A Review of Radio Frequency for Skin Tightening by Dr. Steven Weiner

(Finally! A Radiofrequency System That Makes Sense: The Infini From Lutronic)

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ABSTRACT

Background and Aims: Radiofrequency (RF) energy has gained popularity in skin rejuvenation and skin tightening. More recently, interstitial fractional delivery of RF energy using insulated microneedles introduced a new paradigm in this application of RF, typified by the INFINI™ system from Lutronic. The aim of this article is to clarify for the reader the basic principles of the application of RF energy in skin rejuvenation and tightening, and to suggest the reasons why the INFINI system offers clear advantages over others.

Rationale: RF systems work on the principle of "Joule heating" where resistance in the target tissue to the RF current creates electrothermal damage: the higher the level of the current, the greater the damage. External RF systems, where electrodes are placed on the skin, appeared first: so-called "unipolar" RF where a single delivery electrode was placed over the target tissue and a return electrode was placed elsewhere, and "bipolar" RF, where the delivery and return electrodes were combined in a single handpiece. These systems had problems with accurate depth delivery, necessitated multiple treatments to get any noticeable effect, and required aggressive cooling to protect the epidermis from electrothermal damage. Interstitially-inserted uninsulated microneedle electrodes solved the depth problem, but still required epidermal cooling because the entire needle was the electrode. Finally, insulated microneedles were developed which could deliver precise zones of electrothermal damage limited to the dermis at preset depths, did not require cooling and represented a true fractional approach. The INFINI system uses insulated microneedling fractional RF (MFR), and offers these characteristics.

Conclusions: With microengineered insulated needle electrodes, a unique insertion technology, a large range of depth settings (0.5 mm – 3.5 mm in 0.5 mm increments) and the ability to balance power levels (2.5 – 50 W in 2.5 W increments) with exposure times (100 ms – 1000 ms in 100 ms intervals), the INFINI offers the clinician a new and extremely adaptable approach to RF for skin rejuvenation and tightening. These features make this RF system, in the author's opinion, superior to any other such system currently on the market.

Radiofrequnecy (RF) energy: Background and principles

The practical clinical application of high frequency radiofrequency (RF) electric energy has a history of over 70 years in medicine. The term radiofrequency (RF) energy applies because the oscillation frequency of the current is in the broadcasting band of the electromagnetic spectrum. RF has been used for electrocautery in multiple applications, but the most exciting recent innovations have been in wrinkle improvement and skin tightening. Thermage® in 2002 was the first to market a device which was FDA cleared for use in dermatological procedures for electrocoagulation and in 2009 for non-invasive treatment of wrinkles and rhytides. Since then, there have been a least a dozen devices which have come to market with similar technology including: Exilis, Venus Freeze, Pelleve, Viora Reaction, 3Deep RF, Accent XL, eMatrix, eTwo, TriPolar RF, ReFirme, Sublime, ePrime, Fractora, Evolastin, and most recently the INFINI system (Lutronic, Goyang City, South Korea). The problems with most of these devices have traditionally been:

- The results are variable – most patients get minimal or no results
- Depth of electrothermal delivery is uncontrolled for monopolar or unipolar systems or for "bipolar' systems limited in depth
- Multiple treatments (6 or more) are often needed with 'touch ups' in some of the devices

The aim of this article is to help the reader understand how RF devices tighten skin, the problem with most RF devices (why they mostly don't work), and why Lutronic's INFINI has certain features which make it an outstanding system among RF devices. But first, let me clarify what is meant by tightening skin. The FDA does not recognize this as an indication because it is difficult to define. Tightening of skin does not necessarily mean it shrinks or becomes more stiff, but rather the term refers to the reduction in the appearance of lax skin. Lax skin appears in the form of wrinkles, crêpiness and sagginess. For the purposes of this discussion, I use the term "tighten skin" to refer to the reduction in the appearance of specific aspects of skin laxity.

