Synchronous Fractional Radio-Frequency Ablative and Non-Ablative Treatment for Comprehensive Rejuvenation of Aging Skin

By: Spero Theodorou, *MD, PPS, New York, NY, USA*
R. Stephen Mulholland, *MD, FRCS(C), Toronto, Canada*
Michael Kreindel, *PhD., Invasix Corp, Toronto, Canada*

INTRODUCTION

Facial aging is a combination of intrinsic, hereditary and extrinsic forces. Extrinsic factors, including UV light exposure, smoking and diet, combined with the heretics and intrinsic aging factors results in facial deflation (loss of fat), descent (laxity) and deterioration (aging skin). Skin aging and deterioration is characterized by reduced and abnormal collagen, elastin and ground substances, together with discoloration, both in increased melanin based lesions and vascular proliferation. Anti-aging physicians have generally had to combine various lasers, intense pulsed light (IPL), infrared (IR) and radio-frequency (RF) energy systems to treat the combination of these aging dermal and epidermal elements. (Table 1). Fractional and non-fractional radio-frequency energy systems have become popular options in the treatment of skin laxity and wrinkles, but have not been generally effective in treating vascular and melanin based dyschromia of the aging skin. This paper reports on the comprehensive anti-aging effects of a novel new fractional radio-frequency device, the Fractora (Invasix, Yokneam, Israel).

An analysis of the technologies listed in Table 1 reveals the following therapeutic interventions are required for the wide array of aging effects we see in the skin:

- Pigmented malformation treatment requires superficial ablation or coagulation
- Vascular lesion treatment requires coagulation of blood vessels in papillary and reticular dermis
- Wrinkle treatment requires ablative and/or sub-necrotic heating of the reticular dermis
- Skin laxity improvement requires deeper heating of the reticular dermis and dermal-fat junction

The ideal situation for the aesthetic professional would be to have one technology with the tunable ability to address all the clinical manifestations of aging skin. The principal difference between the ablative and non-ablative RF in the novel device used in the current study, when compared with light based deep fractional ablation is that the action of RF is not limited by the ablation crater and adjacent tissue based upon a chromophore, but rather, RF current flows through the ablative lesion and the entire reticular dermis, creating the potential for additional anti-aging effects [10].

This current study describes the results of the clinical evaluation of a novel fractional radio-frequency ablative and semi-ablative treatment used to treat the multiple aging pathologies of the skin.

Materials and Methods

The Fractora radio-frequency rejuvenation hand piece has a matrix of 600 micron sharp pins and flat side electrodes. The RF current, operating at 1Khz, flows down each positively charged pin, causing epidermal-dermal ablation in a classic CO2 cone-shaped lesion. Following the ablative effect, the RF current then flows from the tip of each pin to the negatively charged side electrodes, closing the RF current loop. Consequently, this flow of energy exposes the entire non-ablated papillary and reticular dermis to a strong non-ablative RF thermal effect. (Figure 1) This unique combination of synchronous ablative RF resurfacing with non-ablative RF remodeling facilitates superficial wrinkle, texture and discoloration improvements with skin tightening in the same pulse.

As demonstrated in Figure 1, the RF current (purple) is concentrated at the tip of the pins, creating the high RF power density for tissue ablation. Following divergence of RF current toward side electrodes, there is a sub-necrotic thermal stimulation (red) in the reticular dermis and dermal-fat junction, leading to a non-ablative, thermal neo-collagenasis and neo-elastosis. The ablative effects of the Fractional RF injury will provide thermal disruption of superifical brown spots, sun damage and melanin based dyschromia, while, if the tips of the Fractora applicator are purposely applied over superifical spider telangiectasia, there will be a coagulation of the vessels.

