PLASMALITE™

FPL™
(An Intense Pulse Light System)

Pro-Facial™
(Skin Rejuvenation)

SKIN REJUVENATION USING A FLUORESCENCE PULSE LIGHT (FPL) SYSTEM: EVALUATION OF 36 CASES

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INTRODUCTION:

Facial aging occurs secondary to gravity-induced tissue ptosis and photo-aging. Photo-damaged skin is characterized not only by wrinkles, but also by epidermal and dermal atrophy, rough skin texture, irregular pigmentation, flushing, erythema, telangiectasias, laxity, and enlarged pores [1]. The optimal treatment should be able to improve each of the different components of photo-damaged skin in order to achieve a more remarkable visible improvement.
Treatment of facial wrinkles has been tried through many methods in order to improve the quality and appearance of the skin. These methods include different topical agents such as glycolic acid [2], retinoids [3], chemical peeling agents [4] [5], dermabrasion [6] and laser skin resurfacing [7] [8] [9].
In recent years, laser resurfacing has gained popularity in the rejuvenation of photo-damaged skin, particularly for wrinkles reduction or flattening.

The laser operates through ablating the epidermis and superficial dermis, while producing a limited amount of thermal damage in the underlying dermis ([10] [11]. Nevertheless, the post-treatment side effects, such as pronounced purpura, changes in pigmentation, unpleasant appearance of the crusts and occasionally prolonged edema, have been a matter of concern to patients [12]. The obligatory long period of “downtime” both from work and social activities is a superadded disadvantage. This prolonged recovery period has provoked a great interest in devices that could rejuvenate the skin with minimal adverse effects [13].
More recently, non-ablative photo-rejuvenation was used to deliver enough energy to promote dermal collagen shrinking (“instant nom invasive facelift”) and collagen regrowth while leaving the epidermis undamaged. Plasmalite™ is the latest technology for selective photo-thermolysis, which is based on a unique combination of patented fluorescent filter technology, selected spectrums of light source emission, light pulse forming and a sapphire based skin-cooling system. The study describes this new application of the Fluorescence Pulse Light (FPL) system and evaluates the degree of visible improvement and complication rate in aged skin following a series of full-face fluorescent pulsed light treatments.

MATERIAL AND METHODS:

This prospective study was carried out during February-August 2001 at the Medical Bio Care (MBC) Center in Gothenburg, Sweden. Thirty-six patients, 33 females and 3 males, aged 35-72 years (mean 49) with class I-IV wrinkles and Fitzpatrick skin types I-IV were entered into the study. The patients were excluded if they had used oral retiniods within the year

prior to the study or had a history of photosensitivity or inflammatory skin disease. The patients were treated with a non-ablative, non-lasing fluorescence pulsed visible light source (Plasmalite™, developed and manufactured in Sweden by Medical Bio Care Sweden AB).

Description of the Device: Plasmalite™ uses filtered and spectrally altered light to selectively target melanin, hemoglobin or collagen by selective photo-thermolysis. A sapphire crystal light-guide conducts the filtered light to each targets chromophore in the tissue. It operates through creation of a directed incoherent light beam of spectrally altered and converted light. There is no UV light. The sapphire crystal light guide transports the resultant longer wavelength from a laser-dye impregnated polymer sheet, which emits the spectrally selected bandwidth ranging from a chosen cut on 535 – 615 nm wavelength and up to about 1000 nm.
Different applicators, automatically chosing various soft ware for each kind of leasion or treatment, houses different lamps that provides purpose customized spectrum that is then refined through wavelength alteration and wavelength conversion. All in co-operation with the unique pulse forming to maximize the effect and minimize the risk of any side effects. Further it should be noted that Sapphire in contact with the skin cools the epidermis 30 times more efficient compare to water, gel or quartz glass, hence it fully possible to to work in direct contact with the skin, without any cooling gel in between.

Treatment Protocol: All patients were treated 3-4 full-face treatments at 3-4 weeks interval with Plasmalite™. The energy density was set on 25-39 J/cm^2 with pulse duration 50 to 80 ms and using 535 nm (yellow) or 580 nm (orange) cut on filter. The energy was delivered through a 10 x 20 mm light guide that was pre-cooled by ice water or cryogen spray. No pre-treatment medication or anesthetic preparations were used. No cooling gel was used, just a very thin film of optical contact gel The same thin gel film is also helping in seeing where one has already treated by leaving a fine and precise footprint, contrary to the diffuse footprints seen in thick, 1 – 3 mm, cooling gel layers. Post-treatment, Aloe vera gel was applied to the treated area.
The treatment started by applying a thin layer of cold optical contact gel over the area to be treated (full-face). A series of short light flashes were passed over from the light-guide. The lighter the skin was the higher the pulse duration (60-70 ms) and fluence (30-35 J/cm^2) with a 535 nm cut on yellow filter.
For the more darkly pigmented patients the 40-60 ms, 20-30 J/cm^2 settings were used with a 580 nm cut on orange filter. Pain during the procedure was reported on a scale of 0-5: 0: no pain and 5: very severe pain.