Importance of inducing the wound healing process

Research has shown that heating the dermis to a high enough temperature will cause collagen coagulation which results in immediate skin shrinkage, and kick-starts the wound healing process. Neocollagenesis and neoelastinogenesis are induced, and during the remodeling process, new collagen gradually replaces the old leading to skin tightening. By heating the skin to 40-48°C, collagen denaturation occurs, causing the hydrogen bonds holding collagen fibers together to denature. As the tissue cools the bonds renature, but some change has occurred in the tissue architecture and a very mild wound healing response is stimulated. At temperatures from 55°C – 70°C and above the collagen is coagulated, the higher the temperature the more intense the degree of coagulation and the shorter the required exposure time to heat is needed. At 65°C a 1 sec exposure results in 63% of the collagen being denatured. As the collagen bundles are coagulated, they dehydrate and immediate tissue shrinkage is seen. This vigorously stimulates the body's own natural healing process, and old, lax collagen and elastic fibers are replaced with fresh, young and better organized fibers. If temperatures are too high or prolonged, the reaction becomes so intense that the potential of heat damage to spread to the full thickness of skin is very high, resulting in excessive damage beyond the scope of the wound healing process, and ulcer formation is very likely. The ideal temperature in the dermis is therefore in the 55° - 68°C range to generate an appropriate coagulation response. The higher the desired tissue temperature, the more RF energy is required, but this also equates to more visible results.

Cutaneous RF devices

The problem with all cutaneous RF devices where the delivery and return electrodes are placed on the skin (including Exilis, Venus Freeze, Pelleve, Viora Reaction, 3Deep RF, Accent XL, eMatrix, eTwo, TriPolar RF, ReFirme, Sublime, ePrime) is that while heating the dermis to a temperature which generates adequate coagulation, safe temperatures must be maintained in the epidermis under the 40°C mark or else epidermal damage is caused which negatively affects wound healing and could result in postinflammatory hyperpigmentation (PIH). So, the solution for almost all external RF devices has been to try to cool the surface aggressively while pumping energy into the deeper layers. This becomes a very difficult and sometimes unpredictable task. RF energy works through the ability of the skin to conduct energy, and under Joule's law, when electrical energy meets resistance, heat is generated. External RF devices therefore rely on the skin tissues to carry the energy to the right level. Differences in skin thickness, hydration and the composition of collagen and fat can lead to placement of the energy at unknown or variable depths. If the energy is placed too deeply, fat necrosis, can occur as was the case with the early devices, and if the focus of the electrothermal damage is placed too superficially, the skin can burn or PIH occurs. In addition, if an adequate tissue temperature is not reached at the target depth, wound healing is inadequately stimulated and not enough new collagen is produced. Multiple treatments are the norm for several of these devices because getting collagen stimulation is very limited and difficult with one treatment. The bottom line is that all cutaneous RF devices have the problem with unpredictable heating of the dermis and limited amounts of coagulation and therefore unpredictable or totally inadequate results.

Fractional delivery of RF energy

The concept of "fractionating" the total energy delivered by a system into multiple discrete points was first seen in the early fractional lasers around 2005, where the affected areas of the skin were surrounded by unaffected normal tissue. The surrounding healthy skin helped wound repair to occur much more swiftly, caused less downtime and minimized side effects for the patient. Because of the obvious benefits of fractional delivery, including faster wound healing, less discomfort and greater safety for the patient, the concept of fractionating energy has spread from lasers to RF devices. This is because the major drawback for the vast majority of external RF devices is that they deliver volumetric bulk heating of tissue, associated with the risk of full thickness damage, discomfort, side effects and longer downtime. By fractionating RF energy over multiple electrodes, as with the INFINI system, the areas of controlled damage are surrounded by zones of undamaged normal tissue, giving less pain, shorter downtime and faster healing with much less risk.

Evolution of interstitial microneedling fractional RF (MFR)

So how can we get more predictability of electrothermal damage depth with RF energy? The answer was found in the evolution of RF energy delivery from external electrodes to interstitial needle electrodes (Figure 1) and was further refined by the use of insulated microneedles which have only the very tip of the needles as the active part of the electrodes (Figure 2).

