Consensus Recommendations on the Use of a Fractional Radiofrequency Microneedle and Its Applications in Dermatologic Laser Surgery

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Background and Objectives
Fractional radiofrequency micro-needle (FRM) has revolutionized the way we treat a variety of cutaneous conditions using radiofrequency technology. A comprehensive guide is required for clinicians using this technology in treatment of a variety of skin conditions in various skin types.

Materials and Methods
The guidelines were made from a recent round table discussion among experienced clinicians and a review of recent medical literature.

Results
We concluded that FRM is a safe and effective modality for treatment of conditions commonly encountered in dermatology, and recommended guidelines for optimal treatment of several skin conditions on and off the face using FRM.

Conclusion
We developed reproducible guidelines for most effective treatment of a variety of skin conditions using FRM. Conduct of large, multicenter trials will be needed for further optimization of treatment parameters.

Key words
Consensus; Fractional; Radiofrequency; Micro-needle
INTRODUCTION

Radiofrequency (RF) energy is widely used in various medical fields. In dermatological field, RF devices have many aesthetic applications, including skin lifting and tightening, body contouring and cellulite reduction.\textsuperscript{1-3} Recently, combining the fractional technique with a classical nonablative radiofrequency device has been introduced and revolutionized the field of skin rejuvenation.\textsuperscript{1,4-7}

Fractional radiofrequency micro-needle (FRM) system delivers an exact amount of RF energy at accurate depth directly into the deep dermal area through micro-needle.\textsuperscript{1,4-7}

Although the use of FRM device has been examined and expanded by some clinicians, the exact parameters and guidelines have not been established. In this article, concrete treatment recommendations for different dermatologic conditions and suitable techniques for pre- and after-treatment will be discussed. Expert dermatologists have met to discuss how to make the best use of the FRM devices (INTRAcel; Jeisys, Seoul, Korea) for various indications and suggest optimal guidelines.

HISTORY OF RADIOFREQUENCY

RF devices are commonly used in our life (Radio, TV broadcasting, wireless internet and phones, microwaves, satellite communications, and so on).\textsuperscript{3,8-10} In the medical field, RF energy has been used for over 80 years.\textsuperscript{2,11} The initial application of RF to medicine was electrocautery in 1920s, but now RF is widely used for many medical conditions, ranging from surgery for minimal invasive technique to aesthetic procedures.\textsuperscript{2,11-15}

RADIOFREQUENCY

Radiofrequency (RF) is a rate of oscillation in the range of about 3 kHz to 300 GHz.\textsuperscript{9-10} RF devices generate electrical current using electromagnetic radiation.\textsuperscript{2,10} When the current is applied to tissue, it encounters resistance, which is an inherent property of the particular tissue, also called as impedance.\textsuperscript{2,10,16} This generates heat energy.\textsuperscript{2,10,16} Namely, thermal heat energy is generated by transfer of energy from the electrical field to the charged particles in the target tissue.\textsuperscript{16,17} The energy output is calculated using the following formula: Energy ($\Delta E$) = $I^2 \times Z \times t$, Where $I$ is current, $Z$ is impedance, and $t$ is time in second. Therefore, Heat energy ($\Delta Q$) is created by impedance ($Z$) to the movement of electrons relative to the amount of currents ($I$) and time that current is delivered to tissue.\textsuperscript{1,3,10} The parts of the body with high blood content have the lowest impedance, namely highest electrical conductivity.\textsuperscript{1,3,18} Bone, for example, has very high impedance and consequently the electrical current cannot penetrate the bone tissue, so the current flows around it.\textsuperscript{3,10,11} In skin, dry skin has high impedance, so in order to enhance electrical current, hydration is necessary.\textsuperscript{2,3,10}

Contrary to laser light which can be scattered and absorbed before reaching the target tissue, RF energy is not affected by tissue diffraction and chromophore absorption.\textsuperscript{2,15} Therefore amount of RF energy is more controllable than laser light and it can be applied to any type of skin.\textsuperscript{1,2,16}

