TriFractional: A Novel Fractional Radiofrequency Technology for Skin Resurfacing and Treatment of Wrinkles
Clinical and Histological Results

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Abstract

Introduction: The need for cosmetic facial enhancement procedures with minimal down time and low risk has led to the development of methods for non-surgical skin rejuvenation. Various ablative lasers were developed, which remove the full skin surface in a controlled manner. However, the prolonged recovery and the significant risks prompted the development of fractional lasers which ablate the skin in a fractional manner, leaving untreated areas to improve healing process. In the past few years, fractional RF systems have been introduced that enable controlled skin resurfacing accompanied with dermal collagen remodeling. The new TriFractional technology from Pollogen® is designed to enable skin resurfacing and treatment of wrinkles using radiofrequency energy. The objective of the current research was to evaluate the safety and effectiveness of the novel TriFractional technology using the TriFractional applicator (A3F) for micro- ablative skin resurfacing and the treatment of wrinkles.

Methods: Healthy volunteers consented to undergo TriFractional treatments for various aesthetic indications. In addition, histological results showing immediate effect of the TriFractional technology were obtained from fresh porcine skin.

A portion of the subjects underwent the complete TriLipo Med™ Procedure which includes 2 TriFractional treatments spaced one month apart, with 2 TriLipo RF + DMA face treatments spaced two weeks after each TriFractional treatment.

Results: Subjects experienced an improvement of wrinkles, skin texture and acne scars along with facial contouring. No significant adverse effects were detected post-treatment. Porcine histology demonstrated immediate TriFractional effects on both epidermal and dermal skin layers.

Conclusions: TriFractional is a promising technology for skin resurfacing, treatment of wrinkles and improvement of additional aesthetic indications such as acne scars. The TriLipo MED™ procedure is a unique combination approach for total facial rejuvenation and contouring.

Introduction

The growing market demand for cosmetic facial enhancement and rejuvenation procedures with minimal down time and low risk, has led to the development of methods for non-surgical skin rejuvenation. Laser skin resurfacing was first introduced in the mid 1990’s to precisely remove the upper layers of photo damaged, aged skin as an alternative to chemical peels. While enabling impressive clinical results, the first generation of laser resurfacing systems were associated with prolonged healing and high complication rates, particularly in darker skin patients2,3. These limitations resulted from the fact that the entire epidermis and papillary dermis were removed, often over large skin areas such as the entire face.

A new generation of laser resurfacing systems was introduced in 2003 with the development of a fractional laser (Reliant)4. Instead of treating an entire skin area, this laser treats a condensed matrix of small “islets” of tissue leaving intact skin in-between these islets. Healing is immediately initiated from these intact skin areas resulting in reduced downtime and reduced complications. Since the introduction of this first fractional laser system, a myriad of “fractional” laser systems mostly based on CO2 and Erbium YAG laser technology, have been developed and cleared for marketing worldwide5.

Radiofrequency (RF) energy is a form of electromagnetic energy. When applied to tissue, rapidly oscillating electromagnetic fields cause movement of charged particles within the tissue and the resultant molecular motion generates heat. This source of heat has been extensively used in surgery for hemostasis and tissue ablation (electro-surgery). In the past decade RF has been widely applied in the field of aesthetics for various indications based on skin tightening generated by deep RF dermal heating with resultant collagen remodeling5,6.

In the past several years, several fractional RF systems have been introduced that allow controlled fractional skin resurfacing, similar to the results achieved with various laser systems. In addition to the epidermal effect, fractional RF systems allow enhancement of the dermal layer thus contributing to a combined effect leading to an effective micro-ablative skin resurfacing and improved appearance of wrinkles, fine lines and acne scars.

Several fractional RF systems have now been cleared for marketing in both Europe and the U.S. based on published clinical results with these RF fractional systems.

Hruza et al. evaluated the effect of a fractional RF applicator (MatrixRF by Syneron) for skin rejuvenation and wrinkle reduction. Their histological findings, immediately post-treatment, revealed demarcated zones of ablation/coagulation/necrosis and subnecrosis up to a depth of 450 micron. Higher energy levels generated deeper effects. Subjects undergoing facial treatment had minimal pain, no permanent side effects, or significant downtime. The investigators' assessment of improvement in skin texture was greater than 40% for approximately 50% of subjects. Higher energy levels and lower coverage rates produced better aesthetic results along with less pain. 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 variable dermatologic conditions.

The novel TriFractional approach using the new TriFractional applicator from Pollogen® is designed to enable fractional skin resurfacing and treatment of wrinkles via controlled epidermal micro-ablation and concomitant dermal remodeling with a long established, highly reliable, and cost-effective technology. Treatment with the new TriFractional applicator can be also done as part of a combination procedure, the TriLipo MED™ procedure, custom tailored to the patient, using additional technologies, TriPollar RF and TriLipo DMA (Dynamic Muscle Activation), incorporated in the same device, the multi-application Maximus system.

