

## Surgen Hybrid Energy - A novel Micro-Needles Technology for Skin Treatment

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## Abstract

**Introduction:** Demand for skin rejuvenation and anti-aging procedures with minimal down time and low risk has led to the development of methods for non-surgical treatment of wrinkles, scars and general facial enhancement. In the past few years, fractional radiofrequency (RF) systems have been introduced that enable controlled skin resurfacing. The new Hybrid Energy™ (HE) micro needles technology delivers hot and electrical energies creating micro ablation thus promoting natural fractional healing process for dermal refilling and skin renewal. The objective of the current research was to evaluate the safety and effectiveness of the novel Surgen device HE applicator for collagen remodeling, skin volume refilling and wrinkles reduction.

**Methods:** HE treatments for various aesthetic indications were performed. In addition, ex-vivo histological results showing effects of the HE technology were obtained.

**Results:** Photos demonstrated skin refilling effect along with improvement of skin texture and irregularities including acne scars and wrinkles appearance. Histology demonstrated immediate and long term HE effects on both epidermal and dermal skin layers with a direct correlation between the treatment parameters and treatment effect.

No significant adverse effects were detected.

**Summary:** HE invisible micro ablation treatment results in a significant dermal enhancement and skin renewal while minimizing epidermal visible response. HE novel technology delivers results with none to minimal pain and no downtime.

## Introduction

A wide variety of non surgical techniques are used for skin rejuvenation to improve the appearance of facial wrinkles, acne scars and skin imperfections. These include non ablative lasers, intense pulsed light (IPL) and radiofrequency (RF) technologies, among them the Apollo™ and Maximus™ systems based on the TriPollar® RF technology, which are widely used for various skin treatment indications via a thermal process leading to dermal collagen remodeling [1-8].

These non-ablative procedures are considered as having a high safety profile and moderate clinical effect. On the other hand, ablative resurfacing lasers such as carbon dioxide (CO<sub>2</sub>) lasers and erbium: yttrium-aluminum-garnet (Erbium YAG) lasers used to be the gold standard of minimally invasive treatments, however these treatments were associated with significant downtime and relatively high risk of side effect [9-12], especially on dark and Asian skin types. The demand for new procedures delivering visible clinical improvement with reduced downtime, has led to the development of fractional lasers [13-14]. Instead of treating an entire skin area, these lasers treat a condensed matrix of small "islets" of tissue leaving intact skin in-between these islets. Healing is initiated from these intact skin areas resulting in reduced downtime and reduced complications. Since the introduction of the first fractional laser system, a myriad of "fractional" laser systems mostly based on CO<sub>2</sub> and Erbium YAG laser technology, have been developed and cleared for marketing worldwide [15].

In the past several years, several fractional RF systems have been introduced that allow controlled fractional skin resurfacing by employing a matrix of miniature RF electrodes placed in contact with the skin surface. In addition to the epidermal effect, fractional RF systems allow enhancement of the dermal layer via volumetric heating thus leading to an effective micro-ablative skin resurfacing and improved appearance of wrinkles, fine lines and acne scars.

The effect of a fractional RF applicator (Matrix™ RF by Syneron) for skin rejuvenation and wrinkle reduction was evaluated by Hruza et al. [16]. Their histological findings, immediately post-treatment, revealed demarcated zones of ablation/coagulation/necrosis and sub necrosis up to a depth of 450 micron. Higher energy levels generated deeper effects. They concluded that RF fractional skin resurfacing results in a safe, tolerable and effective improvement in skin texture and reduction of wrinkles. The depth of tissue ablation, coagulation and necrosis and the relative proportions of these phenomena were found to be controllable and could be modulated to optimize treatment of various dermatologic conditions.

