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Voluderm Micro-Needle Technology for Treating Skin Laxity and Wrinkles-Initial Clinical Experience

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Abstract

Introduction: In the past years, fractional radiofrequency (RF) systems have been popular skin rejuvenation and anti-aging procedures for the treatment of wrinkles, scars and general facial enhancement associated with minimal down time and low risk. These technologies were developed to serve as a viable alternative to the harsher more invasive treatments such as ablative resurfacing lasers. The newest fractional RF technology to come to market is VoluDerm™ (VO). VO delivers energy into the dermis by a matrix of micro-needles that penetrate the skin stimulating a controlled wound effect that promotes a natural fractional healing process for dermal volume enhancement and skin resurfacing. This current article is a summary evaluating the safety and effectiveness of the novel VO technology for collagen remodeling, skin volume enhancing and wrinkle reduction.

Methods: Subjects underwent VO treatments for various aesthetic indications. Some of the subjects underwent a pre-heating treatment with TriPollar radiofrequency prior to the VO as skin preparation for the VO phase of the treatment.

Results: Treatment photos demonstrated skin volume enhancement along with improvement of skin texture and diminished appearance of wrinkles. No significant adverse effects were detected. Conclusion: VoluDerm is a safe and effective micro-needle technology for dermal volumizing and treatment of wrinkles with minimal pain and no downtime.

Keywords: VoluDerm; Micro-needle RF; Fractional Radiofrequency; Wrinkles; Collagen

Abbreviations

RF: Radiofrequency;
VO: VoluDerm;
HE: Hybrid Energy;
GAGs: Glycosaminoglycans;
IPL: Intense Pulsed Light; CO2: Carbon Dioxide;
Erbium YAG: Erbium: Yttrium—Aluminum-Garnets;
RFTZ: RF Thermal Zone;
H&E: Hematoxylin and Eosin

Introduction

A wide variety of non-surgical, non-invasive 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 such as bi-pollar and TriPollar. These established technologies are widely used for various skin treatment indications via a thermal process leading to dermal collagen remodeling and are considered as having a high safety profile and moderate clinical effect [1-8]. These technologies have been clinically and histologically proven for various treatments such as skin tightening, cellulite and circumferential reduction, and wrinkle treatment.

Other technologies using invasive skin resurfacing procedures include ablative resurfacing lasers such as carbon

dioxide (CO2) lasers and erbium:yttrium--aluminum--garnets (Erbium YAG). These procedures were found to be associated with significant downtime and a relatively high risk of side effects [9-12], especially on dark and Asian skin types.

A growing demand for new procedures that delivered visible clinical improvement with reduced downtime and lower risk led to the development of fractional lasers [13-15]. Instead of treating an entire skin area, these lasers treated a matrix of small "islets" of tissue, leaving intact the skin between these islets. Healing was initiated from the intact skin areas resulting in reduced downtime and reduced complications.

There has been an introduction of new fractional RF systems into the market that use controlled fractional skin resurfacing by employing a matrix of miniature RF electrodes placed in contact with the skin surface [16,17]. 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.

In another study the clinical effect of the TriFractional™ RF technology from Pollogen Ltd. for micro-ablative skin resurfacing and the treatment of wrinkles was demonstrated [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. This technology provides a safe, tolerable and effective treatment for facial wrinkles and acne scars.

Devices employing minimally invasive bipolar micro-needle RF electrodes, introduced percutaneously, were also introduced in to the market and gained success in the minimally invasive treatment of wrinkles and skin laxity [18-20]. Studies revealed that such treatments induced an active dermal remodeling process, including neoelastogenesis and neocollagenesis with an intact epidermal layer.

The first micro-needle technology Hybrid Energy™ (HE) from Pollogen Ltd., deploys a combination of RF and galvanic energy delivered through the micro-needles into the dermis. A recently published article by Boisnic and Branchet [21], used histological analysis of skin samples treated ex vivo with the Hybrid Energy technology, to evaluate the safety and efficacy of the HE technology. The effect of this treatment was evaluated by skin morphological evaluation and quantitative analysis using assays of collagen fibers, elastin and glycosaminoglycans (GAGs), reflecting hyaluronic acid content, in addition to epidermal mitotic index evaluation. Histology results 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. Biochemical assays demonstrated a significant increase of the epidermal mitotic index, significant dermal collagen and a significant increase of glycosaminoglycans (GAGs), reflecting increase of the major GAG hyaluronic acid, typical of the wound healing and skin renewal processes.