MONOPOLAR AND BIPOLAR RF

Monopolar RF current is applied between a single electrode tip and a grounding plate, so the current goes through the patient to complete the current cycle.\textsuperscript{2,3} On the other hand, bipolar RF current is applied between two points on the tip of a probe so the current only goes through the tissue between the two electrodes of the instrument.\textsuperscript{2,3} The main advantage of monopolar system is that it can achieve high penetration of emitted current.\textsuperscript{1-3,19} The bipolar RF system has its limitations on treating deeper skin area, but it provides more controlled distribution of energy.\textsuperscript{2,20}

FRACTIONAL RF

Fractional RF is combination of fractional technique with a classical nonablative radiofrequency.\textsuperscript{3,7} Hantash et al. introduced a minimally invasive device, microneedle fractional RF, which adopted microneedle therapy system (MTS) for delivering bipolar RF energy directly into the skin through microneedle.\textsuperscript{4} It generates fractional radiofrequency thermal zone (RFTZ) within the reticular dermis.\textsuperscript{4} The FRM system is a minimally invasive nonablative RF device that delivers mono- and bipolar RF energy in the form of an electrical current that generates heat through the inherent electrical resistance of dermal and subcutaneous tissue.\textsuperscript{4,20}

Device properties

One of FRM system, INTRAcel, consists of a handheld applicator with a disposable single-use treatment tip. The tip contains 49 micro-needle electrodes in 1 cm$^2$ area. The micro-needle electrodes are nonconductive except for the tip, beginning 0.3 mm form the distal end, in order
to protect from radiofrequency heating at the insertion site. Needle length can be adjusted (0.5 mm, 0.8 mm, 1.5 mm, 2.0 mm) for various clinical situations. Needles automatically are inserted into the skin vertically, and RF is emitted 0.2 seconds after inserting the needles for safety. The amount of RF emission differs according to the energy levels. The superficial RF rejuvenation (SRR) tip makes superficial ablation which may synergistic effects if combined with microneedle tips.

**Mechanism of action**

The RF energy is fractionally delivered by MTS and it creates RFTZ. Fractional thermal injury of dermal collagen induces a vigorous wound healing process leading to inflammatory cascade and stimulates new collagen, elastin, and hyaluronic acid formation, eventually resulting in dermal remodeling. Furthermore, skin needling with microneedles has been reported to stimulate migration and proliferation of keratinocytes and fibroblasts by inducing the release of several growth factors. And, untreated areas which are located between treated areas serve as a reservoir of cells that promote and accelerate wound healing.

**Histologic and ultra-structural changes**

Lim et al. histologically evaluated pig skin up to 10 weeks after FRM treatment, using energies from 1.25 to 6.25 J/cm². Examination post-treatment biopsy revealed that thermally coagulated zone was localized in the reticular dermis without damaging the epidermis. After 10 weeks, the coagulation necrosis zone was replaced by new collagen tissue in H&E staining. And RT-PCR studies indicated an increase in heat shock protein, matrix metalloproteinase and extracellular matrix protein. Increased collagen expressions after treatment support the notion that the thermal injury created by the RF device may stimulate a wound healing response.