In a previous study we demonstrated clinical and histological results of the TriFractional™ RF technology from Pollogen Ltd. for micro-ablative skin resurfacing and the treatment of wrinkles [17]. RF is delivered sequentially between pin electrodes and large electrodes which surround the pin matrix. Due to this design, relatively high RF current densities are formed in the tissue under each pin electrode, resulting in localized fractional micro-wounds in the epidermis where there is direct contact with the electrodes while heat is delivered deeper into the dermis. This fractional manner of energy delivery leaves intact zones in between the targeted areas which serve as a reservoir of healthy cells to promote faster, more effective wound healing. TriFractional treatments lead to controlled epidermal micro-ablation and concomitant dermal remodeling.

Recently new devices employing minimally invasive bipolar micro needle RF electrodes which are percutaneous introduced into the skin were introduced to the market for the treatment of wrinkles and skin laxity [18-21]. Published studies revealed that such treatments induced an active dermal remodeling process including ne elastogenesis and neocollagenesis with an intact epidermal layer.

The current research was intended to evaluate the safety and efficacy of the novel Hybrid Energy micro needle technology for skin volume refilling and wrinkles treatment.

## Methods

### Pollogen's Surgen System Hybrid Energy Platform

The Surgen system (Figure 1) is a new platform composed of a main unit and two applicators: The novel Hybrid Energy (HE) micro needles applicator and the TriFractional applicator (same as the previously introduced A3F applicator for the Pollogen Maximus device).



**Figure 1:** The Surgen Device

The disposable HE tip which is placed on the target skin area, is attached to the distal end of the applicator (Figure 2). Two types of tips are available: gen 36 and gen 12 (for small, delicate, curved areas) with 36 and 12 micro needles, respectively. The tip is composed of an array of micro needles which penetrate the treated area in an innovative unique manner enabling efficient, uniform and homogenous penetration coverage with none to minimal pain. HE energy creates invisible micro wounds in the dermal layer characterized by optimized dermal impact and minimal epidermal effect. The micro wounds are surrounded by healthy unaffected skin areas which function as healing centers promoting effective neocollagenesis and skin renewal. The Hybrid Energy treatment triggers the body's natural healing response mechanism in a safe and effective process, with minimal pain and side effects.



**Figure 2:** Hybrid Energy applicator and Gen 36 disposable tip

Hybrid Energy technology combines Dual energy: Thermal RF energy for safe, effective and virtually painless penetration of the skin and electrical energy directly applied to the specific target area, enhancing the total clinical effect. Hybrid Energy combined clinical outcome is composed of targeted thermal skin restructuring reinforced by deep volume refilling.

The Hybrid Energy application provides a dual effect, both on the dermal and epidermal layers of the skin with a major impact on the dermis.

The Surgen system has an advanced, user friendly touch screen with pre-programmed default parameters for each treatment type.

The default Low, Medium and High treatment programs can be easily adjusted and custom tailored according to specific patient needs.

## Clinical Evaluation

An initial evaluation was conducted treating healthy volunteers for various aesthetic indications such as wrinkle reduction, acne scars treatment, skin firming and rejuvenating and facial contouring.

Subjects were photographed at baseline and after every treatment. In addition, results of perioral or periorbital wrinkles were evaluated in selected subjects, with a three-dimensional (3-D) micro-topography imaging system (PRIMOS, GFM, Teltow, Germany).

Topical anesthesia (Emla, 5% Lidocaine prilocaine, AstraZeneca) was used prior to the treatment according to the manufacturer guidelines.

The face was thoroughly cleaned and dried before treatment. Treatment was conducted according to the instructions in the Surgen user manual. The HE treatment parameters for each subject were defined according to the area being treated and the severity of the skin condition. HE applicator was placed vertically on the skin with slight pressure to ensure optimal contact.

During the first visit, the first few pulses were of low level in order to assess the immediate results. Once the initial skin response was assessed the physician decided on the power level according to subject's skin condition. Post treatment, the HE disposable tips were disposed of safely as indicated in the user manual. A new sterile tip was used for each treatment session.