The maximal applied RF energy per pin was 60mJ. 30 patients, with an age range of 29 to 70, Fitzpatrick skin type I to V, and demonstrating multiple cutaneous aging signs, were treated once and observed for a period up to 6 months. Patients with skin type IV and V received a hydroquinone treatment for a period of two months prior the treatment and two months following the treatment to reduce the risk of post-inflammatory hyperpigmentation (PIH). For pain control some Caucasian patients treated with high parameters (40-60mJ/pin) underwent subcutaneous tumescent anesthesia with a mixture of 1 bottle of 1% lidocaine mixed in 1 liter of Ringers lactate and 2ml of epinephrine 1:1000. Approximately 150 cc of infiltrate was used on the brow, cheek and lower face and another 100 cc if the neck was treated. Prior the tumescent anesthesia, supra-orbital, infra-orbital, zygomatical facial, temporal, and mental nerve blocks were performed with 10cc of 1% xylocaine. At medium settings (30-40mJ/pin) nerve blocks were used, while at low energy settings (10-30mJ/pin) pretreatment was performed with a topical analgesia or no anesthesia at all. Antibiotic ointment was applied after the treatments and the skin was kept moist with Aquaphor for 3-4 days, at which point camouflage make-up could be applied.

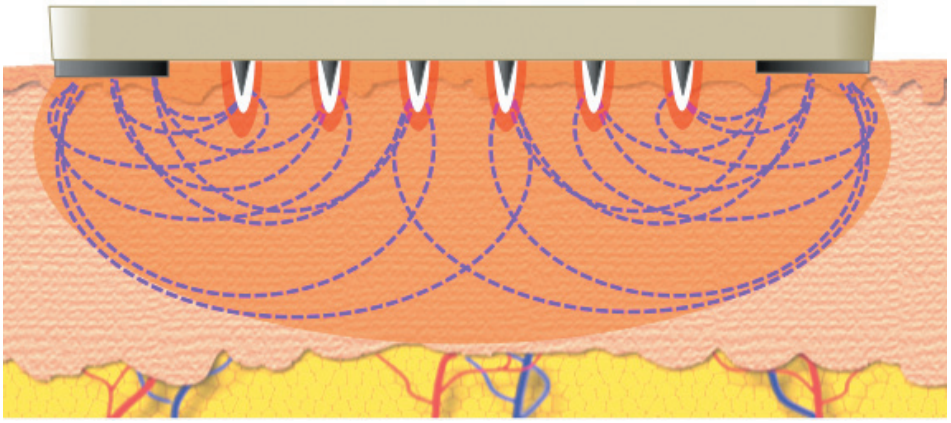
The clinical outcomes were collected using 3 evaluation methods:

- Histological evaluation of treated skin and ablation craters. Histological samples were taken immediately

Table 1. Summary of Technologies by Application

Aging Pathology	Technology	Treatment Effect
Pigmented Lesions	IPL (1)	Coagulation of the portion of the epidermis with higher melanin concentration
	Q-switch Lasers (5)	Selective destruction of melanin
	Dermabrasion	Removes pigmented stratum corneum
	Fractional Laser and RF (6,9,10)	Fractional ablation of the epidermal and junctional pigmented lesions
Vascular Lesions	IPL (1,2)	Coagulation of superficial blood vessels
	Pulsed Dye Laser (2)	Coagulation of superficial blood vessels, including small capillary vessels
	Nd:YAG Laser (4)	Facial telangiectasia
Wrinkles	IR Light (3)	Sub-necrotic heating of the reticular dermis
	IR Lasers	Sub-necrotic heating of the reticular dermis
	Mono-polar and Bi-polar RF (7,8)	Sub-necrotic heating of the reticular dermis and the dermal-fat junction
	Fractional Laser and RF (6,9,10)	Fractional ablation of the papillary dermis
Skin Laxity and Tightening	Mono-polar and Bi-polar RF (7,8)	Sub-necrotic heating of the reticular dermis and the dermal-fat junction
	IR Light (3)	Sub-necrotic heating of the reticular dermis

Figure 1



Cross sectional imagery of the Fractora pulse structure where heat is represented by red and radio-frequency is represented by purple. The white "cone shaped" regions are the zones of RF ablation.

after treatment, 1 and 2 weeks post treatment to analyze the character of fractional lesions and the wound healing process. Samples were stained with hematoxylin and eosin show classic signs of fractional ablative coagulated tissue which include (a) phagocytosis, (b) healing and (c) collagen remodeling. Because different groups of patients are required for different treatment parameters, the histological study consisted of 3 energy settings: 10mJ/pin, 30mJ/pin and 60mJ/pin.

