

CONCLUSIONS

Fractional ablation and resurfacing with the Matrix RF can achieve effective skin rejuvenation with effects on both the epidermis and dermis. Tunable RF delivery can be accurately optimized to treat a wide range of clinical conditions by modulating the energy level and the coverage rate with good correlation with histological signs at the cellular level. This study demonstrated that Matrix RF treatment is safe, easily tolerated and effective in reducing wrinkles with an overall improvement in skin texture.

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FIGURE 4: Physicians' (objective) and subjects' (subjective) assessment of improvement for the different facial parameters (wrinkles, tightness and brightness) 4 weeks following 3 Matrix RF treatments. The Y axis represents number of subjects (percent) for each degree of improvement in facial parameters.

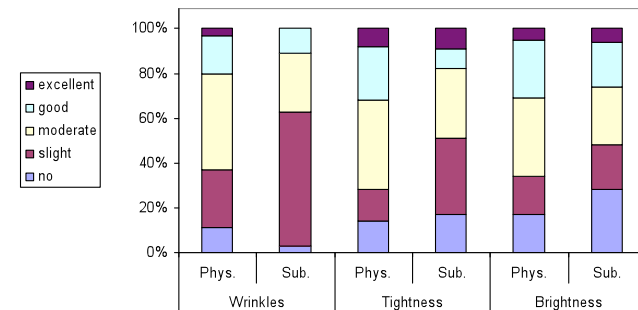
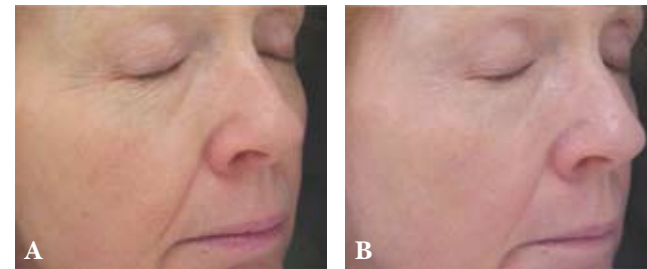
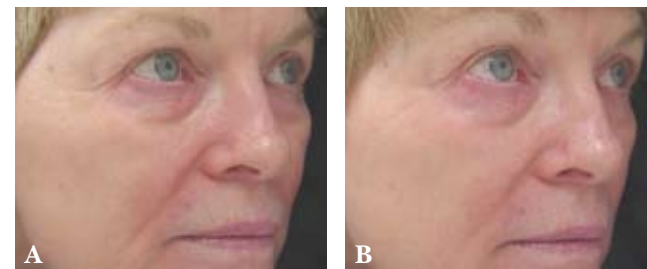


FIGURE 5



Before (A) and after (B), 4 weeks after the third treatment of the peri-orbital and peri-oral areas with the 64 electrode pin, 8-20 J energy level at both 5 and 10% coverage rates. Note the appearance of flattened crow's feet wrinkles.

FIGURE 6



Before (A) and after (B), 4 weeks after the third treatment of the peri-orbital and peri-oral areas with the 64 electrode pin, 10-16 J energy level at both 5 and 10% coverage rates. Note the improvement in skin texture around the crow's feet wrinkles.

Skin Rejuvenation and Wrinkle Reduction Using a Novel Fractional Radio Frequency Technology – the Matrix RF™

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INTRODUCTION

Skin resurfacing has evolved rapidly over the past 15 years from ablative techniques to non-ablative methodologies and, most recently, fractional ablative resurfacing [reviewed in 1]. During fractional resurfacing, microscopic columns of the epidermis and dermis are thermally ablated and/or coagulated at regularly spaced intervals with only a fraction of the skin surface receiving treatment. The intervening tissue serves as a reservoir of cells that accelerate and promote wound healing and the desired therapeutic effect [2]. Overall, this technique achieves far greater efficacy as compared to non-ablative resurfacing, and has a much faster recovery as compared to ablative resurfacing [3-8]. Currently, radio frequency (RF) technology is used for volumetric heating of the dermis and

is therefore indicated in clinical dermatology for non-ablative procedures [9]. The Matrix RF (Syneron Medical Ltd., Yokneam Illit, Israel) applicator is the first bipolar RF-based aesthetic device capable of delivering RF energy that is tunable for ablation, coagulation and heating. The thermal energy is delivered to the skin in a non-homogenous fractional manner via an array of multi-electrode pins. This study analyzed the degree of tissue ablation, coagulation/necrosis and heating, and evaluated the clinical efficacy and safety of Matrix RF for the treatment of wrinkles via skin ablation and resurfacing. The biological effects on skin tissue and their correlations with the clinical performance are further discussed.