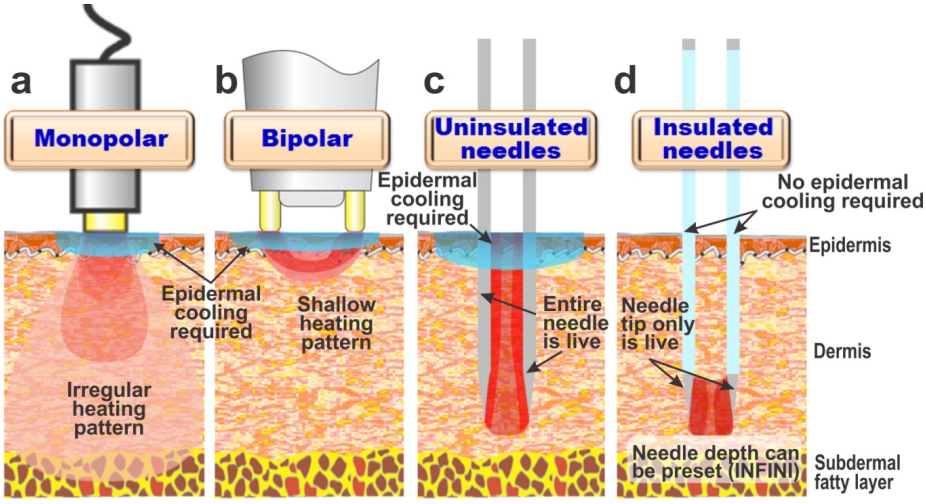

Fig 1: Evolution of insulated microneedling RF (MFR). a: So-called "monopolar" RF, with only the delivery electrode shown (the return electrode is fixed elsewhere on the body). The RF energy travels outwards from the electrode in a fan-shaped pattern as it seeks out the return electrode. b: "Bipolar" RF, where the delivery and return electrodes are mounted in the handpiece. The depth of penetration of the electric current as it passes between the electrodes is limited to one-half of the distance between the electrodes. In both Fig 1a and 1b, the electrodes are associated with a 'hot spot' at the epidermis, and so epidermal cooling is absolutely required. c: RF with uninsulated microneedles. The depth problem is solved, but because of the entire needle shaft comprising the electrode, the electrothermal damage is delivered down the whole needle, thus also requiring epidermal cooling. It is also not truly microfractional because the tissue between the needles is damaged for the whole width and length of the needle. Wide damage zones (>~500 mricons) extending from the epidermis into the dermis can lead to visible imprinting. d: RF with insulated microneedles, as in INFINI. Because the needle is insulated except for the very tip, no electrothermal damage is delivered to either the epidermis or the insulated area of the needle above the tip. This is only way RF can be used to generate fractional zones of coagulation not just mild reversible denaturation. Furthermore with INFINI, the depth and size of the damage zones can be preset and changed by the user.

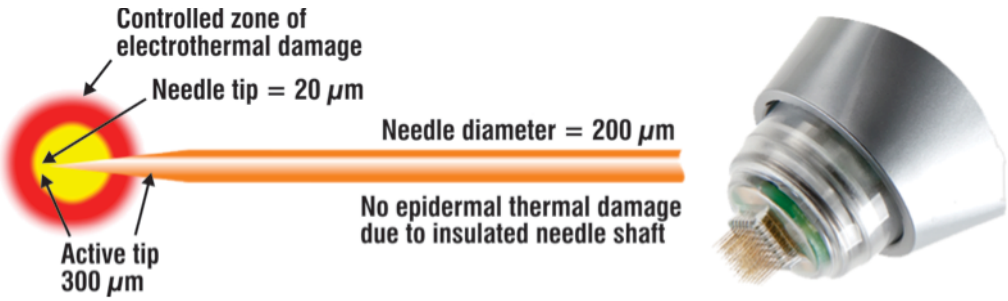

Fig 2: Anatomy of the INFINI microneedles. The extremely sharp surgical stainless steel needle ~34 g is first coated with gold for conductivity to the target tissue, and then coated with a silicon insulating compound except for the 300 μm at the very tip. The business end of the MFR handpiece (7 x 7 needles, 1 cm² matrix) is seen on the right with the needles extended from the disposable tip.