Typically slight erythema and edema appeared immediately, peaked about 30 minutes post treatment and lasted for a few hours. A subtle tiny crust matrix pattern occasionally appeared 1 to 2 days post treatment on few patients and lasted 3 days to one week, depending on the skin characteristics and treatment power. Patients were instructed that it is possible to use make-up one day post treatment to cover the tiny crusts if appeared. Subjects were requested to avoid scrubbing or scratching the treated area and to use sun screen continuously to avoid risk of pigmentary change.

## Ex-vivo Histology Evaluation

Skin fragments harvested from donors undergoing plastic surgery were maintained in survival condition using the Gredeco ex vivo skin model and artificially aged by Ultraviolet (UV) irradiation, as previously described by Boisnic and Branchet(6, 17).

One treatment was performed with the HE applicator using Low and High power programs.

Histological modifications of the skin were analyzed, using H&E staining, at different intervals between Day 0 and Day 10 after the treatment. Additional biochemical analyses were done to identify changes in dermal content. Initial ex-vivo results will be presented in this paper.

## Results

### Clinical Improvement:

The results of the HE treatments demonstrated significant dermal refilling, reduction of wrinkles including nasolabial wrinkles and perioral and periorbital lines. Skin texture improvement was manifested by radiant skin, smaller pores and volume increase.

No undesired side effects were experienced by the subjects. Treatment was well tolerated, pain was none to minimal with no downtime or crusts appearance. Typically, treatment with the Hybrid Energy technology was not associated with skin bleeding in areas of micro needle puncture.

Treatment was characterized by a homogeneous skin reaction and complete area coverage was achieved with all parameters.

Three to five treatments were usually performed, spaced 1-2 weeks apart. Progress of results was correlated to the number of treatments. In case of severe skin imperfections, the High treatment program was used.

Figures 3-7 demonstrate samples of immediate treatment effects and short term and long term clinical results through regular and Primos 3-dimensional photos.



**Figure 3:** immediate effect. A slight erythema is visible immediately after the treatment that subsides one hour later



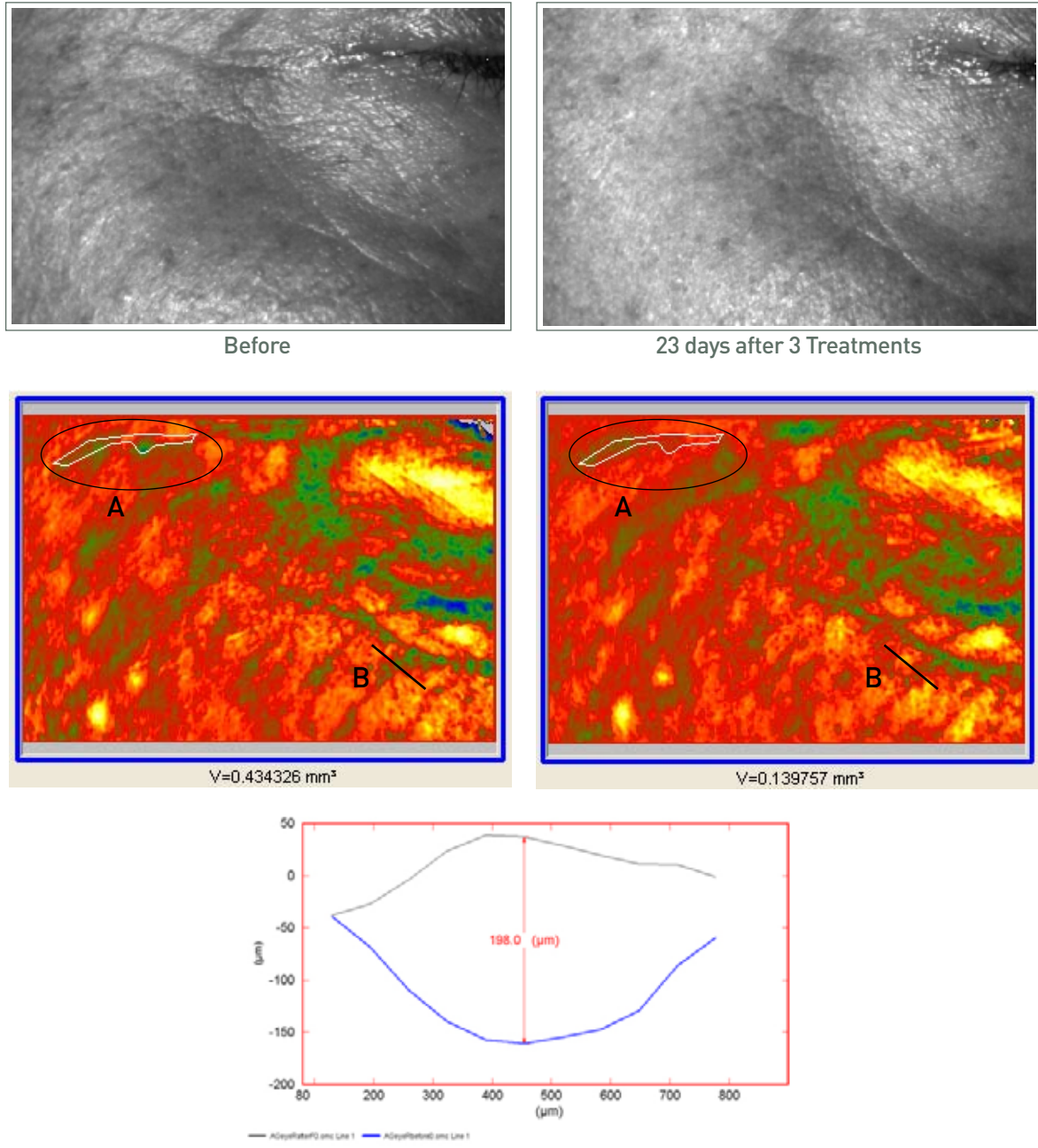
**Figure 4:** Immediate and short term effect. A slight erythema is visible immediately after the treatment. Fine lines appearance continues to improve during the following weeks.



