermis to the window. This time is shorter than the pulse durations of the treatment source (5–100 ms), thereby avoiding epidermal burns. Essentially, any laser or IPL treatment handpiece held in the operator's other hand could be conveniently placed on the vacuum chamber window (Figure 2). Once the negative pressure is high enough and the skin has been stretched tightly against the sapphire window, the light treatment pulse is fired.

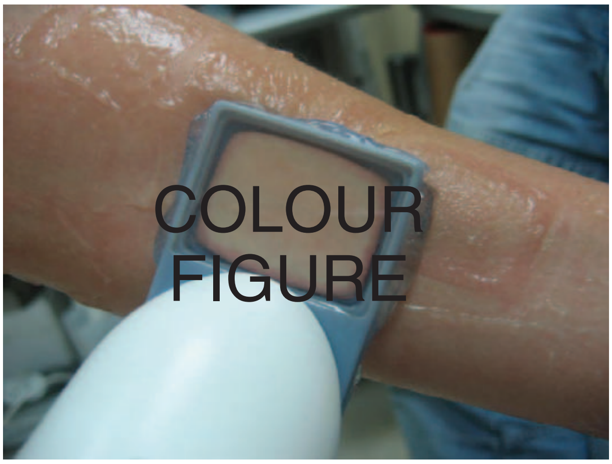

Figure 1. Treatment area under proper vacuum conditions. Blood is temporarily expelled from the treatment area.

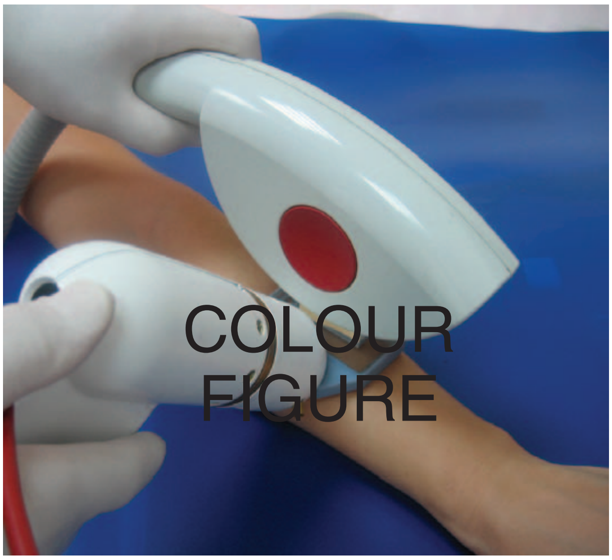

Figure 2. Application of a PSF vacuum chamber with an IPL.

This is automatically followed by ventilation of the chamber, which takes place within less than 0.5 s, 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 pressure nerves in a sufficiently large surrounding area (1,2). The blood expulsion allows more energy to reach the hair shaft and consequently is expected to increase the hair follicle temperature and contribute to instantaneous acute pain. However, inhibition of the sensory nerves eliminates that pain. Reduced erythema is attributed to the blood expulsion from the buffer zone, rendering better selectivity and less excessive heating of tissue. Improved efficacy is attributed to treatment at optimized conditions: uniform light absorption in pneumatically flattened skin; improved penetration of light into the skin entailing higher treatment energy densities. Figure 3 presents the operating principle of the vacuum chamber handpiece as well as the negative pressure, pain blocking effect.

Data collection

Hair removal efficacy. Each treatment site was shaved and photographed before and a few minutes after each session. The measurement of hair removal efficacy was based on hair count before and a few weeks after each treatment and, in one patient, up to 9 months after the treatment. Hair removal efficacy was measured on 10 sites and 10 adjacent control sites.

Post-treatment erythema. Evaluation was done up to 60 min after treatment on 10 sites treated with vacuum and 10 control sites. Treatment areas were also documented with photographs.