Evaluation: An investigating doctor, who had experience in plastic and aesthetic surgery, and the patient, evaluated the results at 3-4 weeks after each treatment. The primary efficacy parameter is the evaluation by the investigator at the time of each treatment. Photographs act as secondary efficacy parameters for analysis and determination of success. The success criteria include absence of unexpected adverse skin effects, improvement as determined by the investigator (fair, good or excellent), improvement as determined by the patient (a result of satisfactory or better) and improvement of wrinkle severity by one or more scores from baseline. The wrinkle severity was evaluated according to Fitzpatrick scale (0-9); 0: no wrinkles, 1-3: mild, 4-6: moderate, 7-9: severe. The overall cosmetic assessment at each follow-up interval, where post-treatment comparisons are made to baseline (pre-treatment), is based on the scale: no improvement, fair, good and excellent.

ETHICS:

All patients signed consent for participation in the study and for using the photographs for presentation purposes.

RESULTS:

All patients received 3 treatments, 26 went through 4 treatments (Table 1). The time required to perform each full-face treatment was ranging from 20 to 26 minutes (average 22). Twenty-seven patients had skin type II, and the remaining had skin type I, III and IV (Table 1). One patient was light smoker (>10 cigarette/day) and 2 patients moderate (10-20 cigarette/day). Five patients exposed their body to the sun or sun beds during the last 3 months before treatment.
Test patch was negative in 29 patients and slight reddening was reported in 6 patients and some blisters in 1 patient.
Most patients reported a mild to moderate stinging sensation, however they tolerated the procedures well. Thirty patients experienced slight to moderate pain and only 1 patient had severe pain (Table 1). This patient received the treatment during the time of menstruation period. Most patients had mild to moderate wrinkle severity before treatment (Table 2). Post-treatment, 27 patients had slight red patches that disappeared after few hours and only one patient had some blisters at the sites of hair follicles (thick black hair).

(Table 1) Skin type and pain scale

Variable	0	I	II	III	IV	V
Skin type	-	4	24	5	3	-
Pain scale	6	3	12	9	5	1

The number of treatments and the investigator and patient evaluations were shown in table 3. Three weeks after the first treatment, 94% of patients were very happy or satisfied with the overall results of their treatments. The remaining patients were not fully satisfied, as they were expecting more impressive changes.

(Table 2) Pre-treatment Skin Characteristics According to Fitzpatrick Scale

Wrinkle class	0	I	II	III
Number of patients (n=36)	-	2	28	6

Wrinkle severity	No wrinkles (0)	Mild (1,2,3)	Moderate (4,5,6)	Severe (7,8,9)
Number of patients (n=36)	-	17	17	2

(Table 3) Patient and Investigator Evaluation Before Each Treatment

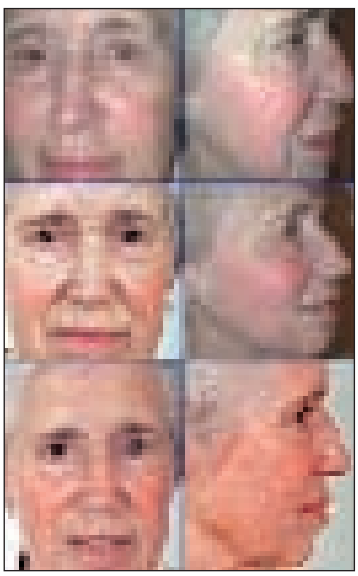
Treatment	Number	Patient evaluation			Investigator evaluation		
		Better	*Satisfied*	*Average*	*Excellent*	*Good*	*Fair*
1	36	Baseline					
2	36	16	18	2	17	17	2
3	36	17	19	-	19	16	1
4	26	18	8	-	20	6	-

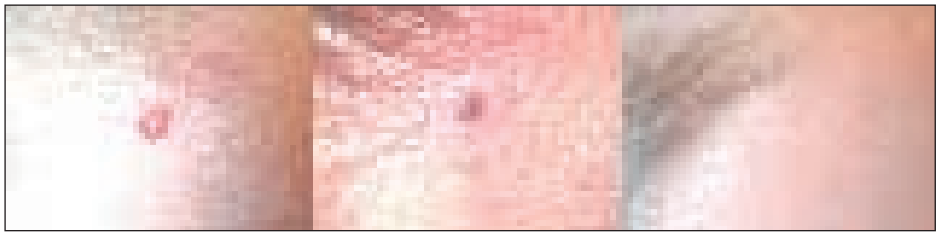
The different aspects of photo-damage including wrinkling, skin coarseness, irregular pigmentation, pore size, and telangiectasias were evaluated and summarized in table 4.

