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Objective: The aim of this study was to evaluate the safety and efficacy of a new combined treatment protocol using a multi-source Radiofrequency, combining in each patient 3 different modalities: [1] Non ablative RF skin tightening [2] Fractional skin resurfacing [3] Microneedling RF for non ablative coagulation and collagen remodeling.
Methods: 14 subjects were enrolled in this study using Endymed Pro™platform. Each patient had 8 non ablative treatments and 4 Fractional treatments (FSR and Intensif).
Results: The Global aesthetic score was used to evaluate improvement. All patients had improvement in skin appearance. 43% had excellent or very good improvement above 50%, 18% had good improvement between 25 and 50 % and the rest of 39% had a mild improvement of <25%. Downtime was minimal and no adverse effect were reported.
Conclusions: Our data shows significant improvement of skin texture, skin laxity and wrinkle reduction achieved using RF treatment platform.

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Keywords: facial tightening, skin rejuvenation, radiofrequency, ENDYMED, 3DEEP®, Intensif, microneedles, FSR, fractional RF, wrinkle reduction, multi-source.

Introduction

The skin is the largest organ of the body, with a total area of about 20 square feet. Genetics and environment affect our skin from the day we are born. The skin is made of two main layers, the epidermis, which is the outer, protective layer and dermis, which is the main layer that gives the skin its volume, strength and elasticity. The dermis consists mainly of an extracellular matrix composed of collagen fibrils, micro fibrils and elastic fibers, embedded on proteoglycans[1]. Sun damage causes brown spots and roughness in the epidermis and decrease in the quantity and quality of the collagen and elastin fibers Dermis. The collagen and elastin loss in the dermis leads to skin laxity and to an increase in fine and deep wrinkles.

In the recent years there's a growth in demand for aesthetic non-surgical procedures to improve skin imperfections. Radiofrequency (RF) devices were found to be very effective for non-ablative skin tightening. Heating the dermal layer to 50-52° Celsius, triggers a physiologic cellular healing cascade stimulating the formation of new collagen and elastin fibers[1-2]. These changes will improve skin wrinkles and skin laxity allowing a noticeable skin tightening and lifting effect. For the epidermis the ideal treatment will be fractional skin resurfacing that will allow partial destruction and latter renewal of the epidermis with minimal down-time.

The first technology which was introduced to the market was monopolar RF. This technology is using a single generator and a single electrode, from which the RF is emitted to the skin, usually towards a grounding pad that is placed on the back or leg of the patient. High energy and intense cooling are needed when using such devices, thus these modalities are associated with pain, discomfort and high occurrences of adverse effects[3-5]. In addition, the energy flows without control towards the grounding pad instead of being focused at the target tissue. Later on, bipolar RF technology was introduced. This technology is using two electrodes which are located on the skin surface, and the energy flows between them. According to RF laws, the energy flows along the least resistance path, the shortest path between the electrodes in this case, making the heating superficial and less effective due to a shallow flow which focuses mainly on the epidermis and upper dermis layers. This technology is usually safe at low energies and sometimes requires active cooling in order to prevent epidermal burns or other safety concerns[6-8] 'Multipolar' RF is using one RF generator connected to more than 2 electrodes. Since these systems use only one RF generator, only two phases can be controlled at one time, the tissue penetration profile will be similar to standard bipolar[9].

In this study we used a sophisticated multi-source RF system platform (ENDYMED PRO™, ENDYMED Medical, Caesarea, Israel) which allows both non ablative skin tightening for different body parts and 2 technologies of fractional RF treatments: Ablative fractional RF and Microneedles RF.

For non-ablative skin tightening, ENDYMED 3DEEP® technology overcomes these drawbacks by using an array of 6 independent RF generators – multiple RF sources - connected to up to 6 electrodes simultaneously, controlling the phase of RF current between each pairs of electrodes. This specific ability to control the phase of the RF in each electrode, allows a sophisticated tissue energy thermal profile in which the dermis and subcutaneous layers are deeply heated with

lowered heat on the epidermis. Safety is optimized through unique built-in temperature, contact and motion sensors[10-12]. Real time impedance measurement provides constant power independently of skin impedance resulting in high predictability of treatment results.