**Figure 5:** Long term results after 3 treatments. Improvement of forehead wrinkles is clearly noticed.



**Figure 6:** Long term results after 3 treatments. Volumizing effect of left and right naso labial area.



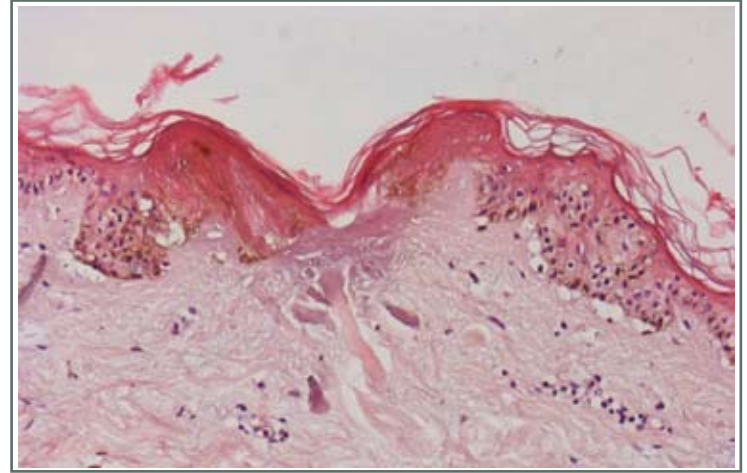
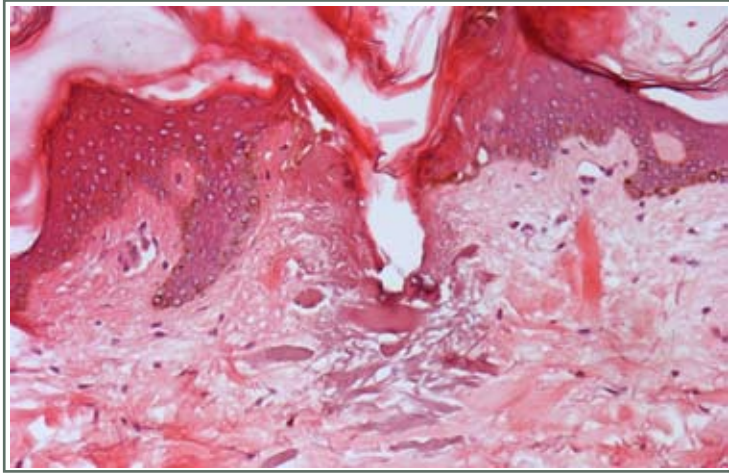
**Figure 7:** 3D Primos imaging and analysis of long term results of periorbital wrinkle reduction 23 days following 3 HE treatments. The analysis was performed on 2 zones of the 3D mapping (Zones A and B, marked on the images above)

