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Journal of Cosmetic and Laser Therapy
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/ijcl20

New vision in fractional radiofrequency technology with switching, vacuum and cooling

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Published online: 25 Jul 2015.

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To cite this article: Monica Elman, Nelly Gauthier & Inna Belenky (2015) New vision in fractional radiofrequency technology with switching, vacuum and cooling, Journal of Cosmetic and Laser Therapy, 17:2, 60-64

To link to this article: http://dx.doi.org/10.3109/14764172.2014.983934

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Journal of Cosmetic and Laser Therapy, 2015; 17: 60–64

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New vision in fractional radiofrequency technology with switching, vacuum and cooling

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Abstract

Introduction: Since the introduction of fractional technology, various systems were launched to the market. The first generation of fractional RF systems created epidermal ablation with coagulative/necrosis of the dermis with sufficient clinical outcomes, but with some limitations. The aim of this study was to evaluate the efficacy and safety of SVC technology, based on the principle of separate biological responses. *Material and methods:* Fifty-two patients were treated for 3–6 sessions using fractional RF handpiece and eight patients received combination treatments with non-invasive RF handpiece. *Results:* All volunteers showed notable to significant improvement in the photoageing symptoms, without any significant complications or adverse events. *Discussion:* Due to its wide spectrum of parameters, the SVC technology can promote different biological responses. Owing to the "Switching" technology, the control of energy depth penetration enables delivery of the necessary thermal dose to the targeted skin layer. In addition, this novel technology includes the "Vacuum" and "Cooling" mechanisms, each contributing to the safety of the treatment. The Smart Heat function reduces the necessary energy levels and thereby reduces the pain level and risks for side effects.

Key Words: *ageing, fractional radiofrequency, skin resurfacing, skin tightening, skin rejuvenation*

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Introduction

Since the first introduction of fractional technology in 2003 (1), various systems were launched to the market including ablative and non-ablative fractional lasers, along with the introduction of fractional radiofrequency (RF) technology in 2009 (2) (Figure 1). The concept of fractional photothermolysis was introduced to address the requirement for effective, but low risk, skin rejuvenation techniques. Unlike conventional ablative (CO_2 or Er:YAG) and non-ablative lasers, fractional modalities treat only a fraction of the skin, leaving up to a maximum of 95% of the skin untouched. The undamaged surrounding tissue allows for a reservoir of viable tissue, permitting rapid epidermal repair (1). The ablative fractional lasers are generally used for skin resurfacing treatments, including improvement of post-acne scars, skin texture and tone, etc. (3).

Due to a wide variety of different technologies, misuse of medical terminology and general confusion in the aesthetic market, in practice, it is essential to understand which technology leads to which biological response. That then gives the ability to use the precise treatment according to each patient's needs. Skin resurfacing techniques are based on the removal of the outer layers of photodamaged skin to create a "new surface" (4). The removal of epidermal and dermal cells is indicated to stimulate re-epithelialization and collagen remodeling and is typically conducted by ablative lasers, deep chemical peels, dermabrasion or ablative RF technologies (4,5). When using energy-based systems, the ablative effect occurs when the skin temperature reaches 100°C or higher (6).

Skin rejuvenation technologies (such as non-ablative lasers, IPLs, monopolar RF or high frequency ultrasound) prompt the body to generate new cells via coagulation and necrosis of dermal layer. For these biological responses to occur skin temperatures must reach above 50°C (6).