**Table 1.** Fractional radiofrequency micro-needle (FRM) treatment level guidelines for skin rejuvenation – face

| Condition | Option | Needle depth/ bi-mono | Energy level (L) | Pass | Interval | Comment |
|-----------|--------|------------------------|-----------------|------|----------|---------|
| Rejuvenation | Eyes (periorbital) | 0.5 bipolar (B) | 4 | 1 | 4-6 weeks | |
| | | 0.5 monopolar (M) | 6 | 1 | | |
| | | Superficial RF rejuvenation (SRR) | 5,6 | 1 | | L6 with significant down time. Stacking application is recommended for beginners. |
| | Forehead | 0.5 B | 4 | 1 | | |
| | | 0.8 B | 4 | 1 | | |
| | Cheek | 0.8 B | 4 | 1 | From midway neck in vector over cheek (care if slight build) |
| | | 0.8 M | 6 | 1 | | |
| | | 1.5 B | 4 | 1 | | |
| | Neck | 0.5 B | 4 | 1 | No overlap | |
| | | 0.8 B | 4 | 1 | | Manual states Depth: 0.8-1.5 mm |
| | Lip (Peri-Oral) | 0.5B | 4 | 1 | | |
| | | 0.5M | 4 | 1 | | |
| | Nose | 0.8 B | 4 | 1 | Ala part is recommended 1.5B / L6, 0.5B has risk of shallow treatment | |
| | | 0.8 M | 4 | 1 | | |
| | Specific Zone | Crow’s feet | 0.5B, 0.8 B | 3.4 | 2 | Vectoring pattern is optional as per personal choice of operator |
| | | SRR | 1 | | | |
| | | Perioral rhytids | 0.5-0.8 B | 3.4 | 2 | Vectoring pattern is optional as per personal choice of operator |
| | | SRR | 1 | | | |
| | | Nasolabial folds | 1.5 B | 5.6 | 2 | Vectoring pattern is optional as per personal choice of operator. For stronger results, 20% overlap treatment directed for unmovable anchoring areas can get better results, and NAR treatment after it, also make better result. |
| | Specific Zone | For intensive rejuvenation for very photo damaged skin on cheeks and neck | 1.5 | 5.6 | 1 | It does not make any difference if monopolar or bipolar first |
| | | 0.8 | 3.4 | 1 | | |
| | | 0.5 | 3.4 | 1 | | |
| | | 2 M | 6.7 | 1 | | |
Application

1) Skin rejuvenation
Seo et al. studied FRM system on facial rejuvenation of twenty five healthy women with ages ranging from 41 to 64 years, with moderate to severe wrinkles and sagging skin. All patients received three sessions of treatments every 4 weeks. The energy levels were determined based on the specific anatomical location and proximity of underlying bones. The treatment depths were altered according to underlying skin thickness (periorbital area: 0.5 mm, forehead: 0.8 mm, chin and temple: 1.0 mm, and cheek: 2.0 mm). All patients showed clinical improvement on wrinkle, skin laxity and skin texture and side effects were minimal and well tolerable.

Consensus panel members agreed that FRM system will not replace standard surgical treatment such as rhytidectomy. However, FRM system may play a major role in the cosmetic improvement of early skin laxity and be preferred by patients who wish to avoid surgery for the fear of its associated risk of complications. And, the panel suggested FRM system would be well combined with other nonsurgical approaches such as Botox, filler agents, and other nonablative laser treatments. The panel members suggested proper parameters based on specific anatomical areas such as forehead, periorbital area, nose, décolletage and dorsum of hands which are shown on Table 1 and 2.

2) Acne scar, enlarged pore and traumatic scar
As FRM treatment appears to be related to dermal matrix regeneration, it may be one of the effective treatment option for improving acne scars and facial pores. A study of the FRM system on thirty patients with acne scar and large facial pores revealed that the grade of acne scars, investigator global assessment of large pores, skin surface roughness, dermal density, and microscopic and composite image improved after two sessions of treatment. Consensus panel members agreed that FRM system could be an ideal treatment option for acne scar as well as other surgical and traumatic scar. Suggested proper parameters by panel are shown on Table 3.

| Condition            | Option     | Needle depth/bi-mono | Energy level | Pass | Interval | Comment |
|----------------------|------------|----------------------|--------------|------|----------|---------|
| Decolletage          | 1.5 B      | 2-3                  | 6 weeks      |      |          |         |
|                      | 0.8 B      | 4                    | 2            |      |          |         |
| Hand rejuvenation    | 0.8 B      | 4                    | 1            |      |          |         |
|                      | 0.5 B      | 4                    | 1            |      |          |         |
| Telangiectasia       | 0.5 B      | 3                    | 1-2          |      |          |         |
|                      | 0.8 B      | 4                    | 1            |      |          |         |

