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-collagenesis and neo-elastosis. The ablative effects of the Fractional RF injury will provide thermal disruption of superficial brown spots, sun damage and melanin based dyschromia, while, if the tips of the Fractora applicator are purposely applied over superficial 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% xylcaine. 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>
<thead>
<tr>
<th>Aging Pathology</th>
<th>Technology</th>
<th>Treatment Effect</th>
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<tbody>
<tr>
<td>Pigmented Lesions</td>
<td>IPL (1)</td>
<td>Coagulation of the portion of the epidermis with higher melanin concentration</td>
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<td>Q-switch Lasers (5)</td>
<td>Selective destruction of melanin</td>
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<td></td>
<td>Dermabrasion</td>
<td>Removes pigmented stratum corneum</td>
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<td></td>
<td>Fractional Laser and RF (6,9,10)</td>
<td>Fractional ablation of the epidermal and junctional pigmented lesions</td>
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<tr>
<td>Vascular Lesions</td>
<td>IPL (1,2)</td>
<td>Coagulation of superficial blood vessels</td>
</tr>
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<td></td>
<td>Pulsed Dye Laser (2)</td>
<td>Coagulation of superficial blood vessels, including small capillary vessels</td>
</tr>
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<td>Nd:YAG Laser (4)</td>
<td>Facial telangiectasia</td>
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<tr>
<td>Wrinkles</td>
<td>IR Light (3)</td>
<td>Sub-necrotic heating of the reticular dermis</td>
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<tr>
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<td>IR Lasers</td>
<td>Sub-necrotic heating of the reticular dermis</td>
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<td>Mono-polar and Bi-polar RF (7,8)</td>
<td>Sub-necrotic heating of the reticular dermis and the dermal-fat junction</td>
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<td></td>
<td>Fractional Laser and RF (6,9,10)</td>
<td>Fractional ablation of the papillary dermis</td>
</tr>
<tr>
<td>Skin Laxity and Tightening</td>
<td>Mono-polar and Bi-polar RF (7,8)</td>
<td>Sub-necrotic heating of the reticular dermis and the dermal-fat junction</td>
</tr>
<tr>
<td></td>
<td>IR Light (3)</td>
<td>Sub-necrotic heating of the reticular dermis</td>
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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 abla-
tive coagulated tissue which include
(a) phagocytosis, (b) healing and (c)
collagen remodeling. Because differ-
ent 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 fol-
low 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 demon-
strated 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 remodel-
ing was observed in both the ablative
craters and non-ablated thermally
stimulated tissue. Figure 2a is the
histology taken immediately follow-
ing 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 af-
fter the treatment. Re-epithelialization
was completed by 48 hours and now
an inflammatory infiltrate and phago-
cytosis is observed in crater region.
The ablated collagen and epidermis is
being replaced by a new collagen, elas-
tin and ground substances. Two weeks
after the treatment the acute heal-
ing 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, specifi-
cally shortening and thickening are
observed. We expected that collagen
remodeling is not limited by 1 week
and continues for a few months.

Thermal evaluation of ex-vivo tissue
shows temperature increase in papillary
and reticular dermis. This thermal stim-
ulation is caused by the non-ablative
flow of RF current from the pins to the
side electrodes. The temperature in-
crease is approximately 10-15 degrees
Centigrade, or 46-51 degrees Centi-
grade, 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 al-
low for the visual depiction of the abla-
tion 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 remodel-
ing results in wrinkle reduction and
skin tightening.

Clinical evaluation of patients dem-
onstrated improvement in skin texture,
wrinkles and fine lines, pigmented le-
sions and some vascular lesions.

Figures 5-7 illustrate some before
and after photos from the study.
Ablation crater histology taken immediately (a), 1 week after (b) and 2 weeks after the treatment (c).

Figure 2

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.

Figure 4

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

<table>
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<tr>
<th>Indication</th>
<th>Average Improvement</th>
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<tr>
<td>Texture</td>
<td>65%</td>
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<tr>
<td>Wrinkles and lines</td>
<td>65%</td>
</tr>
<tr>
<td>Pigmentation</td>
<td>60%</td>
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<tr>
<td>Vascular</td>
<td>45%</td>
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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...
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


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 of 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 patents on medical and aesthetic devices. michaelk@invasix.com. 905.707.6787

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.