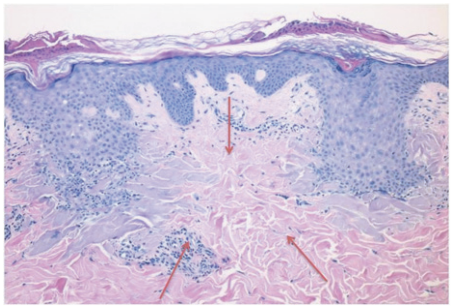
- Evaluation of treatment results using Visio system (Canfield Inc.) before the treatment and at the follow up visits at 3 and 6 months.
- Thermal profile monitoring on ex-vivo tissue using thermal camera FlirA320 (Trek Equipment Corp.). Heat distribution in the cross section of tissues were analyzed to correlate the thermal effect with clinical results.

Results and Discussion

The histological analysis demonstrated that ablation craters are varied from a depth of 250 micron for the lower fluence settings, up to 1000 microns for the highest energies. The coagulation zone around the crater measured 60-100 microns and, over time, consistent collagen remodeling was observed in both the ablative craters and non-ablated thermally stimulated tissue. Figure 2a is the histology taken immediately following the treatment and shows a typical ablation crater. The ablated crater has a triangle or "cone" shape and the zone of irreversible coagulation is clearly observed around the crater. Figure 2b represents histology taken 1 week after the treatment. Re-epithelialization was completed by 48 hours and now an inflammatory infiltrate and phagocytosis is observed in crater region. The ablated collagen and epidermis is being replaced by a new collagen, elastin and ground substances. Two weeks after the treatment the acute healing process is completed and a new epidermis is fully restructured and the reconstituted dermis is undergoing remodeling. (Figure 2c)

Figure 3 shows collagen remodeling occurring in the zones of non-ablative RF stimulation, between the pins and the ablative craters. This is the region of RF sub-necrotic heating in entire dermis induced by the flow of RF current from the ablative pin tips to the side electrodes. One can see that already at 1 week after the treatment visible changes in collagen, specifically shortening and thickening are observed. We expected that collagen remodeling is not limited by 1 week and continues for a few months.

Figure 3



Ablation crater histology taken 1 week after treatment showing collagen restructuring between 2 healing craters.

Thermal evaluation of ex-vivo tissue shows temperature increase in papillary and reticular dermis. This thermal stimulation is caused by the non-ablative flow of RF current from the pins to the side electrodes. The temperature increase is approximately 10-15 degrees Centigrade, or 46-51 degrees Centigrade, depending on energy setting and is well within the therapeutic range required for non-ablative collagen and dermal stimulation and consequent remodeling. Figure 4 demonstrates the temperature distribution in the tissue following the RF ablative pulse.