In addition to non-ablative for skin tightening, ENDYMED's system enables ablative for skin resurfacing (FSR) and skin remodeling (Intensif) on the same treatment platform.

Skin resurfacing and skin remodeling can be performed using mechanical devices, chemical peeling compounds and lasers devices. Although deep chemical peels and ablative lasers are considered to be effective, these procedures are usually painful, involve considerable downtime and high occurrence of adverse effects. The use of RF devices for skin resurfacing has similar efficacy but with usually less downtime, pain and adverse effects, especially when treating dark skin types. The Fractional Skin Resurfacing modality creates 112 fractional ablative micro-dots for epidermal and papillary dermal improvement, allowing textural improvement with minimal pain and adverse effects[13]. The Microneedle Skin Remodeling handpiece (ENDYMED Intensif™), uses non-insulated gold plated microneedles for deep dermal remodeling. The needles are inserted into the skin by a step motor electronically controlled which enables smooth insertion that minimize patient discomfort. The non-insulated technology enables heating of both papillary and reticular dermis in order to encourage the skin to produce new collagen. The epidermis remains intact due to its high impedance[14-15].

Patients and Methods

14 subjects (13 females, 1 male), ages 42-76 years (average 53.71±9.53) were enrolled in this study using ENDYMED PRO™ platform. The subjects were recruited after meeting all inclusion\exclusion criteria and providing informed consent. Inclusion criteria were healthy subjects, age of 21 and up, subjects who are able to comprehend and give informed consent for participation, commit to all treatments and FU visit. Exclusion criteria were any heart disorder, medical or hormonal medications which affect the skin, pregnancy and breastfeeding, history of keloids, skin lesions, clotting disorders, and subjects who had not gone through any aesthetic treatment 3 months prior to study. The subjects' skin wrinkles were classified according to Fitzpatrick Wrinkle Scale (FWS). All 14 subjects were treated for face wrinkle reduction and skin rejuvenation under a protocol that incorporates 3 RF modalities: Non ablative skin tightening (TC), coagulative Microneedle skin remodeling (Intensif™) and ablative Fractional skin Resurfacing (FSR). Each patients had 8 treatments sessions at 2 week intervals, as shown in Table 1.

Each subject has undergone a series of visits including a screening visit, treatment visits and a follow up visit. The protocol combined 8 non ablative tightening treatments, 5 minutes per area every 2 weeks, and 4 minimally invasive treatments – FSR and Intensif™ – 2 of each one, alternating every 4 weeks. A follow up visit was done at one month after the last treatment. Photos were taken at baseline and prior to each treatment and during the follow up visit from 5 angels (Front, 45° right and left, 90° right and left).

Every session started with facial non-invasive tightening treatment using the Small (facial) handpiece. The handpiece is assembled of 4 electrodes parallel one to each other through which the RF energy is been delivered simultaneously

in two pairs: inner and outer. This method enable to create the multiple electrical fields of 3DEEP® technology. The tightening treatment included 5 areas: cheeks (right, left), neck (right, left) and submental. For the non-ablative skin tightening, two preheating passes of 30 seconds each were performed in order to reach therapeutic skin temperature range of 40°-42° degrees Celsius. After this temperature range was reached, eight therapeutic passes (4 minutes) were performed on each treatment area. Every odd session (1st, 3rd, etc.) was followed by minimally invasive session of skin resurfacing (FSR) or skin remodeling (Intensif), as described in Table 1.

The Intensif handpiece uses a tip with 25 non-insulated, gold plated microneedles, which can penetrate up to 3.5mm into the skin. Additional parameters that can be adjusted are pulse duration (50-200 milliseconds) and power (0-25 watts). The tip is placed on the area to be treated and a foot switch pedal initiate the pulse delivery. Energy is emitted only after the needles reach to their desired pre-set depth.

