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INNOVATION IN
SKIN REJUVENATION
TECHNOLOGY

Targeted Energy Delivery with High Intensity Focused Radiofrequency

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Dr. Ross has received research support, loan of equipment, and consulting fees from Lutronic.

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At a symposium held during the annual meeting of the American Society for Laser Medicine and Surgery, an international faculty of leading dermatologic surgeons shared their perspectives on skin rejuvenation with INFINI™ (Lutronic, Inc; Fremont, CA). They described the principles and advantages of using high intensity focused radiofrequency and reviewed clinical outcomes achieved using INFINI in its approved indication to treat facial lines and wrinkles and for off-label treatment of acne scars and laxity of the lower face and neck. Highlights of the session are summarized in this supplement.

Exploring the Best Way to Deliver Radiofrequency Energy

E. VICTOR ROSS, MD

The success of energy-based technologies for skin rejuvenation depends on their ability to address the histological and ultrastructural changes underlying the clinical manifestations. Through its ability to cause collagen coagulation that induces dermal remodeling with new collagen and elastin formation, ablative carbon dioxide (CO₂) laser resurfacing remains the most effective modality for improving the appearance of facial lines, wrinkles, skin laxity, folds, and acne scarring. However, significant pain during the procedure, prolonged post-treatment downtime, and the risk of complications are limitations of ablative CO₂ laser resurfacing. In addition, this modality must be used conservatively for tightening of the neck where the paucity of pilosebaceous units compromise healing of deeper wounds.

Fractional laser resurfacing emerged as one technique to overcome the drawbacks of ablative laser resurfacing. By leaving areas of normal tissue surrounding columns of damage, the fractionated procedure is associated with faster recovery and a better safety profile than conventional ablative resurfacing. However, nonablative fractional techniques are unable to match the efficacy of ablative CO₂ laser resurfacing for improving skin laxity, and ablative fractional laser procedures can still be associated with a longer than desirable downtime.

Radiofrequency platforms were introduced more than a decade ago as another energy-based approach for tightening skin and reducing the appearance of wrinkles. In contrast to laser treatments, the effect of the radiofrequency procedure is mediated via an electrothermal reaction in which heat is generated when the radiofrequency electric current encounters tissue resistance.

Available radiofrequency platforms vary in terms of the design of the electrodes used to deliver the electric current, which has implications for their efficacy and