(Table 4) Skin Characteristics and Severity Score at Baseline and After Treatment

Clinical criteria	n	Severity (median) n=36	
		Baseline	Post-treatment
Smoothness	36	Moderate	Mild
Fine wrinkles	36	Moderate	Mild
Coarseness	36	Moderate	Mild
Laxity	30	Moderate	Mild
Pore size	36	Moderate	Mild
Irregular pigmentation	26	Moderate	No pigmentation
Telangiectasias	10	Moderate	No telangiectasias
Facial flushing	5	Moderate	No flushing

Twenty-eight patients showed some improvement in the quality of skin (Fig. 1, 2, 3, 4, 5). One patient had a cherry angioma on the face, which disappeared after one session (Fig. 6). No patients were found to have total resolution of wrinkles. There was no serious complication, no scar formation (no change of skin texture), and no permanent discoloration. The only side effect was reported after the fourth treatment in one patient. It included some confluent blebs 2 days after the treatment. A thin scab subsequently developed within 5 days, which fell off within 2 weeks. Then the area appeared homogenously, even colored, firm and with smooth texture (Fig. 6).





DISCUSSION:

Non-ablative sub-epidermal remodeling represents the most recent approach to improve photo-damaged skin. Dermal remodeling is thought to occur through increased collagen I deposition with collagen re-organization into parallel arrays of compact fibrils, which results in clinical improvement [14] [15]. This method is helpful for the individuals who do not wish to loose time from their daily activities. It is also valuable for those with sun-induced epidermal pigment changes.

Based on the extensive research on thermal injury to the cornea, it is known that heat-induced collagen shrinkage occurs at temperature of 55-60 ºC [16]. Since significant cumulative reduction of facial wrinkles occurs over a period extending up to 6 months after CO_2 laser skin resurfacing treatment [17], delayed wound healing must be a major component of the mechanism of action. Delayed wound healing, including collagen synthesis, has been documented as an important mechanism of action in reduction of wrinkles by dermabrasion [18]. Histological studies on CO_2 laser skin resurfacing have identified similarities in wound healing and collagen formation in comparison to dermabrasion and other modalities [19] [20]. Heat-induced collagen shrinkage appears to contribute to the improvement in perioral and periorbital wrinkling and photo-damage by tightening the loose skin and folds [21, 22]. However, the biological mechanism of selective photothermal collagen stimulation is not yet fully explained.

The study evaluated the efficacy and safety of a new application of a filtered, non-coherent fluorescence pulsed light system in the non-ablative rejuvenation of photo-damaged facial skin. In this study we showed that there is a good clearance of pigmentations, telangiectasias and flushing and reduction of wrinkles, coarseness, pore size and laxity. Age and gender did not play a role concerning our reported results. Single treatment gave considerably good results; but repeated treatments after 3-4 weeks resulted in visible improvement not only of wrinkles, but also improvement in all elements of photo-damage.

Although the results of patient treatment series are impressive after the last treatment, it is essential to evaluate the long-term results, especially in the patients complaining mainly of wrinkles. This will be reported in the near future. However, more studies are required to determine how long the results will last, what are the most appropriate parameters, and how this technique compares to other non-ablative techniques.

Blisters were seen in only one patient after 4th treatment, which was due to the deficient pre-cooling of the sapphire waveguide. Efficient skin pre-cooling is very important to avoid side effects such as blistering. Epidermal cooling also provides considerable pain reduction.

The fluorescence pulsed light (FPL) system is flexible in selection of the treatment sittings according to the individual patient. This is very helpful in the achievement of excellent results after multiple treatments. Various parameters such as cut-off filter and pulse duration were taken into consideration during the treatment of the present series. The wavelength can be produced with cut-off filters ranging from 535 to 900 nm. Deeper penetration into the skin can be performed with longer wavelengths. The pulse duration can be varied between 40 to 84 ms, so that the energy can be applied to the skin with a controlled power. The parameters were then refined according to the reaction to treatment; so the fluence and pulse duration were readjusted if the first treatment did not result in visible improvement and if there were no side effects.

The Plasmalite™ shows several advantages compared with older laser types. The spot size of Plasmalite™ covers a surface of 2 cm^2, while other systems have considerably smaller spot sizes. The larger surface of the spot size of Plasmalite™ offers a more time-efficient treatment and enables deeper light penetration into the skin. Patients have less pain, there is less edema formation, less erythema, and even if it appears, it only remains for a few hours. Hypo- or hyper-pigmentation during the treatment of facial wrinkles and other elements of skin photo-damage are hardly ever seen. Furthermore, the Plasmalite™ even offers multiple treatment possibilities, e.g., hair removal, treatment of vascular changes, pigmentations and acne.

CONCLUSION:

The present study showed that the technique for skin rejuvenation using serial, full-face treatments with a filtered, non-coherent pulsed light source (Plasmalite™) achieved a high degree of patient satisfaction with very minimal adverse effects, no downtime, and no risk of scarring. The method showed efficacy in evidently improving all aspects of photoaging including fine wrinkles, irregular pigmentation, skin texture, pore size, flushing and telangiectasias. The average treatment duration was 22 minutes and the discomfort of treatments, if any, was quite tolerable without any pre- or intra-operative medication. The only post-treatment finding was erythema, which was always transient and disappeared in a few hours. The only side effect was blistering (in one patient) due to the deficient pre-cooling of the light guide. Otherwise, the treatments were safe, easy and well tolerated by patients. So, the Plasmalite™ is an excellent device for treating photo-damaged skin.

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