

# New Exilis Elite Delivers Advanced RF

## Science for Better Body Shaping and Skin Tightening Outcomes

By Bob Kronemyer, Associate Editor

In March 2013, BTL Industries Inc. (Boston, Mass.) will unveil its highly anticipated second-generation monopolar radiofrequency (RF) device at the annual meeting of the *American Academy of Dermatology*. For patients seeking safe and effective body shaping and skin tightening, the cost-to-benefit ratio of the new Exilis Elite™ is even more appealing than the original Exilis. Besides a much more powerful applicator, Elite's advanced cooling allows for layering of RF energy at various depths. There is also uniform heating of the targeted tissue, and smarter electronics avoid arcing and sparking. The Exilis Elite's ability to achieve the same or better results in fewer treatment sessions is another big advantage for patients.

A new 90 Watt facial tightening applicator provides nearly twice the power of the previous 50 Watt handpiece, and is safer. "You would think this would be very difficult and near impossible to

accomplish," said Robert Weiss, M.D., an associate professor of dermatology at Johns Hopkins University School of Medicine. "However, the BTL engineers figured out a way to extract more energy from the unit in a much safer way because of newly designed 'smart' self-monitoring circuitry."

Specifically, the devices real-time Impedance Intelligence™ is a breakthrough in hardware / software communication between changes in the skin



**Robert Weiss, M.D.**  
Associate Professor of Dermatology  
Johns Hopkins University School of  
Medicine  
Director  
Maryland Laser, Skin and Vein Institute  
Hunt Valley, MD

and the delivery of thermal energy. Dr. Weiss, who is also the director of the Maryland Laser, Skin and Vein Institute in Hunt Valley, Md., explained; "This is

basically a feedback loop to measure and match the resistance or impedance of the area being treated. Local skin impedance is measured at an astonishing 1,000 times per second. "If you are treating over a cheek fat pad versus over the mandible, for instance, the impedance varies greatly. So Impedance Intelligence can respond virtually instantaneously and adjust the current appropriately," he added.

According to Dr. Weiss, the most important feature of the Elite handpiece – contributing greatly to its superior safety profile – is its ability to immediately stop the delivery of energy once the handpiece loses contact with the skin. "Unlike ordinary systems that may potentially create sparking or arcing that can lead to discomfort or even a skin burn, constant monitoring prevents this from occurring," he said. "In fact, we have tested this handpiece on dozens of people, starting with staff and myself, in an effort to 'jump the gap' between the tip and the skin. We could not do it, even though we tried it on about ten different locations: over the forehead, the cheek, the chin and the neck. This was while the device was operating at maximum power. There was complete safety, with no chance of any arc or any spark occurring. This is a tremendous leap in technology compared to other RF devices where the possibility of bridging the gap exists."

Impedance Intelligence also allows for subtle adjustments in energy; for example, from the cheek to the chin to the neck. "The output is automatically adjusted, so there is no sudden surge



Exilis Elite handpiece

in RF," Dr. Weiss conveyed. "This adds an additional level of safety and confidence that a patient will receive optimal RF heating of the skin."

Another upgrade to Elite is an illuminated tip that complements the auditory signal of the older model. "A continuous blue glow indicates that you are positioned properly and delivering desired heat to the entire dermis," Dr. Weiss said. "If the light starts to blink, contact with the skin is not adequate and high impedance is being detected. The illuminated tip ensures a greater level of consistent thermal delivery and patient safety."

While the response rate for the first-generation Exilis was roughly 80% to 85%, Elite should achieve a 95% response rate, Dr. Weiss reported. Elite's additional power also allows for fewer treatment sessions to tighten and lift the mid-lower face and neck. "In the past, it may have taken several minutes to reach the desired temperature of approximately 42° C to 44° C, but due to the higher energy, we can achieve that level much more quickly now – literally in seconds." Treatments are also more effective, reportedly due to acceleration of temperature and the ease of maintaining that temperature for four to six minutes, or even longer.