The VoluDerm technology and the Hybrid Energy technologies share the same micro-needle tip including the unique smart RF assisted penetration method.

The current evaluation was intended to study the safety and efficacy of the novel VoluDerm micro-needle technology alone or in combination with TriPollar skin pre heating for skin volume enhancement and treatment of lax skin and wrinkles.

Materials and Methods

The Pollogen Legend (Figure 1) is a new platform composed of a main unit and four applicators: the novel VoluDerm (VO) applicator and three TriPollar RF applicators.

Figure 1. The Pollogen Legend Device

The VoluDerm Applicator

The disposable tip, which is placed on the skin of the target area, is attached to the distal end of the VO applicator (Figure 2). The tip is composed of an array of 36 micro-needles which penetrate the treated area in an innovative unique manner enabling efficient, uniform and homogenous penetration. The technology deploys a sophisticated RF assisted micro-needle penetration method, resulting in a safe, effective and virtually painless treatment. The VO application provides a dual effect, both on the dermal and epidermal layers of the skin with a major impact in the dermis. The micro wounds are surrounded by healthy unaffected zones which function as healing centers, promoting effective neocollagenesis and skin renewal.

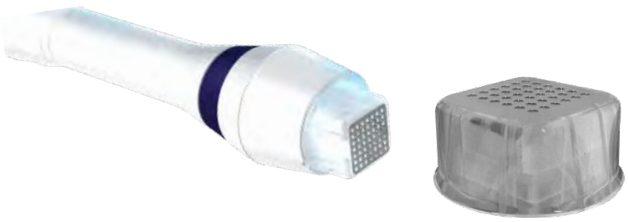

Figure 2. VoluDerm applicator and Gen 36 disposable tip
The VO combined clinical outcome is composed of mild epidermal resurfacing, reinforced by deep dermal volume enhancement.

The TriPollar RF Applicators

TriPollar technology uses three or more electrodes designed to deliver non-invasive RF current into the skin, inducing a focused high density power field between the poles while using low power consumption. The high density power field in the treatment area, results in heat generation in the dermal and subcutaneous layers. Selective and focused electro-heating of the skin is intended to stimulate collagen remodeling in the dermal layer enabling a noninvasive wrinkle reduction. The safety and efficacy of the TriPollar technology for treatment of wrinkles was previously evaluated using the Apollo system. The data reported in this study demonstrates that the TriPollar system offers a safe and effective non-invasive method to improve the appearance of age related rhytides and wrinkles. The Pollogen Legend system has an advanced, user friendly touch screen with pre-programmed default parameters. The VO 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, skin firming and rejuvenating, facial contouring and neck treatment.

All subjects signed an Informed Consent before treatment. Typical treatment protocol included 5 treatments; 3 treatments performed once a week and an additional 2 treatments spaced 2-3 weeks apart.

Subjects were photographed at baseline, after the first treatment and before each following treatment.

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

Clinical experience from VO treatments, performed at Gardens Dermatology center, included a combination treatment of TriPollar RF and VO micro-needles. The TriPollar RF treatment was administered prior to the VO treatment. During the first visit, if patients had no previous RF treatments, subjects were treated with TriPollar RF followed by a treatment with Low level VO parameters, in order to assess the subject's individual tolerance and skin response. If the subjects had TriPollar RF treatments in the past, after the TriPollar RF pre-heating, medium levels of VO were used on the first treatment and high level parameters were used in following treatments according to skin tolerance.

Typically, immediately after treatment, a slight erythema and edema appeared, peaked about 30 minutes post treatment and lasted for a few hours. A matrix of tiny crusts, in the pattern of the micro-needle tip configuration, occasionally appeared 1 to 2 days post treatment and lasted 3 days to one week, depending on the skin characteristics and treatment parameters. Patients could apply make-up one day post treatment to conceal the tiny crusts, if they appeared. Subjects were requested to avoid scrubbing or scratching the treated area and to use sun screen continuously to avoid risk of pigmentary change.

Results and Discussion

Results

The results of the VO treatments demonstrated significant dermal volume enhancement, reduction of wrinkles including naso-labial folds, perioral and periorbital lines. Improvement of neck skin laxity and skin texture, were manifested by radiant skin, smaller pores and general volume increase.