Though skin tightening procedures are often confused with skin rejuvenation or skin resurfacing

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(Received 16 August 2014; accepted 14 October 2014)

ISSN 1476-4172 print/ISSN 1476-4180 online © 2014 Informa UK, Ltd.
DOI: 10.3109/14764172.2014.983934

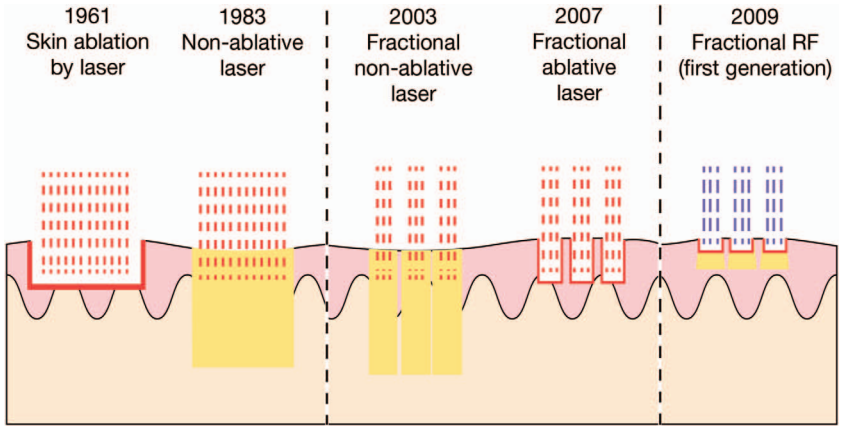

Figure 1. Evolution of the development of skin resurfacing/rejuvenation technologies, including schematic representation of the biological response.

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procedures and vice versa, the skin tightening and lifting effect can be achieved through volumetric thermal heating (40–50°C) of the dermis to stimulate fibroblasts activity, collagen denaturation and remodeling (7).

The first generation of fractional RF systems created fractional epidermal ablation with coagulative/necrosis on the papillary dermis level (Figure 1). Though the clinical outcomes of skin resurfacing and rejuvenation applications were quite sufficient (2,4,6,8), the main limitation of these systems was the inability to create sufficiently deep coagulative necrosis without ablating the epidermal layer, or have the ability to ablate the epidermis without coagulation/necrosis on the papillary dermis (8).

The aim of this study is to evaluate the efficacy and safety of innovative fractional RF technology, based on the principle of separated biological responses: ablation, coagulation, and ablation in combination with coagulation.

Material and methods

Case study group

A total of 52 patients, 39 women and 13 men, mean age 50 (range 22–76 years), with Fitzpatrick skin types I–V (86% II–IV), were treated with a new fractional RF handpiece. The patients were enrolled after obtaining detailed personal and medical histories (i.e. skin type, clinical symptoms, previous and current health conditions, medications, lifestyle, etc.) and signed informed consent forms for the treatment. Inclusion criteria for enrollment were above 18 years of age and an obvious photoaging symptoms. Exclusion criteria consisted of injection of any biological material during the 6 months prior to treatment, a history of injection of any synthetic material, tattoo or permanent makeup in the designated treatment area, any permanent implant in the designated treatment area, blood coagulopathy, active skin disease in the treatment area, tendency to skin disorders, skin cancer, immunosuppressive and endocrine diseases, disease which may be stimulated by heat, deep chemical peel/laser peel in the past 6 months and facial controlled abrasion within the past 3 months, use of Accutane within the past 6 months and use of nonsteroidal anti-inflammatory drugs 7 days before and 7 days after every treatment.

Device description

A Fractional RF handpiece with SVC™ technology (Viora, NJ, USA) was used on all 52 patients in the study. SVC™ technology is a combination of Switching, Vacuum and Cooling mechanisms. The Switching mechanism controls the radiofrequency energy depth penetration by a controlled sequence of paired electrodes at different distances. This is reflected via three treatment programs: Shallow, Medium and Deep. The Vacuum mechanism is activated before the RF energy release, ensuring proper coupling of electrodes to the skin (minimizing the risk of epidermal burns), reducing pain levels (per the "Gate Theory") and obtaining more equal, consistent and symmetrical injury points due to the stretching of the skin. The Cooling mechanism protects the superficial skin layers and reduces pain levels. In addition, the SVC™ technology includes a unique pre-heating function, the "Smart Heat" pulse, which increases skin conductivity prior to the fractional pulse and reduces the needed energy levels, thereby reducing patients' pain levels and post-operative complications or side effects.

