

Novel Temperature Controlled RF Modality Influences New Applications

By Kevin A. Wilson, Contributing Editor

This new temperature controlled radiofrequency (RF) modality, known as ThermiRF from ThermiAesthetics (Southlake, Texas), is changing the way practitioners approach wrinkle relaxation of the aging face. The combination of percutaneous RF energy, delivered via a minimally invasive probe with two temperature feedback mechanisms, is showing a lot of potential, and researchers believe it has additional applications in the arena of tissue tightening on the face and body.

As expressed by Douglas Key, M.D., medical director of the Key Laser Institute (Portland, Ore.), ThermiRF's engineering makes this device ideal for scientific study. "Rigorous science demands empirical data and since we have precise measurable treatment endpoints and the resultant therapeutic capabilities with ThermiRF, we can test, adjust and re-test repeatedly, to reveal new therapeutic applications and optimize protocols," he explained.

Already FDA cleared for creating lesions in nerve tissue, ThermiRF facilitates percutaneous RF neuromodulation of the glabella, or an alleviation of frown lines similar to what is achieved with the use of injectable botulinum toxin for aesthetic purposes. Other clearances are pending.

ThermiRF deploys an RF thermocouple, which includes a partially insulated RF cannula measuring 5 cm \times 22 gauge with a 5 mm conductive tip for finer applications, in addition to a 10 cm or 15 cm \times 18 gauge with 10 mm conductive tip. Featuring single-use cannulas and probes, this device eliminates the need for sterilization and reduces the risk of infection.

Several key features make this unique technology stand out, noted Brian M. Kinney, M.D., a plastic surgeon in Beverly Hills, Calif. The first being thermistor-controlled RF energy delivery. "This is like cruise control in an automobile," he began. "We program the device to sustain a pre-set desired temperature and automatically pause emission once a particular endpoint has been reached (temperature and length of time per treatment area). This prevents unsafe delivery of energy and guarantees we deliver maximum therapeutic energy levels."

Similarly, the addition of external temperature monitoring via infrared visualization (FLIR), which broadcasts wirelessly to a monitor such as an iPad, allows users to see how energy delivery is affecting tissue during treatment. "With FLIR monitoring we can be sure to both fully treat, yet confine energy delivery to the target region," Dr. Kinney continued. Other features include an internal nerve stimulator and integrated anesthetic injection port on the probe, both of which are major enhancements to decreasing discomfort when applying the technology for nerve ablation.

Downtime and treatment discomfort are minimal with the technology for a number of reasons, Dr. Kinney explained. "First, use of a blunt cannula or probe minimizes tissue trauma and precise delivery of RF energy allows us to localize the effect at any given time. Also, we can selectively and precisely deliver a burst of local anesthetic when needed, and because we use few entry points we're further decreasing trauma and risk."



Douglas Key, M.D. Medical Director Key Laser Institute Portland, OR



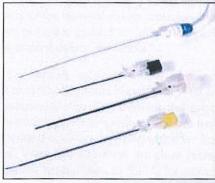
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ThermiRF Probes



Before Tx



After ThermiRF Tx Photos courtesy of Brian M. Kinney, M.D.



Refore Tx



Six days after ThermiRF Tx
Photos courtesy of Daniel Rivlin, M.D.

ThermiRF's ThermiRase catheter features both an internal nerve stimulator and RF emitter. "You start with the second ramus of the temporal branch of the facial nerve, which controls medial collateral movement of the corrugator muscle, and continue up along the nose searching for branches of the angular nerve," said Daniel Rivlin, M.D., of the Miami Beach Skincenter. "Once you find various branches with the internal stimulator you then use the RF emitter to ablate the nerve."

The basic protocol for percutaneous neuromodulation by monopolar RF has been documented in peer-reviewed literature by Kim *et.al.* in a study of 27 patients (22 women, mean age 54.5 years). After mapping of the nerves and introducing combination anesthesia (including nerve blocks, local anesthesia and intravenous sedation as needed) a monopolar RF probe is inserted via a cannula into the skin at specific points through the dermal and muscle tissue to each lesioning site. RF energy at 85° C for 70 seconds is delivered to create lesions. Visual assessment of diminishing glabellar function determines the need for additional lesioning. No suturing is required due to the minimally invasive technique and small size of entry points.

In Dr. Rivlin's past experience with this technology, the use of nerve blocks and local anesthesia inhibited the ability to thoroughly scout the motor nerve anatomy. "Nerve stimulation isn't painful so much as the ablation is. Initially we didn't realize that sensory nerve anesthesia would have such an impact on the motor nerves, but it did, which led to incomplete ablation and lesser outcomes. We were at an impasse; either we avoid the anesthesia, which would make treatment almost intolerable, or we use it at the risk of poor or short-lived outcomes." The integrated anesthetic delivery system available with ThermiRF changed this. "I had theorized the value of this capability in the past so I was eager to perform the treatment with this evolution of technology. It changes everything because we are dealing with fractions of a millimeter. If I found a nerve with the stimulator and then paused to implant concentrated anesthetic, I would risk accidental movement of the probe and missing the nerve. With ThermiRF, I can have the assistant activate the delivery system once I find the ablation point and then ablate precisely. It is this meticulous approach that provides the long-term outcomes this modality is capable of, and saves time, because I don't need to switch gears constantly at the moment where precision is key. Facial nerve anatomy is truly different from patient to patient so without the ability to be precise in locating and ablating, we cannot deliver the results."