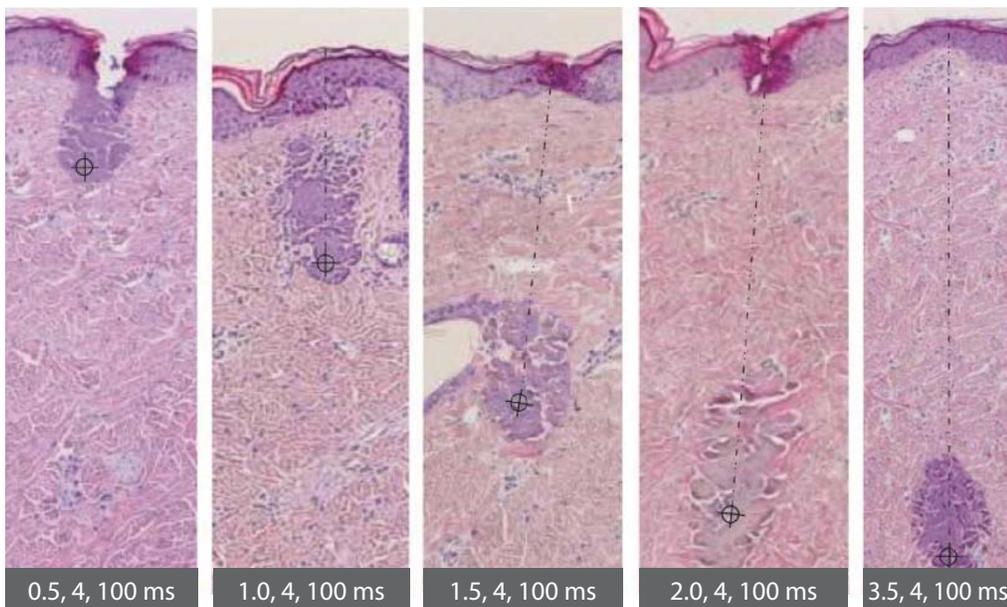


Figure 1. Histometric analysis of specimens obtained from mini pigs immediately after treatments performed at needle depths ranging from 0.5 to 3.5 mm using a constant power (level 4, 10 W) and exposure time (100 ms). Discrete zones of coagulation are seen at the level of the needle tip within the dermis. Space bar = 200 μ m for all, but note that the 3.5-mm depth specimen is at a smaller final magnification to fit the photomicrograph into the figure with the others. (Data on file, Lutronic)

safety. The first radiofrequency devices used monopolar surface electrodes and created large-volume, low-intensity tissue heating. In the monopolar approach, the delivery electrode is in the handpiece that is placed over the target tissue, and the return electrode is attached elsewhere on the body. Subsequently, bipolar radiofrequency devices were introduced in which the handpiece contains both the delivery and return electrodes.

The clinical results achieved with these surface radiofrequency devices intended to tighten the skin, however, have been modest. This shortcoming is probably explained by numerous factors limiting their ability to reliably heat the dermis to a duration and temperature sufficient to cause coagulative damage. Furthermore, the depth of energy delivery with any surface radiofrequency treatment is unpredictable due to interindividual variability in skin characteristics, such as thickness and hydration. Increasing the power and/or time exposure with the aim of increasing electrothermal damage in the dermis is not a viable strategy because it is accompanied by risks for fat necrosis and burn injury.

The use of needles as electrodes improves delivery of radiofrequency energy into the dermis, and various commercially available devices are based on this concept. These systems also differ in electrode design. Some units use uninsulated needles. With that technology, electrothermal damage occurs along the entire length of the needle.

An alternative configuration, which is found on the INFINI system, insulates the needles along the entire shaft except at the tip. This design bypasses the epidermis and results in the delivery of high intensity focused radiofrequency energy specifically to the dermis. The INFINI system also gives the operator the ability to adjust needle insertion depth, energy power level, and exposure time. As demonstrated in a laboratory study using mini pigs as an *in vivo* model of human skin, these features afford control over the exact location and size of the electrothermal damage zone created within the dermis (Figure 1).¹

Advantages of INFINI High Intensity Focused Radiofrequency

With its unique attributes, high intensity focused radiofrequency with INFINI adds value for practitioners wanting to meet growing patient demand for effective rejuvenation procedures that require little downtime.

Tolerability and safety are excellent. Some anesthesia is needed during the procedure to maintain patient comfort, but there is no pain after the treatment is completed. Otherwise, postprocedural sequelae are typically limited to mild erythema and edema that generally resolve within 1 or 2 days. Bruising is sometimes observed and tends to occur more in older patients and with greater insertion depths. The fact that the treatment bypasses the epidermis eliminates the need for cooling strategies during the



Figure 2. Before and 1 month after a single INFINI treatment. (Images courtesy of E. Victor Ross, MD)

procedure and also minimizes the risk for inflammation-induced changes in pigmentation. Therefore, INFINI can be considered a viable option for treating patients of all phototypes as well as on areas of tanned skin.

Patient satisfaction with INFINI high intensity focused radiofrequency is high because the procedure produces noticeable results (Figure 2), and its benefit comes with a low burden of treatment in terms of morbidity as well as cost. Compared with other energy-based modalities used for skin rejuvenation, the INFINI uses relatively low-cost consumables and can produce satisfactory outcomes with fewer sessions. Multiple treatments generally yield increasingly better results, but these are not always needed.

High intensity focused radiofrequency with INFINI is also user-friendly thanks to the ergonomic handpiece and minimal learning curve. In addition, it is easy to incorporate into a clinical practice. Because the INFINI is a class 2 device, the treatment can be delegated to an appropriately trained, nonphysician operator.

In conclusion, the INFINI system embodies optimal technology for delivering radiofrequency energy into the dermis. It can reliably heat the target tissue to a temperature sufficient to cause collagen contraction and stimulate extracellular matrix remodeling, and it provides the operator unparalleled control and flexibility for customization. These features translate into a minimally invasive procedure that is well-tolerated, causes only minor post-treatment sequelae, and results in significant improvement.