As a result, three to five monthly treatments have been reduced to just two sessions, spaced as little as two weeks apart, each lasting about 40 minutes. The lack of consumables (other than an inexpensive disposable grounding pad) also benefits both the patient and clinician. "When there is a costly consumable involved, we have to maintain inventory and pass that cost onto the

patient," Dr. Weiss noted. "We now have much more flexibility. We don't have to plan the treatment ahead. We can even do it on the spur of the moment. This is in contrast to some other devices that require you to stock different size tips, which becomes much more of a logistical problem."

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"Because of the elimination of any hot spots, due to the advanced circuitry, treatment is actually even more tolerable. It feels like a warm comfortable massage, and most of our patients really look forward to treatment."

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Experts feel that this lack of consumables with the Elite allows a practice to become more profitable as well. "Often, much of the profit for these types of procedures is eaten up by the consumable," said Dr. Weiss, who for competing monopolar RF technologies charges up to \$2,000 per treatment



Before Tx



After four Exilis treatments  
Photos courtesy of Josie Tenore, M.D.

session, compared to \$750 to \$900 for a single Elite session.

It is important to note that patients are drawn to Elite not only because of the attractive price, but the lack of pain. "You would think with the increased power of Elite, the more rapid heating and achieving the endpoint more quickly, treatment would be more painful," Dr. Weiss stated. "However, because of the elimination of any hot spots, due to the advanced circuitry, treatment is actually even more tolerable. It feels like a warm comfortable massage, and most of our patients really look forward to treatment."



Before Tx



After two Exilis treatments

Photos courtesy of Alan Liftin, M.D.

David McDaniel, M.D., F.A.A.D., director of the McDaniel Institute of Anti-Aging Research in Virginia Beach, Va., has helped develop a new Elite protocol for tightening the mid / lower face and neck. He calls it "The 6/4, 6/4 method," which is shorthand for minutes: six minutes above the jawline, followed by four minutes below the jawline, then immediately repeating the two time intervals again on the same side of the face. "The most common request at our institute is for mid / lower face and upper neck treatments," Dr. McDaniel said. This 20 minute procedure allows for some thermal relaxation cooling time for better patient tolerance. "With

this method a patient receives two gentler injuries as opposed to one painful injury," he noted. Energy settings are basically the same throughout.

In Dr. McDaniel's opinion, treating the mid / lower face and neck is popular because both women and men "feel those areas make them look tired or older." In addition, sagging along the jawline and neck occurs in many people who lose mid-face and central cheek fat volume. "So even if you have been careful with the sun, you often end



**David McDaniel, M.D., F.A.A.D.**  
Assistant Professor of Clinical Dermatology  
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up with age-related fat volume loss in your face," he shared. "I explain it to patients as: you have the same amount of fabric in your skin, but if it is not being stretched up and filled with volume, that fabric redrapes. Gravity pulls down and results in a sagging jawline and somewhat of a turkey neck."

Dr. McDaniel, who is also an assistant professor of clinical dermatology at Eastern Virginia Medical School in Norfolk, Va., has also developed a new protocol for strictly tightening the neck: "The 4/4, 4/4 method." Again, this refers to four minutes on one side of the neck, followed by four minutes on the other side of the neck, then repeating once. "Like with the face / neck protocol, you are trying to create a more tolerable temperature between 42° C and 44° C," Dr. McDaniel

reiterated. "It is the cumulative effect of two tolerable injuries versus one less tolerable injury."

Owing to Elite's 90 Watt applicator, Dr. McDaniel has been able to reduce the number of sessions for each of his two protocols from four (spaced one month apart) with the first-generation Exilis to typically two (about one month apart). "So far, the results have been very good," he advised. "We have used a number of different RF skin tightening devices over the years. In our hands, at least to date, Elite has been the most consistent, with the best results. Patients achieve a natural-looking lift and tightening."