No significant side effects were experienced by the subjects. There were cases that edema or erythema lasted longer than expected typically, depending on individual factors such as pa-

tient skin condition or sensitivity. Treatment was well tolerated; pain was none to minimal with no downtime and with minimal crust appearance. Typically, treatment with the VO 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. Progress of results was correlated to the number of treatments. In cases of increased levels of skin imperfections, higher treatment parameters and/or more passes were used.

In cases of subjects treated with the TriPollar RF technology prior to the VO treatment, an enhanced response of erythema and edema was observed with no abnormalities.

Figures 3 - 6 demonstrate samples of treatment clinical results through photographic images.

Figure 3. Patient treated with VO technology (with TriPollar preheating).
Left – Before; Right - After 5 treatments.
Note impressive improvement of skin texture and facial contouring.

Figure 4. Patient treated with VO technology (with TriPollar preheating).
Left – Before; Right - After 5 treatments.
Improvement of skin texture is noticed. A significant volumizing is visible in cheek area along with a noticeable reduction of the naso-labial folds.

Figure 5. Patient treated with VO technology (with TriPollar preheating).
Left – Before; Right - After 1 treatment.
Note improvement of neck skin laxity and wrinkles after 1 treatment.

Figure 6. Patient treated with VO technology (with TriPollar preheating).
Left – Before; Right - After 5 treatments.
Improvement of fine lines and volumizing effect is noticed.

Discussion

The popularity of RF micro-needle systems is rising due to the safe and effective manner of the treatment which provides a reasonable alternative to invasive antiaging treatments.

Hantash et al [18] reported that a fractional bi polar micro-needle device (Renesis™, Primaeva Medical Inc. Ca.) was an option for treatment of skin laxity and wrinkles. In their study, treatments were performed on patients prior to their scheduled abdominoplasty at different time intervals. Histological evaluation of the treated tissue demonstrated a wound healing response. The fractional RF treatment generated an RF thermal zone (RFTZ) pattern in the reticular dermis that consisted of zones of denatured collagen separated by zones of spared dermis. Authors reported an increase in reticular dermal volume, cellularity, hyaluronic acid, and elastin content. 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.

Another published clinical study presented results of Primaeva micro-needle RF treatment compared to surgical facelift for treatment of facial skin laxity [19]. Baseline and follow-up digital photographs of patients undergoing micro-needles treatments were randomly mixed with sets of baseline and follow-up images of patients, with the same l evel of baseline facial laxity that underwent a surgical face-lift. Patient satisfaction and adverse events were also evaluated.

Patients in both treatment groups demonstrated a 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 ($P < .001$). 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. They returned to normal activities within 24 hours. There were no adverse events or complications in the micro-needle treated group. All patients in the surgical face-lift group experienced scarring at surgical margins, erythema, edema, and ecchymosis, and returned to normal activities at 7 to 10 days. The authors concluded that minimally invasive micro-needles RF treatment may provide a valid nonsurgical option for the treatment of facial skin laxity, without the adverse effects and complications of surgical procedures.

In a different pilot clinical study [20] using the same fractional RF micro-needle device, various pulse durations (between 1 and 25ms), and lesion temperatures between 60 and 80 Co, were tested in vivo on 15 human subjects. Histology assessment of the thermal effects, were performed using specific staining. Treatment effects and adverse events were also monitored clinically. Histological staining revealed the presence of denatured collagen zones within the reticular dermis. A fractional pattern of lesions separated by zones of unaffected tissue were demonstrated. No major adverse events were observed.

An article presenting in vivo histological evaluation of the VO technology was recently accepted for publication [22]. Treatments were performed on two domestic pigs with the VoluDerm applicator, using disposable tips. A treatment was performed on the 1st day of the study and the animals were kept in standard husbandry until the next treatment time points – 4th, 7th, and 14th day of the study. On the last day (day 14), specimens were obtained after the last treatment and biopsies were taken from treated areas. The treatment performed on day 14, reflected immediate treatment results and the treatment performed on the first day, reflected skin condition 14 days after treatment. Treatments were performed using different energy settings at each time point.

Histologies demonstrated the RF micro-needles treatment impact in the dermal and epidermal layers with a normal healing process. These observations indicated a fractional treatment pattern, with healthy intact islets in between affected areas. A complete healing was demonstrated within 14 days for all treatment power levels, with normal skin appearing in previously coagulated zones. Figure 7 demonstrates the immediate treatment effect on Day 0(D0) and the healing process, following use at Low treatment level. On D0, areas of epidermal necrosis, crust and sub-epidermal coagulative necrosis in the papillary and upper reticular dermis are demonstrated. On D4, areas of partial epidermal necrosis, subepidermal coagulative necrosis with mild lymphocytic infiltrate. On D7, healing process with regenerated epidermis, coagulative change in the papillary dermis and mild lymphocytic infiltrate.