In addition the insulated needles do not all punch into the tissue at the same time, but are inserted serially in rows known as Comfort Flow Technology™. This minimizes pain, aids a more gentle insertion of the needles and helps to eliminate the bounce effect in thinner skin over bony areas of the face. With each RF pulse of Infini, the array of needles is first quickly inserted into the skin in a 100 ms mechanical pulse. After insertion the RF energy at the designated pulse duration is delivered followed by quick retraction of the needles. Because of the very fast and slight offset from row to row of the very fine needles, the needle penetration itself is virtually painless, with some pinpoint bleeding and occasional bruising. Because the shaft of the needles is insulated, there is no electrothermal damage at the epidermis, so no skin cooling is required: there is of course some microdamage from the mechanical needling effect, but that has actually been shown to be beneficial in itself. With this approach, typified and refined in the INFINI system, it is possible to heat the deeper tissues to an adequately high level to coagulate the collagen, leading to greater collagen remodeling, collagen contraction, and stimulation. As a secondary benefit, the actual penetration of the dermis with the microneedles has been demonstrated to mechanically stimulate fibroblasts to produce collagen. There are currently many popular treatments based solely on microneedling (*e.g.*, "Vampire" Microneedling and roller needling).

By creating an opening in the skin with the needles, topical therapeutics can be applied at the conclusion of the treatment that will get to levels much deeper than when typically applied to the surface of the skin, as the skin barrier function of the stratum corneum is temporarily compromised. These can include: growth factors (rejuvenation), Vitamin C (for collagen), hydroquinone (for pigment), and Retin A (rejuvenation and acne). Going deeper into the skin allows for some treatment opportunities which have been poorly addressed in the past with RF devices, or not addressed at all: acne treatment (attacking the *Propionibacterium acnes* in the sebaceous glands), acne or other scarring (particularly in darker skin types), and axillary hyperhidrosis (attacking the axillary sweat glands).

System comparison

There are 3 main commercially-available devices which use this microneedling concept, namely the Evolastin, Fractora and INFINI systems.

Evolastin: This system uses 32 g needles in depths which are between 1-2 mm. The needles enter the skin in a tangential manner, so the exact depth is hard to predict, and there has also been some needle bending reported. The energy is transmitted between paired needles, so the heating is fractional and localized. The major problem is that the patient requires tumescent anesthesia (infiltrating lidocaine mixed with saline) into the area being treated. This adds additional time, discomfort, and risk. Another concern is that this solution actually changes the tissue galvanic characteristics, so the treatment becomes less predictable – maybe more or less effective in different areas due to changes in the resistivity of the tissue, or perhaps safety concerns in certain areas. The system also requires epidermal cooling because of the possibility of secondary conducted thermal damage to the epidermis due to the long exposure time required with the low power levels associated with this system (Figure 3).

Fractora: Uses microneedles which have a fixed depth of 1 mm in combination with plate electrodes (Figure 4 [from the manufacturers]). The energy is transmitted through the very shallow needle electrodes and circles back to the plate electrodes sitting on the surface of the skin. The surface probe has a sensor to monitor the skin temperature so as to maintain it within safe parameters. This is truly NOT fractional because the energy is dispersed in the areas between the needle tips and the skin surface. Here we go again with unpredictable traveling of the energy through the tissues and bulk heating near the skin surface. Concerns for safety and discomfort come to mind

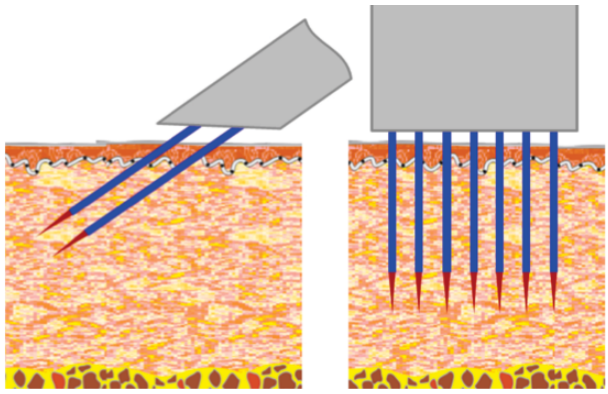

Fig 3: Tangential needle placement with large caliber needles compared to perpendicular needle insertion. Tangential insertion