ThermiRF is monopolar, delivering a predictable, spherical radius of thermal impact that improves ablation. "The original technology was bi-polar and less predictable," Dr. Rivlin pointed out. Internal temperature feedback contributes greatly to the result as well. "When treating, we're aiming for what's called level five nerve ablation," he added, referring to the Sunderland classification², "in which we have complete structural disruption of the nerve. We know that if we are close enough to the nerve and deliver RF energy raising the temperature to 85° C for about a minute, we will achieve that."

With the ability to insert a probe, locate (through low level internal stimulation) the proper nerve branches, precisely deliver a small dose of local anesthetic, followed by RF energy for consistent and predictable nerve ablation, ThermiRF is a

viable alternative to injectable neurotoxin. "What we had before was extremely solid in theory and practice, but was simply not marketable," said Dr. Rivlin, "because we had no satisfactory answer to the classic trade-off between patient tolerance and outcomes. The ThermiRase treatment presents a marketable option that can provide long-term results."

This begs the question: Who is a candidate for treatment? According to the experts, ThermiRF is appropriate for a subset of potential patients who either feel they'd like to graduate from injectables or simply don't like the idea of coming in regularly for treatment. "This isn't meant to make injectable neurotoxin obsolete, and it won't," stated Dr. Rivlin. "I certainly wouldn't want to start anyone on ThermiRase who hasn't first had a neurotoxin experience because the result is much more persistent. However, I do have veteran neurotoxin patients who are satisfied with their outcomes, but have just grown tired of regular maintenance."

In Dr. Rivlin's opinion, there is a significant future for ThermiRase over the entire face. "I envision the use of this technology for permanent, minimally invasive brow lifting, which I know people are trying because it's an obvious use of this device. We have much studying to do before anybody is unveiling protocols in literature, nevertheless there's no reason why it can't work. Once somebody figures out where to ablate, they can simply apply the same principles to make it permanent." Moreover, one might try applications with nerve ablation that wouldn't be as feasible with injectable neurotoxin, he added. "There are a number of treatments we could try if we used enough neurotoxin, but for one it would be cost prohibitive to attain the desired effect. Also, the current lack of concern about neurotoxicity in aesthetic uses is partially based on the fact that we aren't using much toxin at one time. This isn't a concern whatsoever with ThermiRase."

Diane Duncan, M.D., a plastic surgeon in Ft. Collins, Colo. who has authored educational text on temperature controlled subdermal RF and studied the technology ex vivo as well, anticipates future facial applications. "We've been experimenting with protocols for marionette lines and baggy lower eyelids so we've really only begun to fully explore the possibilities with this technology. Also, ThermiRF appeals to men because of the permanent nature of the outcomes. Compared to women, men don't grasp the paradigm of regular maintenance for aesthetic purposes as easily."

Tissue tightening with ThermiRF thermistor controlled subdermal skin tightening, or ThermiTight, causes contraction of the fibrous septal network rather than targeting the skin. The target is the fatty layer, but little fat is removed, explained Dr. Duncan. "In my research over the last few years I've seen subcutaneous delivery of RF create tightening of up to 25%. Much more than that and we have undesirable buckling and irregularity because the skin can only tolerate so much contraction, so this technology is certainly capable of giving us therapeutic outcomes," she reported. "ThermiTight allows us to permanently change the character of pendulous tissue, within reason, which is the effect people are looking for when they want to erase their 'muffin top,' for example. We don't see this effect with other, similar therapies."



Before Tx



Ten days after Thermi RF Tx Photos courtesy of Daniel Rivlin, M.D.



ThermiRF system with infrared visualization (FLIR)



Before Tx



After Tx Photos courtesy of Diane Duncan, M.D.



100 gram tissue specimen injected with 100 cc tumescent fluid after SAL only. Grid pattern shows approximately 9 mm distance between grid points.



Same specimen after ThermiRF Tx. Distance between grid points is 5 mm.
Photos courtesy of Diane Duncan, M.D.

Since it does not approach the problem of tightening from the skin's surface downward, ThermiRF can be used on almost any body location, especially areas too sensitive for treatment with lasers. "We can use it on the neck, knee, upper arm, abdomen, back bra fat area and other regions," Dr. Duncan shared.

