Treatment of Enlarged Skin Pores and Scars by a New Micro-Needle Radio-Frequency Device

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ABSTRACT

Background:

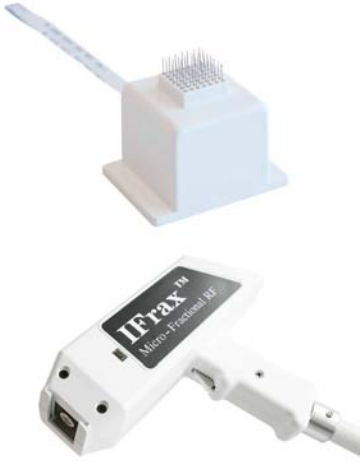
Enlarged pores and scars commonly occur on the face, and many patients seek to minimize and improve the appearance of these common skin imperfections. Along with the inevitable signs of skin aging, other imperfections of facial skin seems to be a result of the combination of intrinsic and extrinsic processes. For treatment of facial ageing, enlarged pores, skin tightening and scars, numerous non-invasive procedures have become popular.

Aim:

To investigate the efficacy of using a new micro-needle, bi-polar (2 MHz) radiofrequency (RF) device for treating enlarged skin pores and facial scars with Asian subjects.

Materials and Methods:

We performed an open trial with the iFRAX Micro-Fractional RF System (Sykor Ltd, Korea) utilizing the D-Pin (sharp micro-needle) tip making a single passes over the entire face and an additional pass over areas evidencing visible enlarged pores and/or scars during each session.



Results:

A 37-year old female Indonesian subject (skin type IV to V) was involved in the study. The subject received two treatments with a treatment interval of 34 days. The procedure was performed with a standard topical anesthetic (9.6% Lidocaine). No adverse effects were observed in either treatment. The efficacy of the procedure and the subject's comfort level were scored as "satisfactory" by the subject. She noted a reduction in pore size as a result of her treatments, and there was no down-time for the subject.

Conclusions:

The iFRAX treatments were determined to be effective in safely treating Asian skin without causing PIH. The treatments were effective in improving the appearance of both the subject's scars and pore size (as shown in the accompanying photographs). In the subject's self-evaluation she stated that she was "satisfied" with the efficacy of her treatments. Although iFRAX™ treatments cannot be deemed to be a substitute for surgical procedures, they may be seen as a way to prolong the time to a patient receiving her first surgical facial lift. The number of subjects treated was small, and no quantitative measurements or histopathology was performed. Hence further studies with a complete series of treatments (i.e., 4 to 6) and a greater number of subjects are necessary.

INTRODUCTION

Volume loss, skin laxity and wrinkling are major findings associated with facial ageing. Skin laxity can also be caused by several heritable connective tissue disorders. In the ageing skin, acquired skin laxity seems to be a result of the combination of intrinsic and extrinsic processes. A major extrinsic factor is ultraviolet radiation (UVR), which can be potentiated by smoking.

For treatment of facial ageing, more and more minor invasive or non-invasive procedures have become popular, like fillers for volume enhancement and sculpturing, Fraxel™ laser, intense pulsed light or chemical denervation by botulism toxins for wrinkles, fractional CO2 laser, and subdermal laser lipolysis for skin tightening. The downside of all laser treatments is that there is no way to "by-pass" the epidermis. With the use of any laser wavelength there is going to be some reaction by the hypersensitive melanocytes typically located in the basal layer of the epidermis.

In recent years, radiofrequency has become another tool for facial rejuvenation. Radiofrequency current is formed when charged particles flow through a closed circuit. As the energy meets resistance in the tissue, heat is produced. The amount of heat will vary depending on the amount of current, the resistance levels in the targeted tissue and the characteristics of the electrodes. The amount of RF energy applied can be configured to target specific tissues. In addition, the water content of skin varies between different areas of the body, with time of the day, environmental humidity, internal hydration and the topical moisturizing agents used. Thus the flow of RF through the skin depends on multiple factors. High-impedance tissues, such as subcutaneous fat, generate greater heat and account for the deeper thermal effects of RF devices.