The current research was intended to evaluate the safety and effectiveness of the novel TriFractional technology and applicator for skin resurfacing and treatment of wrinkles.
Methods

Pollogen’s TriFractional Technology

The TriFractional applicator is indicated for skin resurfacing and the treatment of wrinkles by means of micro-ablation and coagulation. The TriFractional applicator, which is one of the modules on the Maximus system, uses the innovative TriFractional technology powered by a 50W, 1MHz RF generator. A disposable treatment tip, containing a matrix of bi-polar electrode pins, is attached to the distal end of the applicator and is placed on the skin for treatment. TriFractional RF energy is delivered to the skin in a fractional manner via an array of multi-electrode pins.

Radiofrequency current is delivered sequentially between each of the pin electrodes and the large electrode which surrounds 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 treatment micro-wounds in the epidermis which are in 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.

The TriFractional technology emits a “train” of three fractional pulses spaced by very short pauses, in one treatment pulse to achieve an enhanced effect, deeper penetration and optimized efficacy, with less discomfort to the patient. The “train” of three fractional sub-pulses with short Thermal Relaxation Time (TRT) enables achieving a deeper gradual thermal effect (Figure 2). The first sub-pulse causes an ablation in the epidermis followed by a short TRT of tissue cooling. The second sub-pulse heats the dermis, followed by a short TRT of tissue cooling. The final third sub-pulse within the pulse induces deep heating in the dermis, hence increasing stimulation of fibroblasts and therefore stimulating neocollagenesis.

Shortly after treatment there is moderate skin erythema and edema in the treated zone, which resolves within 1-2 days. During the healing phase, small pin-point epidermal crusts appear at each micro-ablated spot. These crusts exfoliate naturally after a few days leading to mild epidermal resurfacing. In the dermis, treatment induces remodeling of dermal collagen (neocollagenesis) and of other matrix molecules leading to dermal renewal.

Clinical Methods

A preliminary evaluation was conducted treating healthy volunteers in order to assess the safety and the effect and clinical extent of the TriFractional technology. The subjects were treated for various aesthetic reasons such as treatment of wrinkles, acne scars and fragile and damaged skin with non homogenous complexion following chemical peel.

The protocol included 2 treatments with the TriFractional applicator at a four week interval. In addition, selected subjects were treated using the TriLipo Med™ procedure which includes:

- Week 1: TriFractional
- Week 3: TriLipo focused RF + DMA
- Week 5: TriFractional
- Week 7: TriLipo focused RF + DMA

The addition of the TriLipo technology which combines TriLipo focused RF and DMA resulted in enhanced improvement of skin texture, toning and lifting of facial SMAS.

Subjects were photographed at baseline and post treatment. Results on perioral or periorbital facial areas were also evaluated in selected subjects, with a three-dimensional (3-D) micro-topography imaging system (PRIMOS, GFM, Teltow, Germany).

The decision whether or not to use an anaesthetic on treatment area was made by the physician based on size or sensitivity of the treatment area, treatment parameters and the subject’s reported general tolerance. Topical anesthesia (Emla, 5% Lidocaine prilocaine, AstraZeneca) were used on some of the subjects prior to the treatment; physicians may elect to use other anaesthesia methods.

The face was thoroughly washed and cleaned with alcohol and the treatment was performed only after the skin was completely dry. The TriFractional treatment parameters for each subject were defined according to the area being treated and the severity of the condition. During the first visit, the first few pulses were of low power 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 TriFractional disposable tips were disposed of safely as indicated in the user manual.

Subjects were asked to give feedback regarding the pain level during treatment and were also questioned about the recovery process following each TriFractional treatment. Typically erythema and edema appeared immediately, peaked about 30 minutes post treatment and lasted for a few hours. A fractional eschar (matrix) pattern typically appeared 1 to 2 days post treatment and typically lasted 3 days to one week, depending on the skin characteristics and treatment strength. Patients were instructed that it is possible to use make-up one day post treatment to cover the tiny eschar pattern pin-head scars. Subjects were requested to avoid scrubbing or scratching the treated area. Subjects were instructed to use sunscreen continuously to avoid risk of pigmentary change.
Histological Samples

To demonstrate the different possible effects of varying TriFractional power levels, histological samples were obtained from fresh porcine abdomen and ear skin samples, exposed to different TriFractional energy levels. Formalin fixed, paraffin embedded sections were prepared and stained with H&E for pathological examination by Patho-Lab Diagnostics Ltd., Nes Ziona, Israel. Ten slides were prepared from each sample. Pathological examination was performed by Andrea Gat, M.D., Head of Dermatopathology Unit, Sourasky Medical Center, Tel Aviv, Israel.