Zone A – Measured reduction of wrinkle volume from 0.434mm<sup>3</sup> to 0.139 mm<sup>3</sup> (68% improvement), this can also be noticed by a reduction of green color in this area translating to reduction in wrinkle depth. Zone B- The Graph displayed above demonstrates reduction of 198 microns in wrinkle depth, as measured by the Primos after 3 treatments.

## Ex-vivo Histology

Initial histology photos demonstrated the microneedles treatment impact in the dermal and epidermal layers and the healing process. Results indicated correlations between treatment parameters (Low or extra High) and the size of the dermal and epidermal effect, extent of effect and duration of the healing. In both parameters, the effect in term of intensity and healing was as expected.

Sample photos are demonstrated in Figure 8.



**Figure 8:** Ex-vivo UV aged skin histology samples at D0 (Left) and D2 in survival medium (Right). (H&E stain, magnification: x200 Left, x100 Right). Left- immediately after treatment with HE at Low level. Micro ablation effect is visible into upper dermal layer. Right- After 2 days in survival medium. Healing process including collagen regeneration and epithelialization is demonstrated

## Discussion

Hantash et al (18) were the first to report on a bipolar, microneedle, fractional RF device (Renesis™, Primaeva Medical Inc. Ca.). This system delivers up to 35W RF energy directly within human dermis via 5 micro-needle electrode pairs. Tissue temperature is held at 72 degrees C for 4 seconds using a feedback system. Superficial cooling is achieved using a Peltier cooling device. Treatment was performed on patients prior to their scheduled abdominoplasty at different time intervals. The wound healing response was evaluated histologically and semi-quantitatively using chemical enzymatic reactions up to 10 weeks post-RF treatment. Fractional RF treatment generated a RF thermal zone (RFTZ) pattern in the reticular dermis that consisted of zones of denatured collagen separated by zones of spared dermis. RFTZs were observed through day 28 post-treatment but were replaced by new dermal tissue by 10 weeks. Reticular dermal volume, cellularity, hyaluronic acid, and elastin content increased. They concluded that a vigorous wound healing response is initiated post fractional RF treatment, with progressive increase in inflammatory cell infiltration from day 2 through 10 weeks. An active dermal remodeling process leads to complete replacement of RFTZs with new collagen by 10 weeks post-treatment. Furthermore, they demonstrated evidence of profound ne elastogenesis following RF treatment of human skin indicating the potential of this technology to provide a reliable treatment option for skin laxity and/or rhytids.

Following this initial study, Hantash et al (19) reported on a pilot clinical study using the same fractional RF microneedles device. A range of pulse durations between 1 and 25 seconds, and lesion temperatures between 60 and 80 degrees C were tested in vivo on 15 human subjects. Thermal effects were assessed histologically using specific staining. Treatment effects and adverse events were also monitored clinically. Histological staining revealed the presence of zones of denatured collagen within the reticular dermis. Lesions were generated at preselected temperatures between 60 and 80 degrees C. Fractional lesions separated by zones of sparing as well as contiguous lesion patterns were demonstrated. No major adverse events were observed.