It is estimated that adult skin loses approximately 1% of its dermal collagen content on an annual basis due to increased collagen degradation and decreased collagen synthesis. When the collagen fibers are heated, some of the cross-links are broken, causing the triple helix structure to unwind. Beyond a certain level, depending on a combination of maximal temperature and exposure time, collagen fibers undergo

denaturation. When the cross-links are maintained, at least partially, collagen shrinkage and thickening are achieved.

Based on this principle, treatments are designed to cause the shrinkage of dermal collagen using heat generated by a radiofrequency current. In addition, the treatment promotes the formation of new collagen via the natural wound-healing response of the skin and a direct effect on the dermal cellular matrix. The extent of collagen shrinkage, fibroblast activation, fibroplasia and overall collagenesis in the different skin layers is based on a complex multivariate mechanism, which depends on the temperature distribution and timing. This enables shrinkage at a certain depth, followed by collagenesis at a different, preferably more superficial layer. Exposure of the skin to heat is also known to increase blood perfusion in the affected area, supporting the fibroblast activity and the overall rejuvenation process.

Transmission electron microscopy studies have shown immediate results of heating with regard to collagen denaturation, with a resultant fibril contraction and tissue thickening. An inflammatory wound-healing response ensues with long-term neo-collagenesis, effecting rhytide reduction and further tissue contraction. In addition, selective heating and tightening of fibrous septae within the subcutaneous layer likely accounts for immediate contour changes in the skin after treatment.

The RF technologies – including fractional RF (FRF) and fractional RF micro-needle devices (FMN) technologies—are being increasingly employed in dermatology to achieve skin rejuvenation with minimal adverse effects and downtime. The latest FRF and FMN technologies—enable physicians to augment targeted tissue layers while sparing melanocytes and the cutaneous surface, thereby preventing dyspigmentation and prolonged wound healing. Recent advances in RF have expanded the array of treatment indications and improved cosmetic outcomes. Future developments are likely to further enhance the therapeutic index of RF.

The iFRAX device delivers a bipolar current via a micro-needle electrode assembly and produces controlled zones of collagen coagulation in the reticular dermis while sparing key structures that promote rapid healing. Wound-healing response after FRF therapy has been evaluated histologically and using reverse transcriptase–polymerase chain reaction, and neoelastogenesis and heat shock protein response have been analyzed using immunohistochemistry. Clinical testing has shown that ten weeks after treatment, histology revealed neocollagenesis, neoelastogenesis, increased dermal cellularity, and deposition of hyaluronic acid. Radiofrequency thermal zones were completely replaced with new collagen via an active dermal remodeling process driven by the collagen chaperone HSP47.

Models that can accurately predict the thermal response of human skin in vivo during treatment with a bipolar FRF system has also been developed, which may be employed to aid physicians in parameter selection to achieve improved efficacy and safety

profiles, particularly because no consensus recommendations for treatment of patients with minimally invasive bipolar RF currently exist. In addition, the relationship between subjective clinical improvement and changes in objective measures of mechanical skin properties has been investigated. Elastometry measurements have been compared with clinical results after treatment of the lower face with a bipolar FRF device. At 3 months after therapy, elastometry measurements showed statistically significant improvement for pressure measurements but not retraction times. Physician grading revealed statistically significant improvements of wrinkles and laxity, and approximately 90% of treated patients were satisfied or very satisfied with the procedure at 3- and 6-month follow-up. Fractional RF technology has also been favorably compared with a surgical face-lift, which is considered the gold standard for treatment of skin laxity, in a blinded randomized study.

An additional advantage of treating with the new FRF technologies such as the iFRAX System is that the exact same treatment parameters (i.e., energy level, duration, etc.) can be used for treating all skin types. The primary difference between FRF and other technologies is that the internal temperature achieved at various depths in the dermis can be precisely controlled. With FRF devices it is possible to create precise zones of thermal injury beneath the epidermis, thereby dramatically reducing the potential for PIH.