As with Dr. Weiss, Dr. McDaniel is also impressed with the Impedance Intelligence feature. "We believe this not only seems to provide greater safety, but more uniform energy distribution," he said. "One of the problems with the in-motion techniques on most systems is that when you go over body areas – the mandible, the jawline or forehead – you have higher impedance and are more likely to burn something." Conversely, soft tissue "is more likely to be undertreated." Overall, Impedance Intelligence, "allows you to deliver optimal controlled energy or injury, so you eliminate the hot spots and spots that are undertreated," he continued. "By doing so, you achieve the uniformity not possible with other RF devices. It is not just a safety feature, but an efficacy feature as well."

Furthermore, the lack of expensive consumables with Elite "allow us to offer the treatment at an affordable

level for a lot more patients in a bad economy," Dr. McDaniel said. "It has also made Elite much more popular, simply because we don't have to pass those consumable costs onto the patients." Compared to competing technologies, the total cost for a package of treatments is significantly less at Dr. McDaniel's practice.

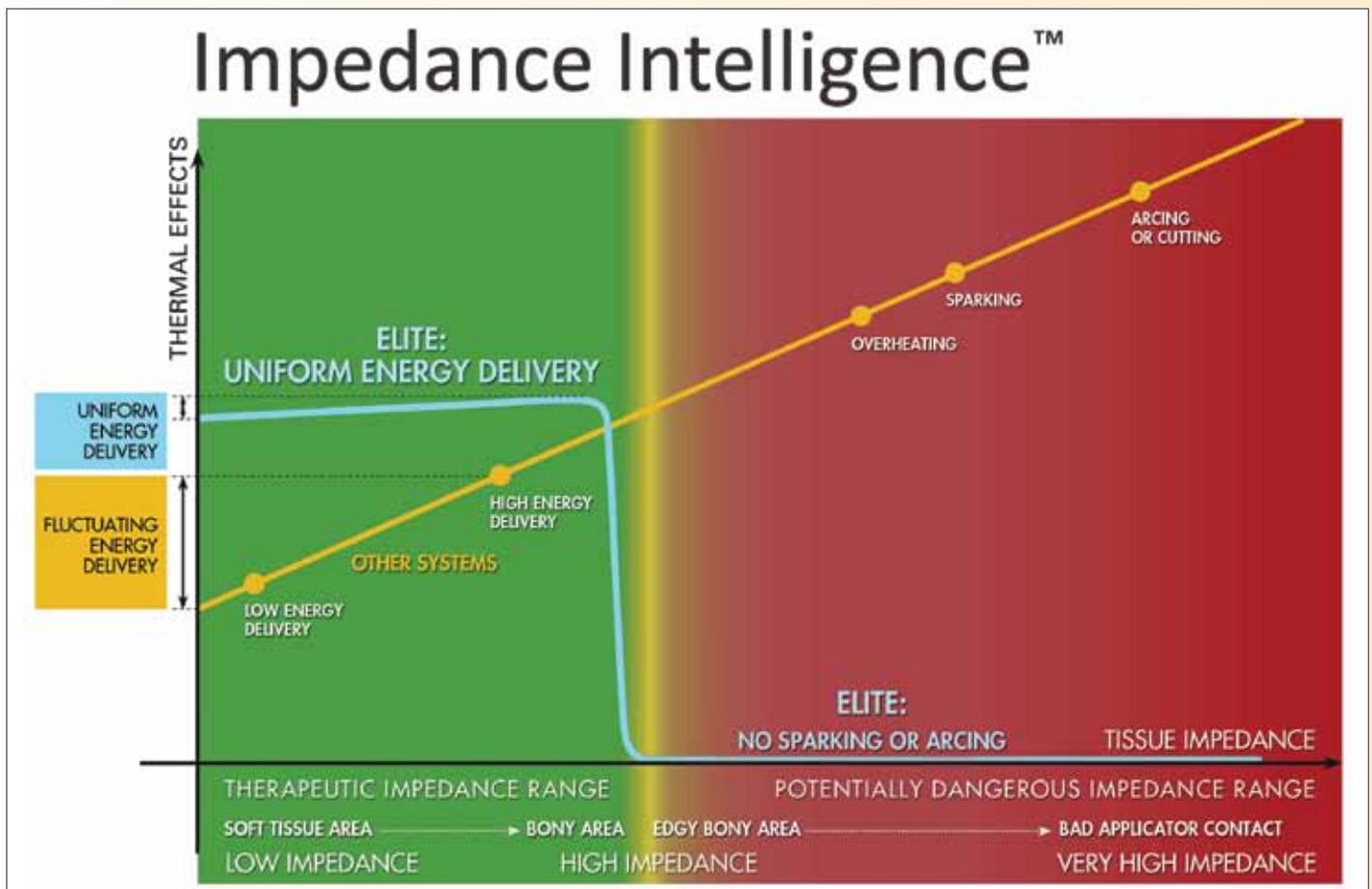
According to Dr. McDaniel, the new Elite applicator has the power and safety profile to potentially become a new standard for tightening. "It is also easy to use," he noted. Besides an illuminated tip, the system has a