How INFINI Works

JOEL L. COHEN, MD

INFINI high intensity focused radiofrequency rejuvenates signs of aging skin and acne scarring by creating fractional radiofrequency coagulation of dermal collagen. The treatment results in immediate collagen contraction and triggers a natural healing response that over time leads to replacement of damaged connective tissue with new, healthier skin. With the ability to control treatment depth and by using a multipass technique, high intensity focused radiofrequency with INFINI can treat multiple layers of the skin to generate a 3-dimensional volumization (Figure 3).

The treatment is performed using a sterile, single-use disposable tip that fits onto a lightweight, ergonomically designed handpiece and contains a spring-loaded, bipolar array of positive and negative electrodes (Figure 4).

The microneedles are 200 μ in diameter and taper at the end to a very sharp, 20- μ diameter tip (~34 gauge). Made of surgical stainless steel, the microneedles are covered with gold to increase conductivity, and they have an outercoating that provides insulation along the entire length of the needle except for a discrete uncoated active area at the distal end.

Once the radiofrequency power is switched on, electric current moves between the active tips of the positive and negative electrodes. Tissue resistance to the current translates into generation of heat, ultimately resulting

in zones of coagulative damage that are limited to the tissue around the active areas of the needle tips.

INFINI treatment depth and intensity are fully adjustable. Using the touchscreen display on the graphic user interface (GUI) or by turning a control dial on the hand-piece, the treatment depth can be set over the range of 0.5 to 3.5 mm in 0.5-mm increments. Radiofrequency power and exposure time are adjusted using the GUI touchscreen display. The radiofrequency power is chosen from among 20 levels representing increments of 2.5 W across the range of 2.5 W (level 1) to 50 W (level 20). The exposure time can be varied from 10 ms to 1000 ms.

When performing a multipass treatment at different levels in the dermis, it is recommended that the needle depth be set at the maximum desired penetration for the first pass and then decreased successively for subsequent passes. As the treatment level becomes increasingly superficial, the power and/or exposure time should also be adjusted to decrease the intensity in order to avoid epidermal damage from conducted heat.

At the shallowest depth of 0.5 mm, the active needle tip is still beneath the dermal-epidermal junction, which explains why there is very little risk for pigmentation changes with an INFINI procedure. The deepest depth, 3.5 mm, may be



Figure 4. The INFINI tip measures 10 mm x 10 mm and contains 49 insulated microneedles in a 7 x 7 array. (Image courtesy of Lutronic)

chosen when treating certain acne scars, although it is generally not used in procedures for rejuvenating aging skin. The depth for the latter procedures is usually ≤ 2.5 mm when treating on the upper lip and cheek and ≤ 1.5 mm on the forehead, around the eyes, and on the neck.

A full-face treatment is completed in about 30 minutes, and treatment for the neck adds another 15 minutes. A procedure that treats the whole face and neck with 3 passes delivers a total of about 1000 pulses, creates about 50,000 microcoagulation zones at selectable depths, and replaces 25% to 30% of damaged collagen per level. The entire procedure is completed using only 1 tip.