Comparisons of RF Devices and CO2 Laser

The mechanism of skin rejuvenation has been well studied in the gold standard CO2 laser. The CO2 laser has a dramatic ‘‘skin tightening effect’’ which is routinely observed by clinicians immediately after the delivery of laser pulses. The mechanism of skin tightening is a heat induced denaturation of the collagen fibers facilitated by disruption of collagen cross-linking bonds that results in an immediate shrinkage. It has been well demonstrated in the literature that thermal induced shrinkage of collagen by various devices repeatedly occurs when connective tissue is heated to 65–75 degrees C. The primary challenge for lasers has always been the “skin melanin effect”. Melanocytes are stimulated by both ultraviolet (UV) light from the sun as well as excessive heat. People with skin of color have more active melanocytes than those with lighter skin, so they produce more pigment. This production increases when stimulated by light exposure or rising hormone levels. Darker-skinned individuals also have hyper-responsive melanocytes. Therefore, any type of skin inflammation – including excessive skin heating—can trigger melanogenesis resulting in PIH and other adverse reactions to some treatments. The fractional micro-needle RF approach offers a potential for a similar thermal tissue effect as lasers at deeper skin levels, with the exception that the detrimental effects of epidermal disruption (and the inflammatory response by melano-cytes) can be avoided. Further investigative work must be focused on the ultrastructural effect of FRF based collagen denaturation.

MATERIALS AND METHODS

This investigation was limited to female patients older than 18 years of age, non-pregnant, and non-lactating. Informed consent is obtained, and a comprehensive medical history was taken. In addition, the patient was screened to make sure that implanted pacemakers or defibrillator were not present, since this is an absolute contraindication for RF therapy. The patient was also screened for the presence of acute systemic infections and local infections such as herpes simplex or impetigo or open wounds in the area of treatment as those conditions would also require exclusion from the study. Patients with genetic disorders of connective tissue, like cutis laxa, are also excluded from iFRAX treatments. The patient was interested in improvement in skin texture, reduced pore size, scar reduction and skin whitening.

We used the iFRAX Micro-Fractional RF System (Sykor Ltd, Korea) utilizing the D-Pin (sharp micro-needle) tip. The D-pin tip utilizes an array of 49 extremely fine micro-needles to deliver the benefits of both multiple micro-puncture and fractional RF energy to the deep layers of the dermis. This equipment utilizes an RF frequency of 2 MHz and has a maximum RF energy output of 25 Joules. The iFRAX fractional bi-polar RF micro-needle system delivers current through multiple contact points arranged in a matrix of 7 x 7 extremely fine acupuncture needles. The iFRAX System has been designed to enable fractional skin resurfacing and treatment of wrinkles via controlled epidermal micro-ablation combined with dermal remodeling with a long established, highly reliable, and cost-effective technology. Treatment with the iFRAX system can be also done as part of a combination procedure utilizing additional modalities such as intense pulsed light, skin care products and/or lasers. The latest advances in aesthetic medicine utilize radiofrequency (“RF”) energy as opposed to light energy. Treatment with the iFRAX system can be also done as part of a combination procedure utilizing other technologies and specialized skin care products including fillers, Botox and chemical peels. Because of the incredible versatility of the iFRAX system, procedures can be custom tailored to the unique attributes of the patient and the patient’s willingness to undergo brief periods of “down time” or not.

iFRAX treatments are indicated for skin resurfacing and the treatment of wrinkles and other indications by means of micro-ablation and coagulation. Re-usable and/or disposable treatment tips, each containing a matrix of bi-polar electrode pins, are attached to the distal end of the hand piece and are placed on the skin for treatment. iFRAX RF energy is delivered either to the whole surface of the skin in a “fractional manner” via the multi-electrode pins. Radiofrequency current is delivered sequentially between each of the pin electrodes and the large electrodes on each side of the pin matrix. Due to this design, relatively high RF current densities are formed in the tissue under each pin electrode, resulting in localized fractional treatment micro-wounds in the epidermis which are in direct contact with the electrodes while heat is delivered deeper into the dermis. This fractional manner of energy delivery leaves intact zones in between the targeted areas which serve as a reservoir of healthy cells to promote faster, more effective wound healing. iFRAX technology emits fractional RF energy in a single “pulse” of variable duration (up to 100 msec in duration). By adjusting both the

energy level (up to 25 J) and interval duration, the operator can achieve different tissue effects as follows:

The patient was treated in a lying position on a standard treatment table. For each treatment, after a 35 minute application of topical anesthetic, the skin was cleansed and the treatment was begun. The D-Pin tip was attached, and various facial zones were treated with energy levels as follows:

Facial Zone	Needle Depth (mm)	Interval (Duration) % (100% = 1000 msec)	Energy Level % (100% = 25 J)
Forehead	1.0 - 1.5	3 – 5 %	15 – 20%
Cheeks	1.5 – 2.0	5%	20 – 30%
Upper Lip	1.0 – 1.5	3 – 5 %	15 – 20%
Chin	1.5 – 2.0	5%	20 – 30%
Jaw Line	1.5 – 2.0	5%	20 – 30%

The entire face was treated with a single pass and areas evidencing visible scars and enlarged pores received a second pass each session. The interval between the two treatments administered was 34 days. In this setting, no cooling of the skin is necessary with the iFRAX System. Photos were taken before and after each session. The patient was asked about her satisfaction with the treatments and was asked to complete a standard self-evaluation form.

RESULTS

The investigation was done with a single female patient of Indonesian descent and skin type IV to V. Each of the two procedures was preceded by a 35 minute application of standard topical anesthetic. The second treatment was performed 34 days after the initial treatment. Normal erythema was observed for about two days following each treatment. No adverse effects, such as skin burning, ecchymosis or pigmentary changes, occurred except that minor bruising occurred in several small spots after the second procedure. Treatments took less than 30 minutes per session. The efficacy of the procedure and the patient's comfort level were scored as "satisfactory" by the patient. She noted a reduction in pore size as a result of her treatments, and there was no down-time for the patient.

Minimal improvement in acne scars was observed after only two treatments but due to the length of time required for the collagen remodeling process it is expected that significant improvement would require more time for follow up observation and would additional treatments (up to six) would further improve results.

The results and effects of the two iFRAX treatments – as seen in the accompanying photographs-- were obvious but not dramatic. Nevertheless, the patient was satisfied with her results. It is believed that the patient's self-evaluation would have rated her satisfaction with results considerably higher had she been afforded the full treatment course generally prescribed which is from four to five treatments. iFRAX™ treatments

may also be used in combination with other procedures such as fractional CO2 laser treatments for even better results.

DISCUSSION

The advantages of fractional, micro-needle bi-polar delivery include both “fractional” delivery (allowing for untreated areas of skin surrounding each needle point for faster recovery) and deep penetration of the emitted power. In contrast to lasers, fractional RF technologies provide “volumetric” heating. The depth of heating is dependent upon the size and geometry of the treatment tip(s) being used. A conductive coupling fluid does not need to be used with the D-Pin tip to enhance the thermal and electrical contact between the treatment tip and the skin as the needles are inserted directly into the dermis.

RF devices have shown clinical utility in aesthetic medicine for the treatment of excessive facial laxity and rhytide reduction. In particular, these systems have proven effective for the reduction of brow ptosis, prominent mentolabial folds and cheek laxity. Since the skin heating is not chromophore dependent, the procedure is also safe for ethnic skin. The mechanism of action for scar reduction results from controlled delivery of RF energy to the dermal layers. Both light and RF are forms of electromagnetic energy, but the mechanisms of action utilized by each are quite different. The mechanism of action for light-based devices is based on “selective photothermolysis”. When photons are absorbed by skin chromophores (i.e., water, melanin, blood, etc.) the light energy is transformed into heat. When tissue heat reaches different levels hyperthermia, coagulation or vaporization can result. When RF energy is applied to the skin surface, rapidly oscillating electromagnetic fields cause movement of charged particles within the skin and the resultant molecular motion generates heat.

RF devices interact with tissue in a different way than light-based devices. With RF energy, the electrical current emitted interacts with tissue to generate a current of ions which incurs resistance as it passes through the tissue. This resistance—also called “impedance”—generates heat in proportion to the amount of impedance. Tissues with high impedance are heated more than tissues with low impedance. The mechanism of action for inducing dual layer skin rejuvenation is comprised of a two stage process.