METHODS

DEVICE DESCRIPTION

The Matrix RF is a hand-held applicator which is fitted with a disposable tip at its distal edge. The tip consists of parallel rows of bipolar-arranged electrode pins, forming an array of positively and negatively charged electrodes for RF energy delivery. An energy level limit of 20 Joules can be delivered at either 5 or 10% coverage rate via 64 equally spaced electrode-pins; each pin has a diameter of ~200 microns. The RF delivery, via dry skin, flows between each pair of positively and negatively charged electrode pins so that part of the electrode-pins array forms a closed circuit of bipolar RF current that passes into the epidermis and deeper to the dermis.

STUDY DESIGN

A group of 35 subjects at two sites (33 females, 2 males, mean age 52 ± 8 years, Fitzpatrick skin types II-IV) completed 3 full facial treatments, using energy levels in the range of 8-16J. The choice of treatment parameters was made taking into consideration the severity of the treated condition as well its anatomic location, such as proximity to the bone or thickness of the skin. Depending on the energy level used, subjects were given topical anesthesia. Subjects were Fitzpatrick skin types II-IV. The desired end points of the procedure were mild to moderate erythema and edema



at the site of treatment. Clinical improvement and response to therapy were evaluated by the clinician and the subject.

An additional group of individuals scheduled for abdominoplasty (7 patients) received Matrix RF treatment on the abdomen area at fixed time points pre-abdominoplasty and using varying energies and coverage rate. Biopsies were excised following the abdominoplasties and tissue samples were routinely processed and stained using hematoxylin and eosin (A&E).

RESULTS

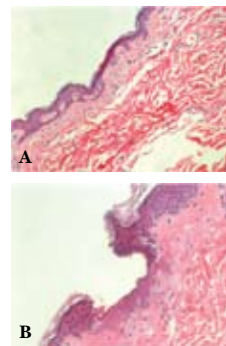
CLINICAL EVALUATION

Subjects undergoing facial treatment had minimal discomfort, no permanent side effects and minimal downtime. At the clinical assessment carried out by the physicians one month following the last treatment, improvement in the different facial parameters was noticed in most of the patients with 83% showing improvement in skin brightness, 87% in skin tightness and 90% in wrinkles. Improvement was greater than 40% for approximately 50% of individuals and the overall skin appearance was tighter

HISTOLOGICAL FINDINGS

Histological findings immediately post-treatment revealed demarcated zones of ablation/coagulation/necrosis and sub-necrosis up to a depth of 450 μm (Figure 1). Higher energy levels and 10% coverage mode had a greater impact on tissue as was evident by the deeper areas affected by ablation, coagulation/necrosis and sub-necrosis (Table 1). Moreover, there was a tunable balance between the relative ratio of tissue ablation and coagulation so that the lower energy level (2 Joules) produced more of a coagulation/necrosis effect, while the main effect of the higher energy level (up to 20 Joules) was ablation (Table 1 and Figure 3).

FIGURE 1

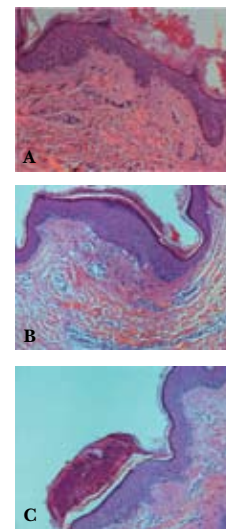


H&E histology (original magnification) demonstrating tunable ablation and coagulation/necrosis effects immediately post Matrix RF treatment using varying energy levels.
A. Skin ($\times 100$) immediately post treatment with the 64 electrode pin, 8 J energy level and 5% coverage showing predominant effect of heating and coagulation.
B. Remarkable tissue ablation with total epidermal removal ($\times 50$) following treatment with the 64 electrode pins, 20 J energy level and 5% coverage.

(Figures 5 and 6). Subjects also perceived improvement in all the above skin parameters (Figure 4). Overall, 80% of users were satisfied with their treatment. The subjects' own evaluation correlated with clinicians' assessment and post treatment elastosis scores (Spearman's $r=0.5-0.56$ for multiple parameters; ANOVA, $P < 0.0001$). Higher energy levels and lower percent of coverage gave better aesthetic results while producing less discomfort.

The recovery phase was initiated by the appearance of wet or dry red scabs in the majority of samples taken 24 hours post abdominoplasty. Complete tissue healing was noted 48 hours following treatment with no evidence of ablated tissue and only slight remnants of coagulation/necrosis in the form of brown scabs. The immediate healing response was characterized by denser and more compact collagen fibers as well as leucocytes infiltrate (Figure 2). Conversely, the long term recovery phase was marked with chaotic and disorganized extracellular matrix.