Viora's non-invasive bipolar RF handpiece utilizes CORE™ technology with multiple RF frequency capability (7), providing up to 130 J/cm^3 of RF energy fluence.

Treatment regimen

All patients underwent a fractional RF treatment course of 3–6 sessions, according to severity and type

of symptoms, with intervals of 4—6 weeks. Each fractional RF treatment consisted of a 35–45 min session.

Eight patients received a combination treatment with the non-invasive bi-polar RF handpiece (with CORE™ technology, (7)). The non-invasive treatments were conducted before the fractional RF treatments, using energy fluence of 60–80 J/cm^3 with 2.45 and/or 1.7 MHz RF frequency, depending on the patient's skin thickness.

For superficial skin resurfacing, which includes skin tone, texture and pigment disorders, the treatments were conducted with the "Shallow" program, on 19 patients at energy fluence range of 4.00–6.75 J and at short pulse durations (10–50 ms). Pulses applied over pigmented spots were conducted without "Smart heat" and contact cooling was turned off. For post-acne scars and deep wrinkles the treatments were conducted with the "Deep" program, on 21 patients at energy fluence range of 3.25–6.50 J and at medium pulse durations (50–80 ms). For skin rejuvenation and fine wrinkles the treatments were conducted with the "Medium" program, on 12 patients at energy fluence range of 3.50–6.25 J at long pulse durations (80–100 ms).

Clinical assessment

Clinical photographic assessments were recorded in two phases: at baseline – prior to the first treatment and 4 weeks after the final treatment of the treatment course. Additionally, the treating practitioners were asked to record and immediately report any adverse or unexpected side effects.

Results

All volunteers showed notable to significant improvement in the photoaging symptoms, except one patient who showed deterioration in skin texture. This particular patient, contrary to treatment guidelines, received biweekly treatment sessions, in which the deterioration can be attributed to an "over-heating" response.

During the trial, no complications or significant adverse events were recorded. One patient expressed transient PIH (post inflammatory hyperpigmentation) for 8 weeks; probably due to sun exposure five days post procedure.

Immediately after the treatments, uniform erythema and/or rectangular shaped edema was detected as a positive end point. When ablative settings where used (high fluence and short pulse duration), a noticeable burning smell from the skin and the tip was detected. When non-ablative settings were used (with pulse duration longer than 70 ms), only uniform erythema was detected. In most cases the edema faded within 40–120 min post procedure; followed by the disappearance of erythema over the next 12–24 h.

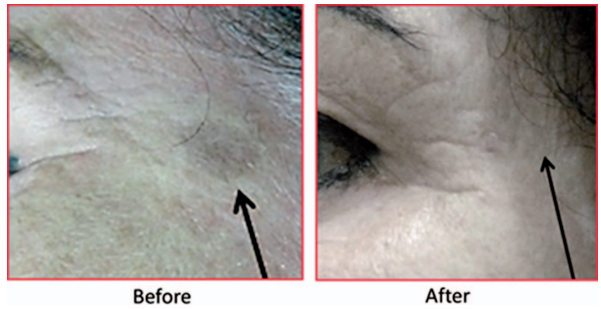

Figure 2. A 55-year-old female before (left) and after 4 fractional RF sessions (right). Results show a noticeable improvement in the age spot.

Superficial skin resurfacing procedures

All nineteen patients who were treated for superficial skin resurfacing procedures showed improvement in skin tone and texture. The total number of treatments ranged from 2 to 3 treatments, except in cases where age spots and solar lentigo were treated. In the case of pigmented disorders, the treatment course was extended to 4–5 treatments (see example in Figure 2).

Skin resurfacing and rejuvenation procedures

Patients displaying photoaged symptoms which require heat penetration up to the reticular dermis were treated with the "Deep" program. Patients with advanced to severe wrinkles received 3–5 treatments (see example in Figure 3), while patients with post-acne scars required up to 6 treatments (see example in Figure 4), depending on the age and skin's characteristics, such as the type of scar, dermal thickness and natural moisture level.