On D14, skin is showing regenerated epidermis and a healed wound.

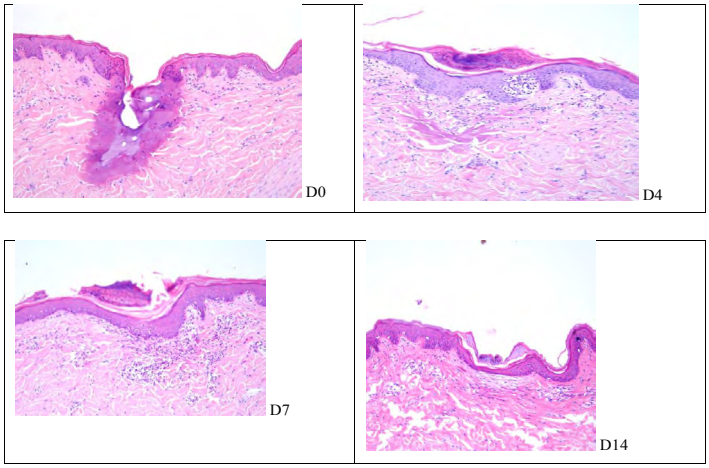

Figure 7. Histology samples of various time points after treatment (D0 - immediately, D4 – Day 4, D7 – Day 7, D14 - Day 14) showing progression of morphology characteristics following VO treatment. (H&E stain, magnificationx20). (Photos courtesy of Pollogen).

These morphological findings clearly support the safety, the normal healing process and the significant impact of dermal enhancement in healed area of the VO fractional micro-needle treatment. The histology samples demonstrated a fractional modality of treatment zones with unaffected zones between wounds.

These morphological findings clearly support the safety, the normal healing process and the significant impact of dermal enhancement in healed area of the VO fractional micro-needle treatment. The histology samples demonstrated a fractional modality of treatment zones with unaffected zones between wounds.

The current clinical evaluation supports the safety and efficacy performance of the VoluDerm technology using intelligent

RF assisted micro-needle penetration to deliver the desired thermal effect in the dermis with minimal pain and no down-time.

VO clinical results demonstrate skin texture improvement, volumizing effects and improved wrinkle appearance. Impressive clinical results are achieved on the neck area probably since the tissue is very thin above the very superficial muscle making the effect more noticeable. The neck area is very difficult to improve using other common methods. Therefore, the added value of the VoluDerm technology is highly significant in the neck area.

Pollogen's TriPollar RF technology, available with the Legend device, is a well-established 3rd generation noninvasive radiofrequency treatment for treatment of wrinkles and rhytides [5-8].

Combining treatment of VO and TriPollar provides an effective method for enhancing dermal structure improvement and for treatment of wrinkles and rhytides. Preheating the tissue, using the TriPollar technology, prior to a VO treatment, enhances the VO treatment effect as the vasodilatation induced by the preheating may enhance the wound healing process immediately post the VO treatment. In addition, alternating weekly TriPollar and VO treatments may be an effective protocol for optimal dermal enhancement. In such cases, a treatment protocol can be custom tailored according to the specific dermal or epidermal specific indications.

Clinically, the ability to provide enough tissue tightening to reduce the naso-labial folds is significant. In addition, reducing the marionette lines and improving the angle of the corner of the mouth at the same time are beyond what early RF devices could consistently achieve. Once collagen is tightened, a clinical expectation would be improvement in texture with reduction of pore size. To see a reduction in the naso-labial folds, marionette lines, and corner of the mouth with a non-invasive procedure brings this next generation of RF devices one step closer to the optimum goal of a facelift. Improvement in volumization simultaneously with tissue tightening gives both the superficial and deep improvement necessary for RF to take the next step.

Conclusion

The novel VoluDerm micro-needle technology is a safe and effective treatment for wrinkles, skin tightening, volumizing, texture improvement and natural looking skin enhancement in facial and neck areas with negligible side effects, minimal pain, and quick visual healing.

Acknowledgements

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Conflict of Interest

The author reports no conflicts of interest.

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