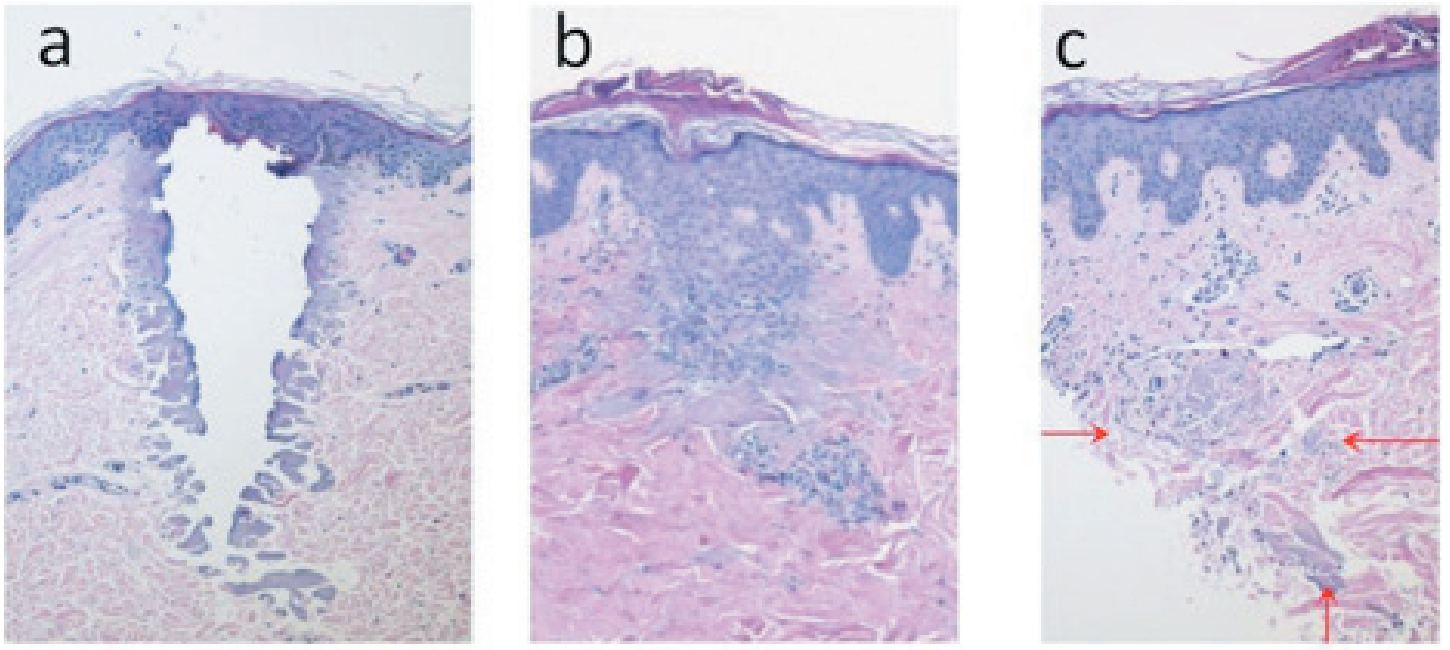
It is important to note that ablation craters are not visible in the image. Due to the very short pulse duration, the spatial camera resolution does not allow for the visual depiction of the ablation zones with a size of 100 microns.

Sub-necrotic heating in the dermis is very uniform with only a minor reduction of temperature in the center and a depth of the heating zone depth reaching of 2.7 mm. This uniform deep heating matrix of the dermal tissue allows energy to penetrates through the entire papillary and reticular dermis to the dermal-fat junction, and remodeling results in wrinkle reduction and skin tightening.

Clinical evaluation of patients demonstrated improvement in skin texture, wrinkles and fine lines, pigmented lesions and some vascular lesions.