Figure 3. A 61-year-old female before (left) and after 5 fractional RF sessions (right). Results show a noticeable improvement in wrinkles, skin texture and tone.

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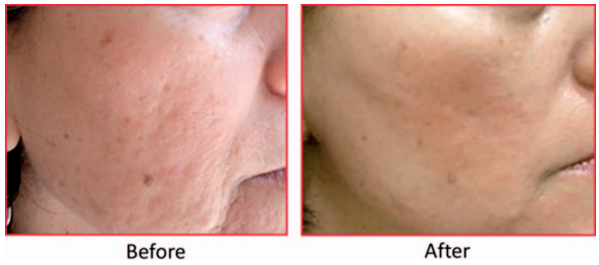

Figure 4. A 65-year-old female before (left) and after 6 fractional RF sessions (right). Results show a noticeable improvement in the post-acne scars and general skin texture.

Skin rejuvenation procedures

General skin rejuvenation, fine wrinkle reduction or any procedure requiring heat penetration up to the upper dermis (papillary dermis) were conducted with the "Medium" program. The treatment course ranged between 3 to 5 sessions (see example in Figure 5).

Skin resurfacing and tightening procedures

Patients exhibiting both textural and laxity problems, received a combination treatment with a non-invasive bipolar RF handpiece, followed immediately with a fractional RF treatment, and showed notable improvement in skin tightening and textural changes (see example in Figure 6).

Discussion

One of the main challenges in addressing different photoaging symptoms with one system or technology is the fact that different skin conditions are specific to different skin layers. For example, while treating epidermal hyperpigmentation, the epidermal layer needs to be targeted. Post acne scars, on the other hand, require a multilayer approach, targeting epidermal layers up to the reticular dermis. An additional challenge in anti-aging procedure is that different skin conditions react to dissimilar biological responses and external stress modalities. Typically, hyperpigmentory disorders react best to ablative response, achieved by ablative lasers or RF. Skin rejuvenation procedures require coagulation and

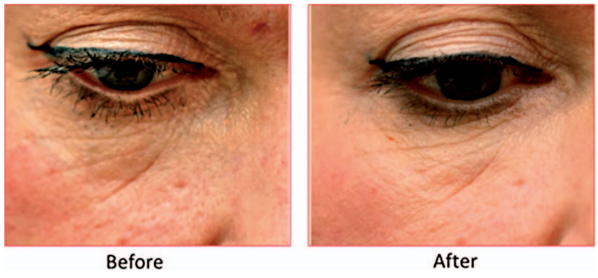

Figure 5. A 45-year-old female before (left) and after 1 fractional RF session (right). Results show a noticeable improvement in fine lines, skin texture and pore size.

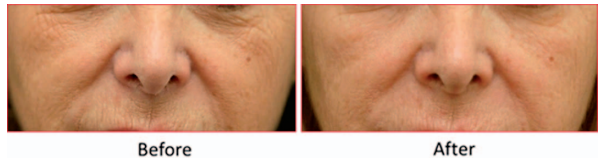

Figure 6. A 59-year-old female before (left) and after 1 combination session of non-invasive bi-polar RF and fractional RF (right). Results show a noticeable improvement in fine lines, skin texture, pore size and laxity.

necrosis of the dermal cells to produce new cells. Finally, fibroblast stimulation and collagen remodeling responses are desirable for skin tightening and lifting effect, which are enhanced due to volumetric heating of the dermal layers.

Due to its wide spectrum of parameters and features, the novel fractional RF SVC™ technology can promote different biological responses via reciprocity between the energy fluence and pulse duration. For skin resurfacing procedures, where an ablative effect is required, the treatment parameters are set to high energy fluence with short pulse duration. For skin rejuvenation procedures, where coagulative necrosis is necessary, a much longer pulse duration is used to deliver a sufficient thermal stress dose for coagulative response. In the case where both types of biological responses are required (ablation of epidermis and coagulative necrosis of the dermis), such as post-acne scars, medium pulse durations is typically used. Finally, for a skin tightening and lifting effect only volumetric heating is needed, which can be achieved by using a low energy fluence and the long pulse duration.