Each Treatment Session Places 50,000+ Microcoagulation Zones

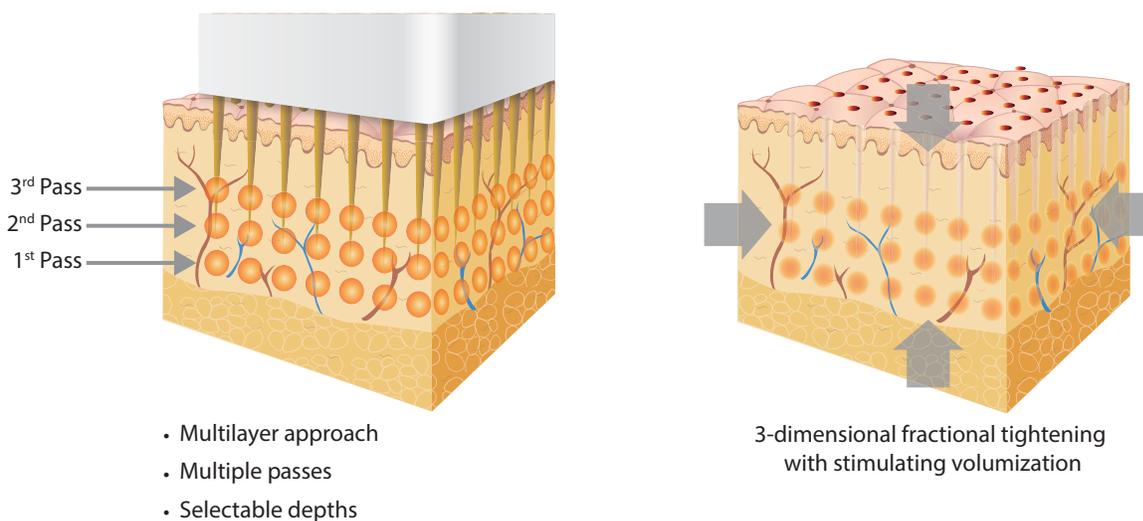


Figure 3. High intensity focused ultrasound performed in a multilayer approach with 3 passes at varying depths results in 3-dimensional fractional tightening with stimulating volumization. (Image courtesy of Lutronic)

Patient Experience

Each patient will tolerate the procedure differently in terms of comfort. Most patients tolerate the procedure well using only a topical anesthetic. Local nerve blocks may be used if desired and may be particularly requested by patients with a lower tolerance for pain. However, the fact that patients are eager to undergo additional sessions attests to the tolerability of the procedure and to its early efficacy.

Discomfort during the procedure tends to be most intense when treating over bony areas of the face, such as on the forehead, zygoma, or chin. Pinching the skin or pushing on it to raise the tissue up away from the bone is helpful to mitigate pain at those sites. When rejuvenating the neck, however, it is advisable to stop the treatment above the level of the clavicle because treating over that bony area can be more uncomfortable.

Depending on the treatment depth, pinpoint bleeding may be present when the procedure is completed, but the bleeding stops quickly. Patients can expect some erythema and edema, but as with any other cosmetic procedure, there is some variability in the post-treatment sequelae in terms of initial severity and persistence. The amount of swelling that occurs depends on the aggressiveness of the settings, but it is generally mild and short-lived, usually resolving within 12 to 24 hours. The erythema is also typically mild. It tends to disappear within 1 to 2 days, and until then, it can be easily concealed using some makeup or tinted sunscreen. Using only light camouflage, some patients may not experience any significant social downtime.

In addition to having limited downtime, patients also want to see noticeable improvement, and INFINI delivers there as well. Whether treating acne scars, neck wrinkles, or lower face and neck laxity, we have seen some wonderful results with INFINI, and our patients agree.

Clinical Outcomes of High Intensity Focused Radiofrequency Treatment

Neck Wrinkles

JEREMY B. GREEN, MD

There are many options available today for safe and effective skin rejuvenation. However, there have also been

a number of devices that failed to live up to their promise and fallen into disuse. Against this background, we have learned to carefully assess new technology in order to determine whether it does what it claims to do. And, with an already replete arsenal of skin rejuvenation tools, we must also consider whether a new system provides any unique advantages compared with existing devices or if it fills any unmet needs.

It is with this critical eye that my associates and I agreed to trial high intensity focused radiofrequency with the INFINI. While skeptical that we would be impressed enough to consider adding it to our practice, we were quickly convinced otherwise after just a few treatments. In the 6 months that have passed since our initial experience, the INFINI has become a reliable workhorse in our practice for skin rejuvenation procedures and treatment of acne scarring. As our practice is located in Miami, FL, the ability to safely treat patients with tanned and darker skin types is a real asset of the INFINI.

When used to treat the aging neck, the INFINI stands out for its ability to safely and effectively improve horizontal rhytides as well as skin texture and laxity (Figure 5). Its multidimensional benefits are explained by the combined effects of microneedling and delivery of bipolar radiofrequency energy. Furthermore, because the user can control treatment depth and intensity with the INFINI, the treatment can be performed over the entire neck, and the results are superior to those achieved with many other energy-based devices. For more complete rejuvenation of the aging neck, the INFINI procedure can also be combined in the same session with laser or light modalities to treat the dyschromia and pigmentary changes associated with photodamage.