| Condition            | Option     | Needle depth/bi-mono | Energy level | Pass | Interval | Comment |
|----------------------|------------|----------------------|--------------|------|----------|---------|
| Pore treatments      | Cheek      | 0.5 B                | 5            | 1,2  | 4-6 weeks| L5, 0.8 x 2 passes and L5, 0.5 x 2 passes gets great results. In case of deep treatment, (1.5, 2.0 mm + L5, 6, 7); nerve block recommended. |
|                      | 0.8 B      | 5                    | 1,2          |      |          |         |
|                      | nose (ala area) | 1.5 B                | 6            | 1    |          |         |
|                      | 0.8 B      | 4,5                  | 1,2          |      |          |         |
|                      | glabella   | 0.8 B                | 4            | 1    |          |         |
|                      | 0.5 B      | 4                    | 1            |      |          |         |
|                      | mentum     | 0.5 B                | 4            | 1    |          |         |
|                      | 0.8 B      | 4                    | 1            |      |          |         |
| Acne scarring Cheeks | 0.5 B      | 4                    | 1            |      |          |         |
|                      | 0.8 B      | 4,5                  | 1            |      |          |         |
|                      | 1.5 B      | 4,5,6                | 1-2          |      |          |         |
| Acne scarring body areas, backs, arms etc | 0.5 B | 5 | 1-2 |
|                      | 0.8 B      | 5                    | 1-2          |      |          |         |
| Traumatic scars      | 0.5-2 B    | 4                    | 2-3          |      |          |         |
|                      | 0.8 B      | 4                    | 1-2          |      |          |         |
3) Acne vulgaris
FRM devices have been used to treat acne vulgaris. A study of the FRM system on 20 patients with moderate inflammatory acne revealed clinical improvement as evidenced by a reduction in lesion count and reduction of sebum secretion. Side effects included temporary erythema, tingling, and burning sensation after treatment, but resolved in 2 days after the treatment. The panel contended that FRM treatment helped in decreasing inflammatory acne lesion and sebum secretion and suggested proper parameters shown on Table 4.

4) Striae distensae/atrophic scar
Striae distensae are atrophic dermal scars with overlying epidermal atrophy that may cause significant cosmetic problems. Although a variety of laser and light sources have been used for the treatment of striae distensae, to date no definite ‘gold standard’ treatment modality has been determined. A study of the FRM system on 30 female patients with moderate to severe striae distensae showed optimal clinical results with minimal side effects. The panel contended that FRM system could be one of the suitable options for treating striae distensae and atrophic scar and suggested proper parameters which are shown on Table 5.

Pretreatment regimen
Right before the treatment, the face needs to be cleaned with facial foam cleanser and 70% alcohol. Patients with a history of herpes simplex may be given Valacyclovir 2 g orally every 12 hours on the day of treatment. Some suggest that all patients take pretreatment Valacyclovir because the treatment with FRM has triggered herpetic outbreaks in patients with no known history of the condition. For anesthesia, physicians recommend a topical anesthetic applied one hour before the procedure to an area no greater than 300 to 400 cm² and removal of the topical anesthesia before the treatment.

Post treatment care
After treatment, the patient needs to avoid washing his or her face for one day and is advised to apply topical antibiotic application for two to three days after the treatment. The panel advised that patients avoid prolonged exposure to direct sunlight and apply sunscreen with SPF30 or greater. Recently, to decrease the intensity and duration of post-treatment erythema, light-emitting diode treatment has been performed immediately after FRM treatment.

Side effect
Common side effects were mild pain and temporary erythema during and after procedures. In general, incidence of side effects of FRM treatment is lower than conventional fractionated lasers. And the risk of post-inflammatory hyperpigmentation is minimal, and if it occurs, it usually resolves within 4 weeks. There might be some vesiculation and superficial burn after treatment, but mostly it is attributed to uneven electrode contact to skin. In area such as forehead and temple where underlying bones are close to the skin surface and applying high RF energy could be dangerous, clinicians must lower RF energy and depth of the needle. There were no reports of infection or scarring from any of the patients of the panel. The panel advised that clinicians must use appropriate parameters, including energy level needle depth according to the cosmetic units of the face. The panel also emphasized that proper contact of electrode to skin surface is important to reduce adverse event.

Conclusion
Consensus panel members agreed that FRM system...
could provide a viable, minimally invasive treatment alternative for skin conditions commonly encountered in the dermatology practice. And they developed reproducible parameters and guidelines in order to most effectively treat a variety of skin conditions using FRM device. However, for beginners, it is recommended one level down of this guideline, and auto mode minimally 0.65-0.8s when use level 5 or 6. Large, multicenter trials are needed for further optimization of treatment parameters and guidelines.

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