Alexiades-Armenakas et al. (20) performed a blinded, randomized, quantitative grading comparison of micro needles and surgical face-lift to treat skin laxity using the Primaeva system. Fifteen patients with facial skin laxity enrolled in the trial and completed treatment and follow-up. Baseline and follow-up digital photographs of patients undergoing micro needles treatments were randomly mixed with 6 sets of baseline and follow-up images of patients undergoing surgical face-lift with equivalent baseline facial laxity grades. Five independent blinded evaluators graded randomized baseline and 3- to 6-month follow-up photographs using a 4-point laxity grading scale. Quantitative changes in laxity grades were calculated and compared statistically for micro needles treatments vs. surgical face-lifts. Patient satisfaction and adverse events were also evaluated.

Results demonstrated statistically significant improvement in facial laxity, with a mean grade improvement of 1.20 for patients in the surgical face-lift group and of 0.44 for micro needles-treated patients on a 4-point laxity grading scale ( $P < .001$ ). The mean laxity improvement following a single micro needles treatment was 37% that of the surgical face-lift.

Patient satisfaction was high (dissatisfied, 0%; neutral, 7%; satisfied, 60%; and very satisfied, 33%). All participants in the micro needles treatment group experienced transient erythema, mild edema, and mild to moderate purpura that resolved in 5 to 10 days, and they returned to normal activities within 24 hours. There were no adverse events or complications in the micro needles group. All patients in the surgical face-lift group experienced scarring at surgical margins, erythema, edema, and ecchymosis, and they returned to normal activities on suture removal at 7 to 10 days. The authors concluded from this study that minimally invasive micro needles RF treatment may provide an important nonsurgical option for the treatment of facial skin laxity, without the adverse effects and complications of surgical procedures.

Several other RF microneedle systems are being marketed worldwide, such as Intracel, Jeisys Medical Inc. which employs 49 RF microneedles inserted vertically into the skin, the Flora, BS Medical system with 25 pins inserted to a depth controllable from 0 to 3 mm or the Viol Scarlet system which employs an array of 25 or 49 microneedles inserted to a depth of 0.5-3.5 mm. Peer reviewed clinical results with these systems are not yet available.

In a company “white paper” publication, Park et al. [21] report on the use of the Scarlet system for the treatment of wrinkles. They performed three treatments on 29 females and 3 males, mean age 54.5 years, skin types III & IV. Clinical assessment was performed by two blinded dermatologists. They found that 36% of the patients had minimal improvement, 32% had moderate improvement, 16% had marked improvement and 16% near total improvement. Depth of needle penetration was 0.8-1.2 mm in the periorbital area, 1.5-1.8 mm on the forehead and 2.5-3 mm on the cheeks. They also observed an increase in dermal collagen content in histologies taken 4 weeks after the final treatment session, as well as an increase in Cutometer, Corneometer and Mexameter measurements taken during the study.

The current clinical evaluation supports the safety and efficacy performance of the novel Hybrid Energy technology which combines two energy sources: RF and an additional electrical energy. The blend technology enables optimized skin penetration and augmentation of internal energy input to stimulate the clinical effect and wound healing process. Increased energy input is achieved without increasing RF heating but through a chemical reaction thus benefiting from two types of minimal invisible micro ablation ‘generators’ affecting the skin and causing the required trigger to stimulate natural healing and skin renewal. The two types of energy sources complement each other to optimize clinical effect, reducing the pain to minimal.

Pollogen’s TriFractional technology, which is also available with the Surgen device, has a higher epidermal impact as compared to the Hybrid Energy technology. Hybrid Energy major impact is on the dermal layer thus HE treatment is associated with less to none down time, less patient discomfort and less predisposition to side effects compared to no-needles fractional technologies. With HE, the visible impact on the epidermal layer is relatively minor and less prominent compared to the TriFractional or other no-needle fractional technologies. A combination treatment of HE and TriFractional is highly recommended in cases of severe epidermal and dermal imperfections. In such cases, a treatment protocol is custom tailored according to the specific dermal or epidermal relative indications.

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