(left) means the actual depth between the needle tip and epidermis is uncertain, and cooling of the epidermis is required. There is also a limitation to the number of needles than can be incorporated in the head. Perpendicular insertion (right) ensures a more accurate awareness of the depth of damage delivery in the dermis, and allows for more needles in the tip to cover a larger area.

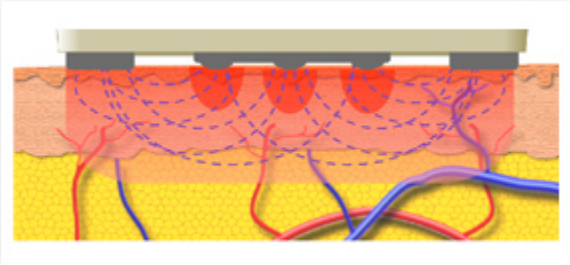

Fig 4: Schematic of the mechanism of the RF mechanism of action of the Factora system as supplied by the manufacturers. Note that it is not exactly correct as the RF energy will take the path of least resistance between the needle and the plate electrodes, and the depth will be more shallow, limited to one-half of the distance between the needles and their nearest plate electrode.

Infini: Uses ultrasharp needles which are 200 microns in diameter (very fine ~34 g) and offers user-variable depths of penetration from 0.5 mm to 3.5 mm in 0.5 mm increments so that in the same treatment session, several different levels of the dermis can be predictably treated. It must always be remembered that the skin of the face varies in thickness depending on the anatomical area, with the cheeks being the thickest and the periorbital skin being the thinnest, so the ability to use shallower penetration settings is invaluable to allow safe treatment of the entire face. The maximum depth of 3.5 mm is much deeper than the other two MFR devices and sufficient to reach into the subcutaneous tissue. The energy is transmitted only between the microneedle tips which results in discrete fractional RF ablation at precise depths and with discrete damage volume sparing the epidermis minimizing risks and downtime.

Img 1: Infini Before (left) and After (right) images, 8 weeks after 1 Tx.

INFINI has a very flexible range of power level settings, from 2.5 W to 50 W in 2.5 W increments, which can be balanced with an equally flexible range of exposure times (100 ms to 1000 ms). The power level determines the intensity of the electrothermal damage, and the exposure time determines to what extent the volume of secondary thermal damage will extend via the conducted heat effect. The energy and heat are confined to very discrete thermal injury zones so there is no added discomfort from bulk heating that would otherwise activate all of the pain endings in the whole area. (The more distance the energy travels through tissue, the more pain is felt.) The epidermis, and the dermal tissue up to the proximity of the needle tips, is unharmed because the needles are insulated. In fact most of the pain endings are located in the upper dermis and lower portion of the epidermis. However, when treating the face or any other area with several passes, as the needle depth become shallower the power and exposure settings must be reduced to avoid secondary conducted epidermal thermal damage.

Img 2: Infini Before (left) and After (right) images, 8 weeks after 1 Tx.

The treatment time is fairly quick: in the author's experience, full-face treatment sessions take about 30 minutes, as do the neck procedures. For optimal results, it can take 2-3 treatments and full results take around 4-6 months post-treatment to achieve the maximum effect (when the collagen remodeling is complete.) Figures 5 and 6 illustrate an INFINI procedure schematically.

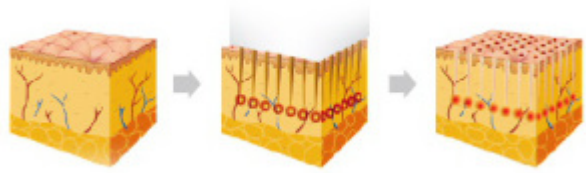

Fig 5: First pass with the INFINI. The needles enter the skin, deliver the RF energy (center) and withdraw, leaving a discrete zone of dermal damage at the preset depth (right).