The first phase of the skin rejuvenation process is the immediate skin response to both the mechanical and thermal injury resulting from the fractional RF energy delivery and the injury resulting from the micro-puncture of the skin. The selective delivery of RF energy to both the epidermal and dermal skin layers from the micro-electrodes stimulates immediate collagen contraction (shrinkage) and destruction through both mechanical and biochemical pathways. The first phase of treatment also results in tissue regeneration leading to the release of skin growth factors and triggering fibroblast proliferation.

The second phase of the process results in long term collagen remodeling and elastin formation leading to more youthful and beautiful skin appearance. The controlled thermal injury to the dermal layers results in the production of new collagen, elastin and hyaluronic acid for increased skin volume, elasticity and thickness. As a result of the energy delivered deep into the dermis, collagen remodeling via a controlled wound healing response occurs over time with associated neocollagenesis. Thus collagen remodeling also results in the highly desirable “skin tightening” that is observed with iFRAX treatments. Collagen remodeling can help reduce the appearance of scars. The same mechanism of action can be helpful in reducing pore size as the inner walls of the pores can be reduced by the dermal remodeling combined with thermal stimulation and mechanical action resulting from the application of RF energy.

The advantages of using FRF and FMN devices instead of lasers in avoiding the “skin melanin effect” has been confirmed by this study. Melanocytes are stimulated by both ultraviolet (UV) light from the sun as well as excessive heat. People with skin of color have more active melanocytes than those with lighter skin, so they produce more pigment. This production increases when stimulated by light exposure or rising hormone levels. Darker-skinned individuals also have hyper-responsive melanocytes. Therefore, any type of skin inflammation – including excessive skin heating—can trigger melanogenesis resulting in PIH and other adverse reactions to some treatments. The fractional micro-needle RF approach results in a similar thermal tissue effect as lasers at deeper skin levels, except that the detrimental effects of epidermal disruption (and the inflammatory response by melano-cytes) is avoided.An additional advantage of treating with the new FRF technologies such as the iFRAX System is that the exact same treatment parameters (i.e., energy level, duration, etc.) can be used for treating all skin types. With FRF and FMN devices the internal temperature achieved at various depths in the dermis can be precisely controlled, and it is possible to create precise zones of thermal injury beneath the epidermis, thereby dramatically reducing the potential for PIH.

The patient for the present trial was an Indonesian female with Fitzpatrick skin type rated as between type IV and V. We observed a marked improvement in skin laxity and fine wrinkling, in particular on the lower eye lids and the Crow’s feet. Adverse effects were not noted. The treatment is safe and convenient. It is not time consuming and may be performed as a lunch procedure.

An option for further improvement of outcome might be the multi-pass vector RF therapy. By this technique, more edema was noted, but severe adverse effects were not seen. In this trial, we limited the application to two passes only. More passes might increase efficacy, but this has not been investigated in detail. Other major advantages of fractional bi-polar RF micro-needle technology are its applicability to various age groups and ethnicities. Although the final outcome might be better in biologically

younger facial skin, there is no age limit and no skin classification is excluded. Nevertheless, when a surgical intervention is necessary, RF treatments are not a substitute for a surgical facelift. On the other hand, micro-fractional RF treatments might prolong the time to the first surgical facial lift.

This study has some limits — small number of patients (only one), minimal number of treatments undertaken (only 2), no objective measurements for the treated indications, and an insufficient of follow up period for the “after” photos. Therefore, multi-center trials would be most useful to increase the number of patients and introduce more sophisticated measurements of the effect. Within these limits, the fractional bi-polar micro-needle RF device has proved to be an affordable and useful tool with a high safety profile and high levels of patient satisfaction.

TREATMENT ONE (MARCH 25, 2013)

Before

TREATMENT ONE (MARCH 25, 2013)

After

TREATMENT TWO (APRIL 28, 2013)

BEFORE

TREATMENT TWO (APRIL 28, 2013)

After