user-friendly interface and is ergonomically designed to reduce operator fatigue. "It is more comfortable for the staff to use than other devices."

"In short, the Elite separates itself from other RF devices with its ease of use, safety, reduced patient discomfort and a very uniform energy deposition," said Dr. McDaniel, who is part of an ongoing multisite study of Exilis Elite to demonstrate the efficacy of new treatment protocols and the handpiece, by using primarily pathology and high-resolution ultrasound imaging.

Dr. McDaniel also appreciates the high level of training and support from BTL. "The company's trainers are extremely knowledgeable, which is important" he stated. "Honestly, it is not just the equipment alone that makes for safe and effective treatment."

For Marek Kacki, M.D., medical director of Visage MedArt in Nashville, Tenn., Exilis is the most effective non-invasive fat-removal device he's encountered. "Exilis delivers visible results, with no downtime and no side effects, in a truly predictable fashion," he stated. "You can really tailor the delivery



Impedance Intelligence provides more uniform energy distribution for increased safety. Source: BTL

of the RF energy and fat reduction in every single patient and every area." The most popular areas of the body that Dr. Kacki treats with Exilis are the abdomen and flanks, thighs, buttocks, lower face and the neck.

Dr. Kacki pointed out that the Advanced Peltier Cooling allows for much deeper penetration, without damaging the epidermis. In my opinion, BTL invested in a very wonderful



Marek Kacki, M.D.  
Medical Director  
Visage MedArt  
Nashville, TN

and simple application of cooling. By manipulating the cooling system, you can predictably sculpt the body."

Over the past six months, Dr. Kacki has been able to confirm BTL's animal

study findings about the effectiveness of Exilis by documenting 14 patients for *in vivo* temperature monitoring at various depths, using his triple energy-layering protocol for optimal outcomes. Treatment begins with cooling delivered at 10° C, which allows adipose tissue to reach peak temperatures up to 3 cm deep, followed by 20° C cooling with maximum temperature recorded between 1.6 cm and 1.8 cm deep, and then concluding at 30° C at a depth of roughly 0.7 cm to 1.6 cm. Patients normally schedule four sessions, spaced one week apart.

To date, Dr. Kacki has treated approximately 70 patients with his new protocol. "There have been zero side effects," he said. Since Dr. Kacki is able to achieve much higher temperatures – up to 47° C – an abdomen can now be treated in less than 15 minutes. "I myself have been able to tolerate only 43° C."

Compared to competitive technologies such as cryolipolysis, focused ultrasound or other RF modalities, Dr. Kacki believes Exilis is superior. "Exilis absolutely fits the mechanics and dynamics of clinical apoptosis, yet to prove this cellular documentation is required," he pointed out. "No one has such documentation from *in vivo* human studies. These claims are based on very reasonable assumptions and indirect conclusions, and it is quite possible that apoptosis indeed is occurring. So far, though, the quoted references are limited to *in vivo* studies on porcine models, and *in vitro* studies using animal adipose cells."