FIGURE 2



H&E histology (original magnification) at three recovery time points post treatment with 64 electrode pins, 8 J energy level and 5% coverage.
A. Six hours post treatment reveals partial re-epithelization of the epidermis with a significant inflammatory response.
B. Initial appearance of wet scab and continuous re-epithelization of the skin surface at 12 hours post treatment. Note the appearance of compact and denser collagen fibers and leucocytes infiltrates.
C. At 24 hours post treatment the epidermis has completely re-epithelized and necrotic debris (crust) is observed at the skin surface.

TABLE 1: Morphological parameters and degree of ablation, coagulation and necrosis in relation to Matrix RF treatment parameters.

Matrix RF Program (Energy Intensity in J)	Depth of Tissue Effect (Depth in μ)	Tissue Effect
A: 2-10 J 64 electrode pins	150*	Coagulation, necrosis and sub-necrotic tissue heating; no or minimal ablation.
B: 6-16 J 64 electrode pins	250*	Some ablation, coagulation, necrosis and heating.
C: 10-20 J 64 electrode pins	350*	Ablation and some coagulation and necrosis, only residual heating.

*These represent an average of depths. For each program, the depth of penetration into the tissue is up to 50 μ higher with the 5% coverage rate, and up to 50 μ lower with the 10% coverage rate.

DISCUSSION

The current study reports on a novel fractional ablative RF-based device designed for skin rejuvenation treatment via fractional skin resurfacing and wrinkle reduction. The current general medical concept suggests the use of RF technology for nonablative skin tightening via volumetric heating of the deep dermis [9]. The Matrix RF applicator is the first RF (non-laser, non-light) based device capable of inducing skin ablation/coagulation/necrosis and resurfacing impacts. We have demonstrated that RF energy delivery via the Matrix RF applicator can target the skin's surface with fractional ablation of the epidermis and is capable of dermal coagulation/necrosis and sub-necrosis, leaving intervening areas of minimally affected tissue to initiate healing and facilitate recovery. The device is tunable in the sense that the relative proportions of ablation/coagulation/necrosis, the depth of the ablated zones and the extent of the surrounding coagulated tissue may be controlled and customized to design procedures targeted for specific indications and treated areas. Clinically, the current report on the outcome of 35 patients treated with the Matrix RF clearly supports the safety and efficacy of the applicator for use in skin resurfacing.

The non-homogenous fractional manner by which Matrix RF affects the skin tissue is formed by the arrangement of the multi electrode-pins array together with the mode of application – on dry skin without cooling added. The RF current flows via the skin between the electrode pin rows, having spatial and depth related impact with the highest effect at the electrode-skin contact points. Diverse energy densities along the RF current's path create different impacts not only at varying tissue depths but also in between the electrode pins themselves. Due to the physiological characteristics of the tissue at the skin's surface (the dry stratum corneum) where the impedance is high, the RF energy flows via each pin by itself (similar to monopolar RF), leading mostly to

ablation [10]. Inside the tissue (deeper epidermis and dermis) however, the impedance is lower since the tissue is enriched with water and electrolytes and therefore the RF energy flows in between the electrode pins (as it does in bipolar RF) creating a wider diffused effect in the form of coagulation/necrosis with less tissue ablation. As opposed to skin zones under irreversible RF impact (e.g. ablation or coagulation/necrosis), the RF energy density is further decreased deeper and occasionally laterally to the coagulated zone. This results in additional areas of coagulated/necrotic, sub necrotic or stimulated tissue. Additionally, a zone of heat-derived reversible impact is formed at a depth to which the RF energy reaches but its density is below the threshold at which any other biological impact occurs.

Our clinical findings correlate with the histological changes. We found that both the energy level and the coverage mode had a major impact on the improvement in skin texture so that treatment at a higher energy level and/or lower coverage mode enhanced the results. Clinically, the effects achieved contributed to skin rejuvenation and entailed minor adverse sequelae (transient mild to moderate swelling, redness and heat sensation) and minimal discomfort. Thus, the technique is an improvement over any sort of homogenous full surface ablative technology (either laser or RF based) in which the entire skin tissue is affected thereby resulting in prolonged healing process, recovery and patient downtime [3]. Based on our clinical experience, fractional RF delivery via Matrix RF can be used safely in most if not all skin types, giving a significant objective improvement in skin smoothness, tightness, brightness and wrinkles. Moreover, the Matrix RF appears to be at least as effective as scanning fractional photothermolysis techniques with the added benefit of being a much easier procedure for the user to perform [4, 5].

FIGURE 3