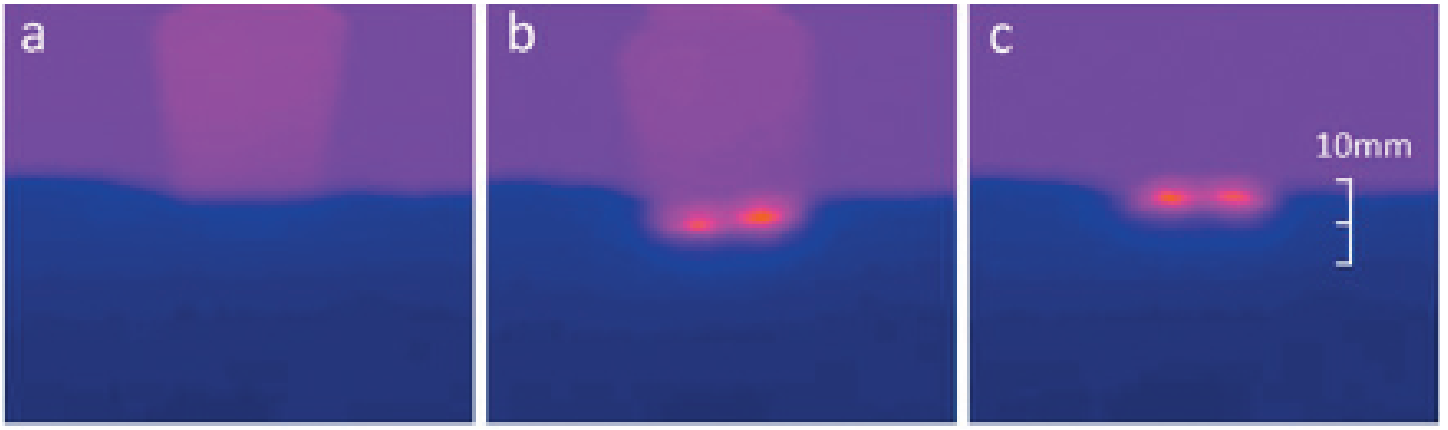
Figures 5-7 illustrate some before and after photos from the study.

Figure 2



Ablation crater histology taken immediately (a), 1 week after (b) and 2 weeks after the treatment (c).

Figure 4



Thermal image of tissue treated with Fractora: before the treatment (a), at the end of the pulse (b) and 1 sec after the pulse (c). The orange and yellow zone is the result of the non-ablative RF heating.

Table 2 –Visia measured Improvements of the Signs of the Aging Face 6 Months after Treatment

Indication	Average Improvement
Texture	65%
Wrinkles and lines	65%
Pigmentation	60%
Vascular	45%

The Visia system (Canfield Inc.) was used for quantitative analysis of treatment results. The results were tabulated in Table 2.

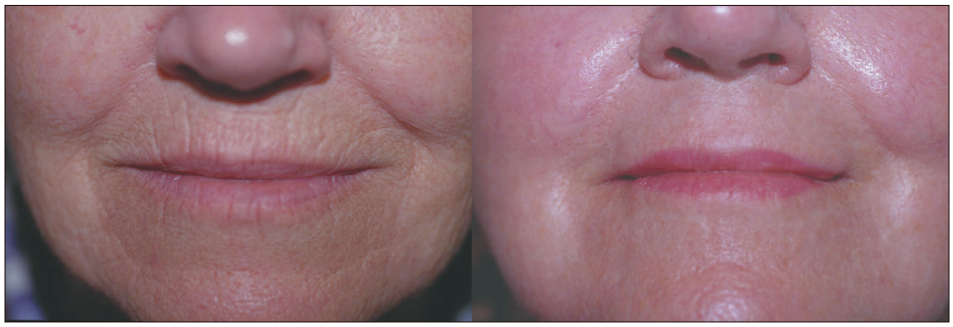
Conclusion

A single full-face Fractora treatment is able to demonstrate more than 50% improvement in an array of indications for the aging face. Wrinkle and tightening improvement was slightly better at the 6 month follow-up than after 3 months, indicating a long process of collagen remodeling. There was no difference in pigmentation between two follow-up visits. Only two patients in the study were presented with vascular lesions and both responded with vascular reduction, however, more clinical research is required to assess the versatility treating a variety of vascular lesions. It is not uncommon for an aesthetic physician to invest in 3-4 aesthetic devices to treat myriad

Figure 5

Female patient with skin type V demonstrating multiple signs of aging skin pre-treatment (pigmentation, poor skin texture, wrinkles and lines) and 6 months after a single full face Fractora treatment.