Pain. Acute pain evaluation was performed on 27 PSF sites and compared to 18 regular non-vacuum control sites. The vacuum level was 500–600 mmHg. The evaluation was based on a modified McGill Pain Questionnaire, which is commonly used in pain evaluation (3). Pain was

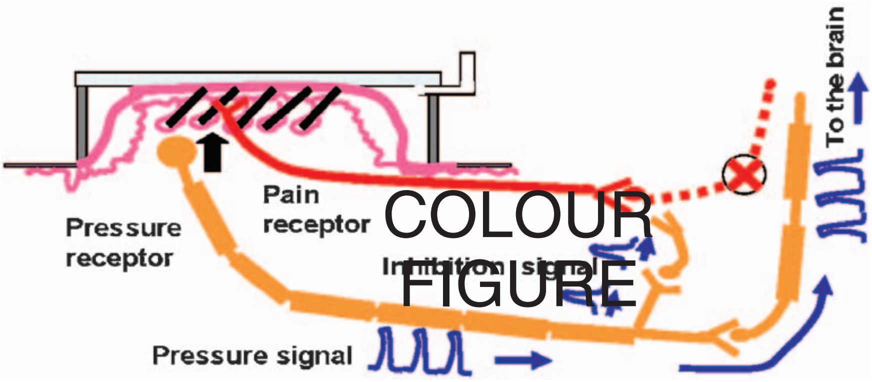

Figure 3. Operating principle of pneumatic skin-flattening technology. Skin is elevated in a vacuum chamber and flattened against a sapphire window. Fast conduction myelinated pressure sensing nerves conduct a pressure signal to the vertebral column. That signal blocks the synaptic gate, which is normally used by slower, non-myelinated pain nerves to transmit pain signals to the brain.

graded according to a five-level scale: I – patient barely feels the treatment pulse; II – the patient can feel the treatment pulse but there is no pain; III – mild and tolerable pain; IV – acute but still tolerable pain; V – intolerable pain. Patients reported on the level of pain. Differences among groups were evaluated using the chi-squared test. The pain level was also tested on 10 sites at milder vacuum levels (100–400 mmHg). Skin was pneumatically flattened; however, the pressure applied on pressure receptors in the skin was lower, and the expected pain level inhibition was lower.

Results

Hair removal efficacy and treatment speed: 650 nm and above wavelengths

The hair removal efficacy of the PSF technique has been found to be identical to or better than the efficacy of regular non-vacuum hair removal at identical energy density levels and pulse durations on all patients. The long-term efficacy of hair removal lasers and IPLs is well documented (3,4). The LightSheer diode laser and Harmony broad-band IPL have also been studied by several authors in the past (5,6). Figure 4 shows the treated area on the back of a male patient treated with a 650–950 nm IPL with and without negative pressure skin effacement 7 months after the second treatment. The energy density was 20 J/cm^2 and pulse duration 30 ms. Results of both techniques are identical in that case: 60–75% hair reduction on the back after two treatments. Figure 5 compares a right arm treated with vacuum to a left arm treated without vacuum for identical treatment parameters (16 J/cm^2 on the skin, 40 ms). The arm treated with PSF shows a better result. We have also been able to utilize higher energy densities with the PSF technique without pain, such as with the LightSheer case shown in Figure 6, further enhancing efficacy with reduced pain and skin risk (see below). Although topical anesthetics were not used, there was no need to pause and treatment speed was similar to normal.

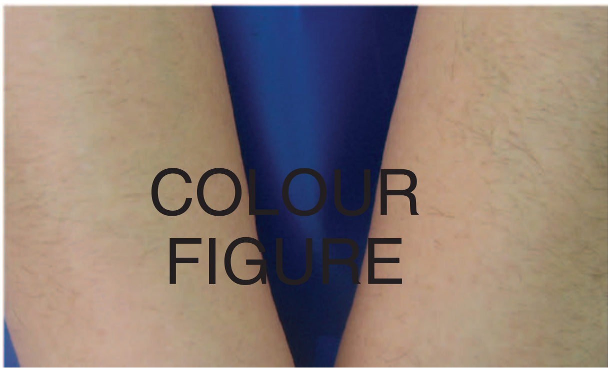

Figure 5. Arms of a patient 90 days after a third treatment. The right arm was treated with IPL and PSF; the left arm was treated without vacuum. Energy density 16 J/cm^2 on the skin; pulse duration 40 ms.