Acne Scarring

GIRISH S. MUNAVALLI, MD, MHS, FAAD, FACMS

Acne scarring is a common problem that can have a negative impact on quality of life. There are many different surgical modalities that can be used to treat acne scars, but the specific role of these options may vary depending on the scar type. High intensity focused radiofrequency with the INFINI, however, represents a minimally invasive procedure that can be used successfully to treat a range of acne scars.

A published study from investigators in India further demonstrates the efficacy of high intensity focused

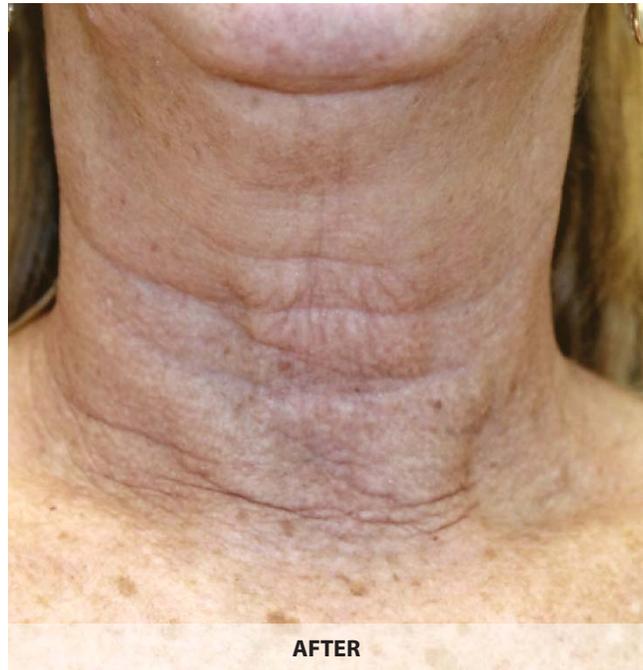
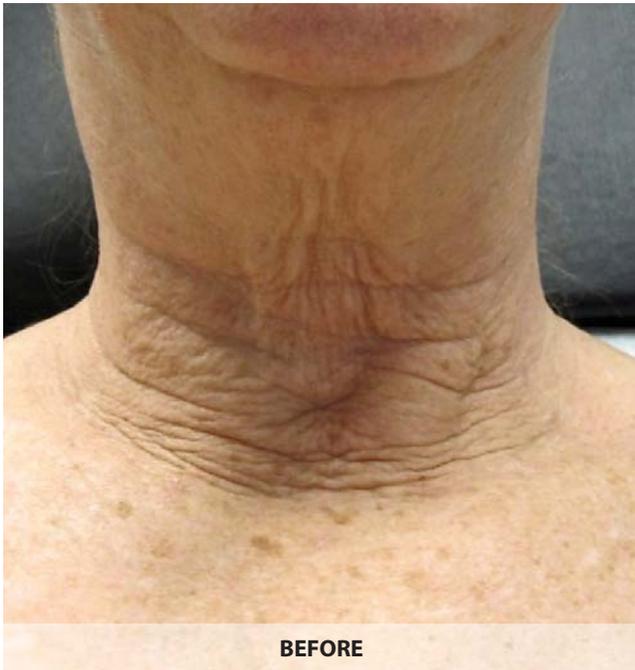


Figure 5. Before and 6 weeks after a single INFINI treatment. (Images courtesy of Joely Kaufman, MD and Jeremy B. Green, MD)

radiofrequency for treatment of acne scars.² This retrospective analysis reviewed pre- and post-treatment photographs of 31 patients with skin types 3 to 5 who had moderate-to-severe atrophic acne scars (grade 3 or 4 on Goodman and Baron's qualitative acne scar grading system). The treatment parameters were individualized based on scar characteristics, but all patients had 4 treatment sessions with an interval of 6 weeks between sessions.