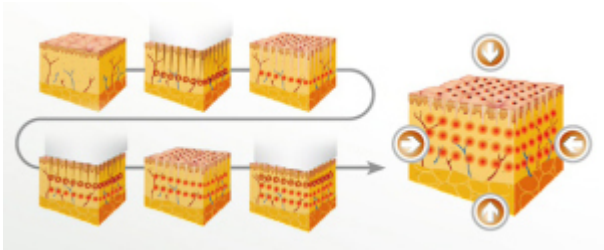

Fig 6: The needle depth is reset as required and the second and third passes are made, remembering to decrease the settings as the needle tips near the epidermis (left). The net result is a three-dimensional volumetric tissue shrinkage (right). Note the mechanical microdamage to the epidermis caused by the needling alone, recognized as being beneficial for good epidermal renewal to give a young-looking epidermis over a rejuvenated and tightened dermis.

The wide spectrum of indications of the INFINI includes:

- Improving superficial fine lines and wrinkles in all skin types and in tanned skin [currently cleared for the US under an FDA 510(k)]
- Improving the elasticity of intrinsically aged and solar damaged "thin" skin (not yet FDA cleared in the US)
- Treating scars of all types but particularly acne scars (not yet cleared by the FDA in the US). In the author's opinion this system offers a great advantage over laser for darker skin types. The author suggests that INFINI might turn out to be the "go to" device for scars compared with certain fractional laser systems because of deeper treatment levels (*e.g.*, 3.5 mm vs 1.8 mm in the Fraxel system) and without the pigmentation risks in darker skin types associated with lasers
- Tightening loose skin on all parts of the body including: arms, chest, knees, abdomen (not yet cleared by the FDA in the US). There are no limitations as to where the skin can treated on the body.
- Potentially a treatment for acne and hyperhidrosis (not yet FDA cleared)
- No exclusion of patients based on skin type and minimal risk of hyperpigmentation
- Downtime is limited to only about 1-2 days of a sunburn-like sensation and slight redness. Patients can gently wash their face on the evening of treatment and apply makeup from the following day

Ultrasound as a skin tightening modality has recently attracted attention, such as treatment with the Ulthera® system (Ulthera Inc, AZ, USA). When comparing INFINI with the Ulthera, the differences are:

- Ulthera is more for lifting than for the superficial lines and wrinkles
- Ulthera is only used on the face and neck at the present time
- Ulthera is still being evaluated for acne scars
- Ulthera can be used in conjunction with INFINI for even greater tightening and lifting then just INFINI or Ulthera alone

In summary

To summarize, RF skin tightening has over a 10 year history and has been fraught with several different technical hurdles: uncertain depths, unpredictable results, discomfort, downtime and safety concerns. Using INFINI to deliver MFR, the energy can be precisely delivered down to the required level in the dermis with more accuracy and a greater degree of safety. INFINI would appear to have the right combination of the transmission of energy through the insulated microneedle tips and variable depths taken together with the flexible balance between power levels and exposure times, making INFINI the ideal "RF Skin Tightener" at the present time. In our hands we have used it effectively for a broad list of indications including acne scars, skin tightening on the body, and improving the fine lines and wrinkles of facial skin.

About the Author:

Dr. Steve Weiner is a facial plastic surgeon, trained at Johns Hopkins, who "laid down his scalpel" in 2005 and now concentrates solely on non invasive and minimally invasive cosmetic procedures at The Aesthetic Clinique. Dr. Weiner takes pride in being at the forefront of new technologies and procedures and is one of the first 15 adopters of the INFINI system in the United States. His website is http://www.theclinique.net. [Telephone (+1) 850.622.1214].

[For some more opinions on INFINI, Please follow this link (http://digital.miinews.com/publication/?i=174629) from a European Round Table discussion in the Autumn 2013 *European Aesthetic Guide* about Lutronic's INFINI and Q-switched Nd:YAG system, SPECTRA™ (both of which are used in the author's clinic). The INFINI discussion starts on page 7.]