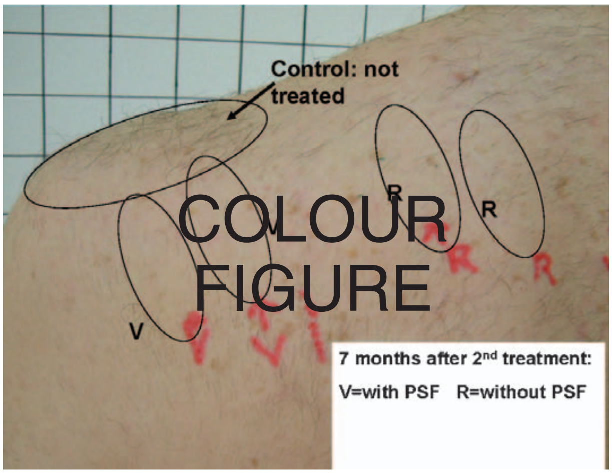

Figure 4. Hair removal from the back of a male with skin type IV 7 months after a second treatment. Left side (V) was treated with vacuum. Right side (R) was treated without applying vacuum to the skin. Efficacies of both techniques are identical (2–4 hairs/cm^2). Notice the full growth of hair on untreated areas (8–9 hairs/cm^2). Skin was treated with a 650–950 nm IPL, energy density 20 J/cm^2, pulse duration 30 ms.

Shorter wavelengths

By using the Harmony shorter wavelength IPL treatment handpiece (540 nm filter) and shortening the pulse duration to 15 ms, the efficacy of thin hair removal on light skin (types I–III) was considerably higher than with the 650 nm handpiece. Energy density was 15–17 J/cm^2. The enhanced efficacy is attributed to better penetration of the yellow and green light into the blood-free skin, as well as better absorption of light by the thin hair shaft.

Post-treatment erythema

Post-treatment erythema was considerably reduced and almost eliminated in all patients by applying the vacuum assisted PSF technique. Figures 6A and 6B show the back of a patient treated with the LightSheer (810 nm, 30 ms). Treatment was applied in four sections designated by a blue marker at an energy density up to 42 J/cm^2. Contact cooling was applied without the application of topical anesthetic cream.

The lower right side was treated with vacuum-assisted PSF at 42 J/cm^2, whereas the upper right was treated with PSF at 38 J/cm^2. The left side was treated without vacuum at a variety of energy densities, 38 J/cm^2 (upper) and 26–42 J/cm^2 (lower). As illustrated in the picture, within 10 min

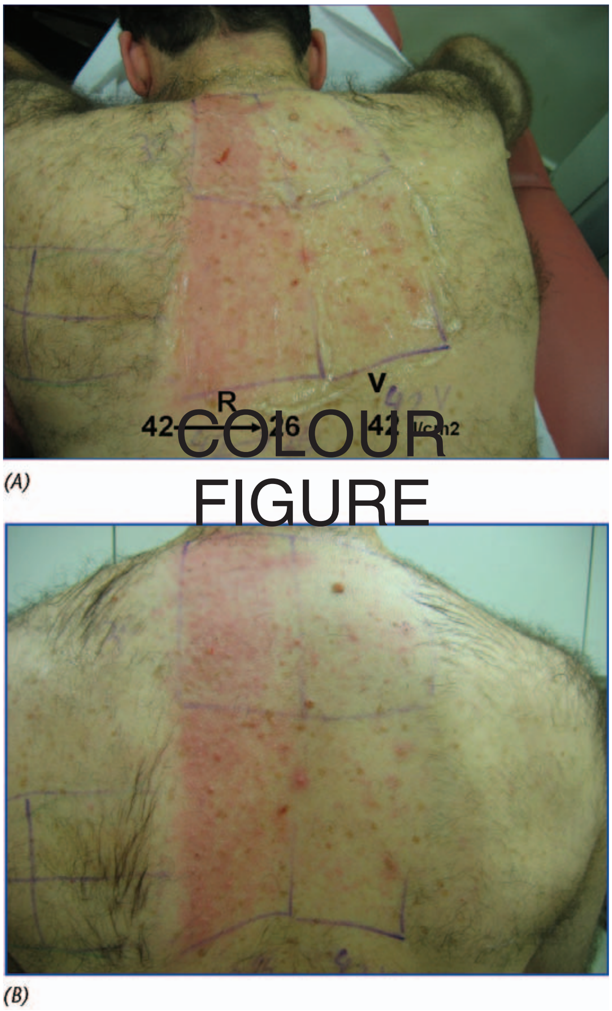

Figure 6. (A) The back of a patient immediately after a treatment with the LightSheer (Lumenis; 810 nm, 30 ms) at an energy density up to 42 J/cm^2. The upper right side was treated with vacuum at 38 J/cm^2. The lower right section was treated with PSF at 42 J/cm^2. The upper left side was treated without use of the PSF vacuum chamber at an energy density of 38 J/cm^2, and the lower section with vertical passes ranging from 26 to 42 J/cm^2. Erythema was virtually absent on the right side and present on the left side. The pain on the upper left side was intolerable (level V). Pain on the lower left was intolerable except at the 26 J/cm^2 vertical pass. The treatments on both right-hand sections were comfortable at pain levels II–III. (B) Skin reaction – 10 minutes post-treatment.