As an example, Dr. Kacki singled out one company whose physicians' website features six studies. "If you review those studies, not one of them was conducted on a live human being," he said. "In fact, all six quoted references either suggest that apoptosis may be

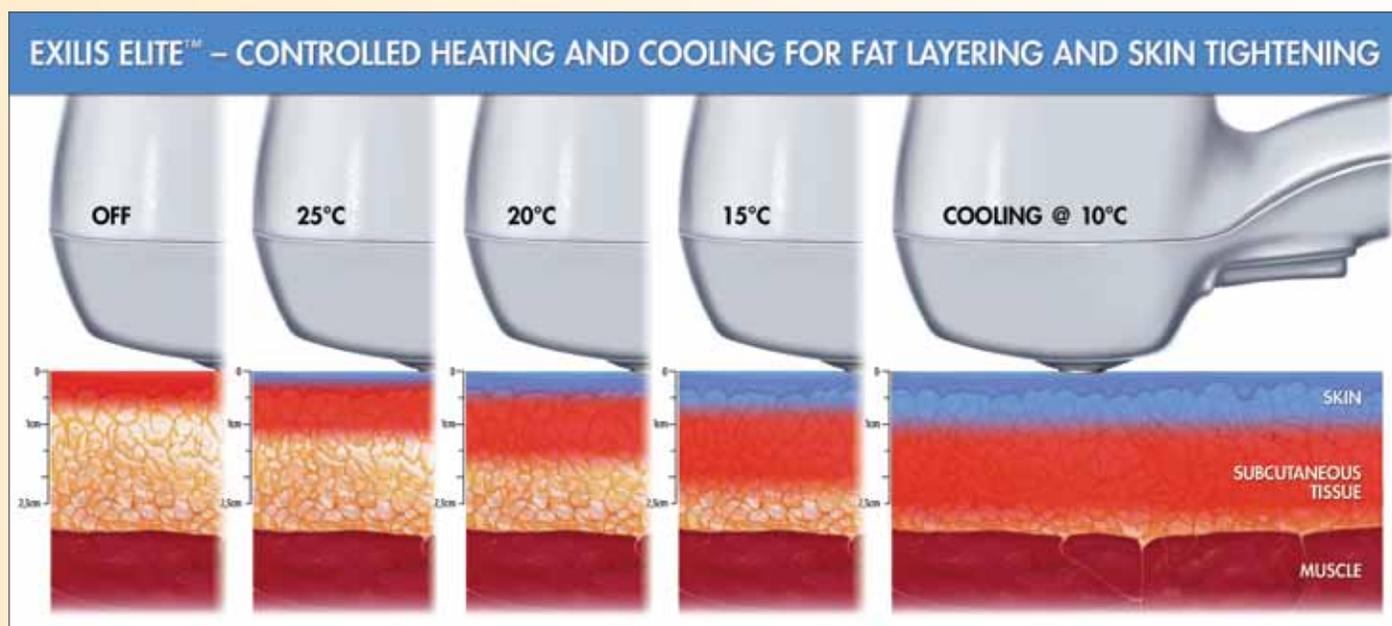


Image courtesy of BTL

the mechanism for a response or refer to these suggestions."

In Dr. Kacki's opinion, what counts are the results. "Either you have visible results or you don't," he said. "Yes, it is much more elegant to have apoptosis because it is very gentle and a more 'physiological' cell death pattern occurs over time, with a progressive decline in the fat layer. However, if you take another, more extreme method of killing cells by applying more intense heat and inducing cell necrosis (as with Exilis), the treatment works much faster." Dr. Kacki also stresses that even the most intense application of Exilis treatment is not nearly as aggressive as liposuction, "which still remains the gold standard."

Today, Dr. Kacki feels he can virtually guarantee patients that they will attain significant, visible reductions of fat, very predictably, with Exilis. "My goal is to achieve excellent results in fewer than four treatments," he said. Moreover, "if you can make treatment comfortable for the patient, there is practically no limit as to what you can accomplish within a matter of just one or two minutes of exposure to high temperatures."