The FSR handpiece uses a tip with 112 pins (flat electrodes) through which the energy is delivered in a scan method row by row. The high energy density through each pin create an ablative effect on the skin results in small scabs 1 to 2 days after the treatment. Both Intensif and FSR treatments are been performed in a stamping method, pulse by pulse, after applying topical anesthesia (5% lidocaine) for subjects comfort.

Results

All patients completed a series of 8 sessions according to the trilogy protocol (table 1). One subject did not complete follow up due to a long travel abroad. No adverse effect, such as prolonged swelling, prolonged erythema, and arc burn caused by RF current, was reported. Typical recovery time after odd sessions (1st, 3rd, etc.) where FSR or Intensif were performed was up to 12 hours of edema and erythema. Following FSR treatments small scabs appears 2-5 days following the treatment. Those scabs are naturally peels as the skin rejuvenate. Average recovery time after TC treatment (2nd, 4th, etc.) only was 20 to 30 minutes of erythema.

Patients' feedback was carried out using subjective questionnaires filled by the patients following the series of treatments. Non-ablative treatment were painless. Pain sensation of the fractional skin resurfacing and microneedle RF treatments was evaluated by questionnaire at the end of the treatment series. 21% of patients reported minimal pain, 72% reported moderate pain and only 7% reported significant pain. All patients' experienced subjective improvement. 72% of patients reported a very good (50-75%) or good (25-50%) improvement in cosmetic level change while 28% reported lower improvement of less than 25%.

Most patients reported that the treatment had met their expectations in full or in some extent. The satisfaction with the treatment was higher one month following the treatments (Fig. 1). 79% of all subjects were satisfied with the treatment results and would recommend it to their friends and colleagues

The objective improvement was evaluated by 2 uninvolved clinical researchers. The Global aesthetic score was used to evaluate improvement. All patient had an improvement in skin appearance. 43% had excellent or very good improvement

above 50% scale, 18% had good improvement between 25 and 50 % and the rest of 39% had a mild improvement of less than 25%. (Fig. 2,3,4).

Discussion

The aim of this study was to evaluate the safety and efficacy of a new 'Trilogy' treatment protocol using the multi-source RF treatment platform, combining in each patient 3 different technologies: [1] Non ablative Multi source RF for skin tightening and wrinkle reduction; [2] Multisource fractional skin resurfacing allowing fractional ablation (150-200 Micron) with simultaneous volumetric dermal heating (2.9 mm); [3] Intensif™ Microneedle RF applicator for fractional non ablative coagulation and collagen remodeling (up to 3.5mm).

To the authors' knowledge, this is the first study to evaluate the combination of three radiofrequency methods for skin rejuvenation. Harth et al[15] treated 20 subjects with depressed acne scars using Intensif, non-insulated microneedles, using similar platform. All subjects had a topical anesthesia using Emla before the treatments. They received 1 to 5 sessions at one-month intervals. Subjects' satisfaction, assessed by questionnaires, showed that 95% of the treated patients experienced some improvement. 25% experienced very good to excellent improvement (defined as >50% improvement) additional 30% experienced good improvement (defined as 26% - 50% improvement).

The downtime after the treatments are considered to be an issue for most potential subjects. Trying to balance the social downtime, discomfort, efficacy and safety of combined aesthetic treatments has been an important theme over the years. The combination of non-invasive non-ablative method followed by FSR or Intensif treatments attempts to reduce the number of sessions, thus make the whole series of treatment easier for the subjects. In general, RF treatments are considered to have low downtime and less side effects.

The results obtain in this study demonstrate significant improvement of skin texture, skin laxity and wrinkle reduction. Combining three different RF methods ablative and non-ablative targets both layers: dermis and epidermis. The dermis was effectively heated using TC handpiece and Intensif microneedles, while epidermis was effectively heated and ablated by FSR handpiece for skin resurfacing.