Dr. Duncan has studied various modalities for tissue tightening ex vivo using donated abdominoplasty tissue. "Since this excess tissue is viable for about 12 hours after removal, it is ideal for study," she explained. "We took 100 g sections of skin and fat and tattooed them with a grid pattern of 10 mm squares. After introducing 100 cc of tumescent solution, 17 cc of lipoaspirate was drawn from each segment (suction-assisted liposuction, or SAL)." Next, some segments were additionally treated with either Smartlipo from Cynosure, Inc. (Westford, Mass.), Cellulaze (Cynosure), FaceTite from InMode (Richmond Hill, Ontario, Canada), or ThermiRF. "With SAL alone or Smartlipo we saw 10% reduction in surface area, or 9 mm intervals (versus original 10 mm). With Cellulaze we saw 8 mm intervals, 7.5 mm intervals with FaceTite, and intervals of 4 mm to 6 mm with ThermiRF."

Dr. Key investigated off-label tightening of tissue with temperature controlled subdermal RF in a study of 47 subjects, including 16 for the submental neck and jowl, and 24 for the submental neck area only. The results were presented at the American Society for Laser Medicine and Surgery April 2013 conference in Boston, Mass. "Most technologies designated for skin or tissue tightening approach the problem from the outside inward with transdermal delivery of energy, be it ultrasound, RF, or the wide-range of laser wavelengths," explained Dr. Key. "Our goal was to demonstrate the safety and efficacy of subdermal tightening with this technology and perhaps change the way we look at this indication."

In his study, Dr. Key stipulated that safe and effective subdermal tightening, depends on bringing together several important concepts: 1. the small size and blunt tip of any invasive probe to minimize trauma; 2. controlled, tight confinement of delivered energy; 3. automatic internal tissue temperature sensing with computer-controlled automatic shut-off to ensure the maximum delivery of energy at safe levels; and 4. adequate external skin temperature monitoring, which allows users to visualize energy delivery and temperature elevation. This is exactly what ThermiRF is capable of. "With this technology we have an 18 gauge blunt-tipped probe cannula with thermistor temperature feedback, tight energy confinement at 50° C via the isotherm limited to a radius of 2 to 3 mm, and external visualization through infrared monitoring," he said. "This helps us maximize both safety and delivery of therapeutic energy."

Before treatment, patients in the trial underwent tumescence with 0.125% lidocaine plus epinephrine dilution of 1:800,000 (preheated to 37° C). "Not much tumescent solution was introduced," noted Dr. Key. "I call this 'thin tumescence.' In this case minimal tumescence is desirable because not much is needed for the anesthetic effect, and we want to minimize the addition of fluid because whatever we introduce must also be heated during treatment." Energy delivery temperature was set between 50° C and 60° C with automatic cut off (averaging 56.4° C during treatment). The skin surface temperature endpoint was set

at 41° C to 45° C, measured by the high pixel count thermal imaging camera. "It is important to note that measurements using a handheld monitor under-read temperature peaks by an average of 4° C, so the likelihood of skin injury would have been greater if we relied on them only." When needed, fat aspiration was syringe-assisted using 14 gauge and 16 gauge Klein finesse microcannulas.

The result was visible tissue tightening. "What's remarkable here is that in 21 cases we aspirated less than 1 cc of fat, with 14 of those patients having no fat aspirated," Dr. Key reported. "This demonstrates that we don't need to focus so much on fat removal, but on the energy delivery, for tightening. This is not to say nobody needs fat removed, but rather that we may have been looking at the issue of tightening from the wrong perspective for a long time, especially considering that we must be careful in removing facial volume when lipoatrophy is part of the etiology of the aging face. This device allows us to deliver treatment safely and consistently, and since it is predictable and measurable, subdermal RF distribution will be easy to study as we move forward with exploring the utility of this technology."

Of the 47 patients in the investigation, 43 indicated they would repeat the procedure or recommend it to a friend. "We saw a single incident of focal surface vesiculation that was the result of an unintended temperature peak measured at 49° C. Simply put, the default was set to 60° C and the skin surface temperature rose too quickly so we saw a local vesicant response, which resolved fully," said Dr. Key. "In this case we feel we should have used a lower temperature default, so I now recommend subsurface default temperatures be set at 50° C or lower to start, and perhaps even less for thinner-skinned areas.

Another application under study is axillary hyperhidrosis. "ThermiRF's ability to cause and measure tissue temperature elevation for a disruptive thermal effect means that it may be applied for the therapeutic disruption of overactive sweat glands," said Dr. Kinney, "which is a very promising avenue of study because treatment would likely create a permanent result."

Overall, the future of ThermiRF technology lies in its reliance on objective measurement of therapy and results, as much as the associated safety and efficacy, Dr. Kinney advised. "As we continue to study and use this technology we are developing a catalogue of protocols that, because of the empirical nature of the data, can be repeated with predictable results. This means we can safely study ThermiRF for various applications with confidence in the results, if studies are correctly designed."

References:

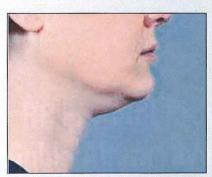
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Before Tx



Four months after ThermiTight Tx Photos courtesy of Douglas Key, M.D.



Before Tx



Seven weeks after ThermiTight Tx Photos courtesy of Dauglas Key, M.D.