Figure 6



Female patient before and 6 months after a single full face Fractora treatment. The patient shows dramatic improvements in peri-oral wrinkles and improvements in skin tightening.

Figure 7

Improvement in nasal telangiectasia 6 months after treatment. Vasoconstriction resulting from RF heating allows results to be seen immediately after the Fractora treatment.

of diverse aging skin pathologies. Fractora Fractional RF is a tunable device that allows for the selection of ablative and non-ablative approaches, and may provide a single, cost effective, versatile option to owning multiple technologies. In general, deep RF fractional treatment with Fractora was effective for most aging face signs and can be a versatile solution for medical-aesthetic practices dealing with the many complexities of the aging skin. ◆

REFERENCES

1. Li YH, Wu Y, Chen JZ, Gao XH, Liu M, Shu CM, Dong GH, Chen HD. Application of a new intense pulsed light device in the treatment of photoaging skin in Asian patients. Dermatol Surg. 2008 Nov;34(11):1459-64.
2. Galeckas KJ, Collins M, Ross EV, Uebelhoer NS. Split-face treatment of facial dyschromia: pulsed dye laser with a compression handpiece versus intense pulsed light. Dermatol Surg. 2008 May;34(5):672-80.
3. Carniol PJ, Dzopa N, Fernandes N, Carniol ET, Renzi AS. Facial skin tightening with an 1100-1800 nm infrared device. J Cosmet Laser Ther. 2008 Jun;10(2):67-71.
4. Vascular lesions. Ting PT, Rao J. Curr Probl Dermatol. 2011;42:67-80.
5. Kim S, Kang WH. Treatment of congenital nevi with the Q-switched Alexandrite laser. Eur J Dermatol. 2005 Mar-Apr;15(2):92-6.
6. Schwartz RJ, Burns AJ, Rohrich RF, Barton RE, Byrd HS. Long term assessment of CO2 facial laser resurfacing: aesthetic results and complications. Plast Reconstr Surg. 1999;103:593-601.
7. Weiss RA, Weiss MA, Munavalli G, Beasley KL. Monopolar radiofrequency facial tightening: a retrospective analysis of efficacy and safety in over 600 treatments. J Drugs Dermatol. 2006 Sep;5(8):707-12.
8. Yu CS, Yeung CK, Shek SY, Tse RK, Kono T, Chan HH. Combined infrared light and bipolar radiofrequency for skin tightening in Asians. Lasers Surg Med. 2007 Jul;39(6):471-5.
9. David J. Goldberg, Alexander L. Berlin and Robert Phelps, Histologic and Ultrastructural Analysis of Melasma After Fractional Resurfacing, Lasers in Surgery and Medicine 2008;40:134–138.
10. Hruza G, Taub AF, Collier SL, Mulholland SR. Skin rejuvenation and wrinkle reduction using a fractional radiofrequency system. J Drugs Dermatol. 2009 Mar;8(3):259-65.

Dr. Spero J. Theodorou, plastic surgeon, Manhattan, New York, is an expert in aesthetic plastic surgery and non-invasive laser, light and RF based cosmetic treatments. Dr. Theodorou is a member various organizations, including the American Anti-Aging Society, American Association for the Advancement of Wound Care and American College of Surgeons. info@bodysculpt.com. 212-517-5678

Dr. R. Stephen Mulholland is a plastic and reconstructive surgeon, certified by the Royal College of Physicians and Surgeons of Canada and by the American Board of Plastic Surgery. He currently restricts and focuses his practice solely to Cosmetic Plastic Surgery. info@spamedica.com. 416-642-1330

Dr. Michael Kreindel is the Founder and Chief Technical Officer of Invasix Ltd. Dr. Kreindel was previously involved in the development of laser, light and RF based products at Syneron Medical Ltd. And ESC/Sharplan and holds over 50 worldwide patients on medical and aesthetic devices. michaelk@invasix.com. 905.707.6787