Conclusion

Demand of minimally invasive low downtime skin rejuvenation treatments is increasing due to the increased efficacy of these procedures. Multi-source radiofrequency allows multiple different types of handpieces for different indications. This applications can be used as a single modality or in a combined fashion. Previous studies have proved the efficacy of non-ablative multisource RF as a single modality for both facial skin tightening and body contouring[10-12]. Other studies have shown the efficacy of microneedles RF as single modality[14-15] and the efficacy of a combination of non-ablative RF and fractional skin resurfacing in another[13]. In this study we evaluated for the first time the combination of 3 different RF applicators in each single patient.

The advantages of the Trilogy protocol tested in the current study is that it combines the bulk heating of tightening for laxity and lifting, multisource fractional ablative skin resurfacing to target both the epidermis and papillary dermis, and the Intensif™ microneedle RF targeting the depth of the dermis.

The FDA cleared, ENDYMED 3DEEP® treatment platform, was proven in this study to provide a very skin rejuvenation for all skin layers with minimal down-time and very high patient satisfaction rate.

Disclosure: Endymed Medical supported the purchase of the consumables used in this study.

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Figure Legends

Figure 1: Subjects' recommendation of the treatment to friends and colleagues.

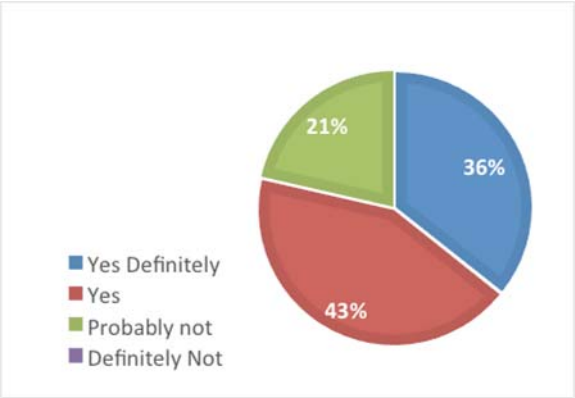

Figure 2: Objective improvement evaluated by 2 uninvolved clinical researchers.

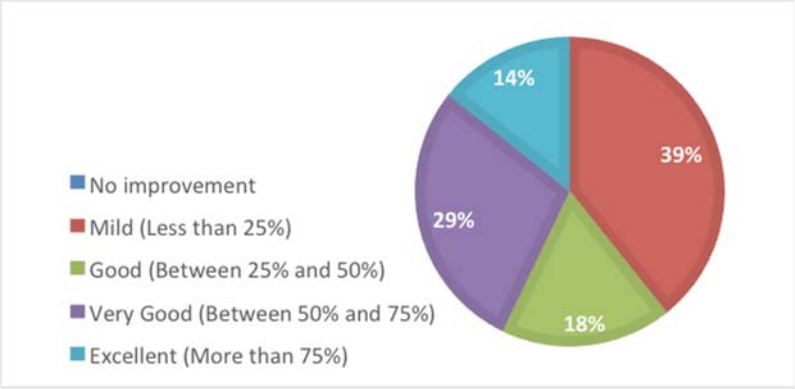

Figure 3: Female, age 67 years, before and after 7 sessions of combined ENDYMED treatment (Non ablative skin tightening, Fractional RF skin resurfacing and microneedles RF Intensif treatment), showing significant improved contour of jaw lines, skin tightening, with significant improvement of skin texture.

Baseline After 7 sessions

Figure 4: Female, age 57 years, before and after 2 and 4 sessions of combined ENDYMED treatment (Non ablative skin tightening, Fractional RF skin resurfacing and microneedles RF Intensif treatment), showing significant improvement of skin laxity and skin texture. Improvement has been seen after 1 Intensif session and 2 TC, and became greater after additional TC and FSR.

Table Legend

Table 1: Trilogy Protocol. Treatment done according to weeks

Session #	Week #	TC	Intensif	FSR
1	0	■	■	
2	2	■		
3	4	■		■
4	6	■		
5	8	■	■	
6	10	■		
7	12	■		■
8	14	■		