The investigators reported substantial improvement in the appearance of all types of acne scars characterized by softening of the contours and reduction in depth. A 2-grade improvement in scar severity score was achieved by 86% of patients with grade 4 scars and 76% of those with a grade 3 scar, and all of the remaining patients achieved a 1-grade improvement.

Mild erythema lasted up to 2 days post treatment. Other transient adverse events included edema persisting for more than 3 days in 2 patients, postinflammatory hyperpigmentation in 5 patients, and track marks from the probe in 2 patients.

The ability to heat at variable depths with the INFINI allows for treatment of different acne scar morphologies, and in

my hands, good results have been achieved using the INFINI to treat all types of atrophic acne scars, including ice pick, rolling, and boxcar scars.

High intensity focused radiofrequency with the INFINI is showing promise for flattening papular scars, and it is suitable for use in combination protocols. In particular, treating patients in the same visit with the INFINI and the SPECTRA™ Q-switched Nd:YAG laser using the Gold handpiece (Lutronic, Goyang, South Korea) has been helpful for simultaneously addressing the atrophic defect and the postinflammatory erythema that may also be present in some acne scars.

Neck and Lower Face Laxity

MATTEO TRETTI CLEMENTONI, MD

The opportunity to safely and effectively correct laxity of the lower face and neck skin with high intensity focused radiofrequency treatment is an important advance considering that previously, reliably good results could be achieved only with incisional surgical lifting procedures.

Over time, I have refined my protocol for treating skin laxity in these areas using the INFINI, and my technique



Figure 6. Before and 3 months after 3 INFINI procedures performed at 4-week intervals. (Images courtesy of Matteo Tretti Clementoni, MD)

now involves 3 passes. Because neck skin on average has a thickness of around 2 mm, the first pass is performed at a depth of 1.75 or 2 mm, using a mid-range power setting, an exposure time of around 300 ms, and moving the handpiece laterally in an oblique direction from the midline. The depth, power, and time settings are decreased for each successive pass. The second pass is done in a vertical direction, and the oblique approach is used again for the final pass. Next, the triangle under the chin and then the lower one-third of the face are each treated with 3 passes in which the treatment parameters are progressively reduced.

In order to quantify the results of the procedure, we used computerized digital image analysis to calculate changes in the gnathion and cervicomental angles in a series of 30 patients.³ The study group included men and women ranging in age from 36 to 74 years (mean age 51.5 years). Most patients underwent 3 treatment sessions at intervals of 4 weeks.

The results showed statistically significant improvements in both anatomic measurements. At baseline, the mean cervicomental angle was 137°, and it was reduced by 27.2° (mean change –19.8%, $P < .01$). The mean gnathion angle was 107° at baseline and decreased 16° post treatment (mean change –15%, $P < .01$). As further evidence of the procedure's efficacy, 2 blinded, independent

physicians correctly differentiated between the pre- and post-treatment images for all patients. Figure 6 shows before and after images from a patient included in the study. The remarkable improvement is representative of the results achieved.

In conclusion, INFINI high intensity focused radiofrequency treatment brings a new level of precision to skin rejuvenation procedures through the ability to control the intensity of energy delivered and its depth. By using insulated needles and sparing the epidermis, it has distinct advantages over other devices for treating laxity of the neck and lower face, and it is also unique in its efficacy and safety profile as a treatment for facial wrinkles and acne scars in all skin types. While we can expect to see a growing list of applications for the INFINI in the future, there are enough reasons now to encourage clinicians to adopt this novel system.

REFERENCES

1. Zheng Z, Goo B, Kim DY, et al. Histometric analysis of skin-radiofrequency interaction using a fractionated microneedle delivery system. *Dermatol Surg.* 2014;40(2):134–41.
2. Chandrashekar BS, Sriram R, Mysore R, et al. Evaluation of microneedling fractional radiofrequency device for treatment of acne scars. *J Cutan Aesthet Surg.* 2014;7(2):93–97.
3. Clementoni M, Panchaprateep R, Kosari P, Munavalli G. A pilot study to treat mild to moderate laxity of lower face and neck with a bipolar fractionated microneedle radiofrequency device. Presented at the 2015 annual conference of the American Society for Laser Medicine & Surgery, Kissimmee, FL, April 24, 2015.