of treatment at 38 and 42 J/cm^2 the vacuum-assisted area is nearly free of erythema, whereas the area treated normally without vacuum shows severe erythema at all energy levels above 26 J/cm^2. The same phenomenon was also observed with IPL treatments.

Elimination of acute pain level

In reference to Figures 6A and 6B, the level of pain felt by the patient on the negative pressure skin-flattened side was in the range of II–III, and the patient felt comfortable during the treatment without topical anesthetic cream. In contrast, the level of pain on the normal non-vacuum-assisted side was intolerable (level V) at 42 J/cm^2. Only at a lower and less effective 26 J/cm^2 energy density did the pain level of the regular non-vacuum technique attain level III. Referring back to Figure 4, the pneumatic skin-flattened side had a low level II pain, whereas the non-flattened side had a high pain level IV.

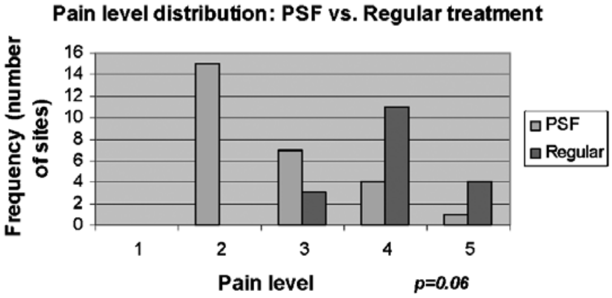

Figure 7. Perceived pain reduction of PSF technology.

Figure 7 summarizes the statistical distribution of pain level with the PSF technique as compared to pain level in adjacent control sites without applying the PSF technique. The figure shows that only 20% of the patients treated with PSF felt any pain, none was intolerable and 80% felt that treatment was comfortable. Among patients treated with regular non-vacuum techniques, 80% felt acute pain and only 20% did not feel pain. The chi-squared statistical test shows that PSF is significantly less painful than non-vacuum treatments ($p<0.06$). That result holds for all treated areas. Moreover, PSF-assisted treatments of entire backs and legs of five patients were reported to be comfortable and quick while treatments of patients without PSF were painful and considerably slower, with some patients choosing not to continue treatment.

Table I shows the relation between pain level reduction and the vacuum level in the PSF chamber. As expected, pain reduction was found to be greater at higher vacuum levels since pain blocking was created by impulses from pressure sensing nerves. We have found that 500–600 mmHg is the threshold for virtually painless treatments.

Table I. Dependence of pain level reduction on the level of vacuum in the PSF chamber.

Applied vacuum (mmHg)	Level of pain reduction
0	0
100	0
200	0
300	1
400	1
500	2 (perceived as highly substantial)

Discussion and conclusions

The application of over 500 mmHg negative pressure to the skin and its flattening against a transparent sapphire window inhibits acute pain transmission and essentially ensures substantial pain reduction in IPL or laser-based hair removal procedures. Moreover, higher energy densities may be utilized in treatment, thereby enabling efficient long-term results. Higher efficacy is obtained in many cases even at identical energy densities. A synergic benefit is the blood expulsion from the treatment area, which makes the skin appear more transparent. As a result, average skin temperature elevation is avoided and post-treatment erythema is also eliminated.

In addition to pain elimination and enhanced safety with traditional hair removal wavelengths (longer than 650 nm), the technology enables safer utilization of the shorter yellow and green wavelengths in light-skinned patients and the use of shorter pulses, further enhancing the efficacy of thin hair removal.

The pneumatic skin effacement technique is adaptable to any high energy density IPL or laser hair removal device, eliminating the need for chilling the skin.

Acknowledgement

Note: the pneumatic skin flattening and vacuum-assisted modification of spectral properties of the skin as well as the dermatology pump are patent pending.

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