Due to the "Switching" technology, the control of energy depth penetration enables the delivery of the necessary thermal dose to target each skin layer (epidermis, papillary or reticular dermis) according to the location of the symptoms. In practice, while conducting treatments according to the biological reasoning described above, the clinical outcomes are significant, as evident in this study group. Challenging symptoms, such as stria or post-acne scars, requires the deepest heat penetration and complex biological responses. On the one hand, ablation of the epidermal layer will produce a nice resurfacing effect, but coagulative necrosis of the deep dermis will produce a skin rejuvenation effect, improving the entire appearance of the scar. In the current study, the majority of patients (82%, data not shown) showed moderate improvement already 4 weeks after the first treatment (see example in Figure 7). This was due mostly to the selective adjustment of treatment parameters. The only case where deterioration in skin texture was detected was when the patient received fractional treatment every 2 weeks, contrary to treatment guidelines,. In "over-heating" cases, when treatments are performed too often, the skin usually reacts with transient deterioration since new collagenases and other wound-healing processes take longer than immediate collagen denaturation.

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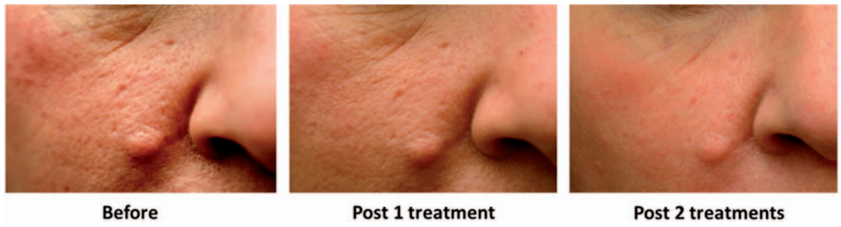

Figure 7. A 45-year-old male before (left) and 4 weeks after 1 treatment sessions (middle) and 2 treatments (right). Results show a noticeable improvement in the post-acne scars and skin laxity.

In addition to the "Switching" technology and control over pulse duration, the SVC™ technology includes the "Vacuum" and "Cooling" mechanisms, both contributing substantially to the safety of the treatment, by protecting the epidermis from superficial burns (9–11). In addition to the safety contribution, the pain level drops dramatically after introducing the vacuum function, from 6–7 on the VAS scale, to 0–4. This is due to the "Gate Theory". The smart heat function, prior to fractional RF pulsing, produces volumetric "bulk" heat of the target area, reducing the necessary energy levels and thereby reduces the pain level and risk for side effects. Since tissue conductivity of RF energy is significantly correlated to tissue temperature, an increase in skin temperature lowers skin impedance and consequently provides selective heating by the RF current (12). In other words, pre-heating the target tissue by "smart heat" increases skin conductivity.

In summary, the novel fractional RF handpiece utilizing SVC™ technology represents the next generation of fractional RF devices for aesthetic and dermatological skin resurfacing and rejuvenation. The "Switching" technology enables the targeting of specific skin depth, while control over pulse duration and energy fluence dictates the biological response—ablation, coagulative necrosis or a combination of superficial ablation and deep coagulation/nercosis. The availability of enhanced control over biological responses enables better targeting of specific skin conditions while improving patients' treatment experiences and safety due to the combination of vacuum, cooling and smart heat functions.

Acknowledgments

Dr. Belenky is the guarantor for this article, and takes responsibility for the integrity of the work as a whole. Dr. Belenky is a manager of Viora's clinical department. Dr. Elman and Dr. Gauthier do not have any financial interest in Viora, Inc.

***Declaration of interest*:** The authors report no declarations of interest. The authors alone are responsible for the content and writing of the paper.

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