Results

TriFractional Facial Treatments Results

The results of the TriFractional treatments included improvement of acne scars, a general improvement of skin texture and scar tissue, skin brightening, skin tightening, reduction of fine wrinkles, improvement of skin irregularities following chemical peel and reduction in pore size. The subjects treated with the TriLipo Med procedure displayed an additional facial contouring effect especially visible on the jaw-line area. No significant undesired effects were experienced by the subjects and they reported a tolerable pain level. All subjects expressed satisfaction with the clinical results.

Figure 3 demonstrates results following a treatment with the TriFractional for improvement of skin non-homogenous complexion following chemical peel, causing perioral hyperpigmentation. Results demonstrated a substantial improvement after only one TriFractional treatment with a short recovery time. One week post treatment there were no scabs or other residual signs of the TriFractional treatment.

Figure 3: Skin revitalization - Before (left), after one week post one TriFractional treatment (right).

Figure 4: Treatment of acne scars. Baseline, multiple acne scars with uneven skin (left), 2 weeks post one TriFractional treatment (middle), 2 weeks post 3 TriFractional treatments (right).

Figure 4: Treatment of acne scars. Baseline, multiple acne scars with uneven skin (left), 2 weeks post one TriFractional treatment (middle), 2 weeks post 3 TriFractional treatments (right).
TriFractional™
byPollogen®

TriLipo MED Procedure Results

Figures 5 - 7 demonstrate the effect of the TriLipo MED procedure for improvement of wrinkles and scars and for general facial contouring. The subjects underwent treatments with the TriFractional applicator on selected problematic areas, while they received complementary treatments with the TriLipo RF and DMA applicator on the entire face. Results indicate a significant facial contouring in lower cheeks and jaw line as well as improvement of wrinkles and acne scars. These results clearly demonstrate the additive value of the TriLipo MED procedure, combining TriFractional, TriLipo RF and TriLipo DMA technologies for facial skin rejuvenation and facial contouring.

Figure 5: TriLipo MED Procedure – effect on acne scars. Before (left) and after (right).  
Figure 6: TriLipo MED Procedure showing the improvement of wrinkles and skin texture. Before (left) and after (right).

Figure 7: Primos 3D representation of the improvement of periorbital wrinkles. Before (left) and after (right).
Histological Results

In all treated porcine skin samples there is thermal injury in the epidermis alone or up to and including the upper dermis, depending on the treatment parameters and thickness of skin fragment. The epidermal changes are characterized by elongation of nuclei, and by epidermal necrosis to various extents. The dermal changes are characterized by condensation in the dermal connective tissue.

Depth of injury is in direct correlation to the energy level used. In samples from abdomen skin treated with low power, epidermal injury was the least prominent and only the basal lower spinous epidermis layer was involved and the dermis was spared. The epidermal changes in this series were focal with skip area of normal epidermis in between the involved foci. All the other series showed both epidermal and dermal injury correlated with the level of energy in terms of depth and width.

The ear skin samples are significantly more sensitive compared to abdomen skin samples, and even at low energy levels, there are areas of complete damage.

The histological results of the effect of varying power levels on the porcine skin emphasize the importance of careful selection of the treatment parameters. Figures 8 - 10 demonstrate the histological findings immediately following TriFractional treatment.

Figure 8: Abdomen skin fragment treated with low energy (H&E stain, magnification x200). Normal skin "with a skip area" between 2 electrodes (left). Epidermal thermal effect under electrode. Elongation of epidermal nuclei mainly in basal layer and lower spinous layer. No thermal effect observed in dermis (right).

Figure 9: Abdomen skin fragment treated with relatively high energy (H&E stain magnification x100). Normal skin with a skip area at both sides (area under electrodes). In between at ~0.5mm width, effect is moderate. At bottom of skip area elongated nuclei are seen due to penetrated heat dispersion effect. Condensation of upper dermis is seen. Depth of injury ~ 0.5mm.

Figure 10: Abdomen skin fragment treated with relatively high energy (H&E stain, magnification x200). Minute crust present on the surface.

Conclusions

The TriFractional is a promising technology for skin rejuvenation, treatment of wrinkles and acne scars and for general improvement of skin texture, with minimal down time and minimal discomfort to the patient. Combining the TriFractional treatment with intermediate TriLipo RF and TriLipo DMA using the TriLipo MED Procedure, enhances facial toning and enables a holistic approach to facial rejuvenation and enhancement.

The fractional mode of the treatment enables a faster, more effective healing process, eliminating patient downtime resulting in a safe, tolerable effective skin rejuvenation.

References