Notably, Dr. Kacki has even had success using Exilis to treat his daughter's small knee lipoma in just two sessions. "Monopolar RF is the only way to reach certain depths non-invasively," he said. "With bi-polar, you are limited for technical reasons." Furthermore, "to date, I have not seen one published photographic documentation of any non-invasive fat reduction method that renders results even minimally better than Exilis," Dr. Kacki maintained.

Exilis continues to be a valuable device for Patricia Wexler, M.D., a cosmetic dermatologist in private practice in Manhattan. Since acquiring the system over two years ago, "we use it to perform significant body shaping and tightening. We are able to diminish fat



Patricia Wexler, M.D.  
Cosmetic Dermatologist  
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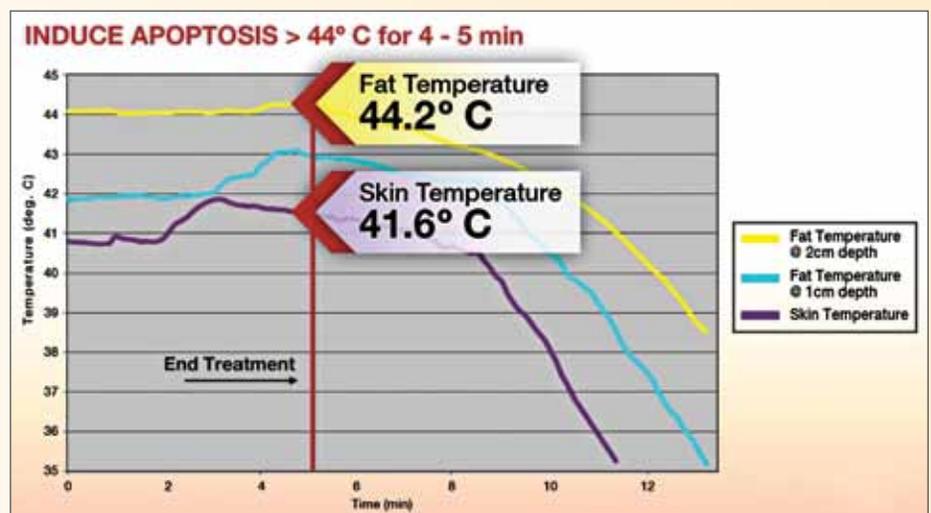
in various areas on the body and tighten the skin over it, so we use Exilis on multiple levels." Dr. Wexler also uses the device on the face, specifically the lower-third of the face, "to change texture and tone."

Exilis allows Dr. Wexler to keep up with the demands and requests of patients, foremost non-invasive body contouring. "These are patients who have small areas that they want contoured

or patients that have loose skin without necessarily the need for shaping," she said. "So treatment can consist of shaping and tightening of the skin together, or just one or the other alone." Presently, Dr. Wexler receives more requests for body than facial treatment.

"There is no doubt that patients are seeking non-invasive alternatives to face-lifts and liposuction," Dr. Wexler observed. "I think patients have the fear that invasive procedures are permanent and that those results might not please them." The cost, pain and anesthesia (safety) associated with permanent procedures also concern patients.

Since Exilis contours the body, creating a thinner fat layer and placing heat directly into the dermis for a tightening effect, Dr. Wexler has been able to abandon numerous competing non-invasive body shaping and tightening devices that are limited to just providing one or the other. "Although I have tried different technologies, I found Exilis to be significantly more versatile and more



Exilis Porcine Study  
Source: BTL



Abdomen before Tx



Abdomen after four Treatments

Photos courtesy of Marek Kacki, M.D.

effective," she said. "Some of these systems are limited to very small areas of the body, whereas you can use Exilis on virtually any area of the body. In addition, other systems require a certain dimension of fat to treat small areas." Competing technologies may also "have a pain factor that is too difficult for the patient to tolerate," Dr. Wexler said. In essence, she believes Exilis is the safest technology, providing consistent results and the widest range of applications.

As with other practitioners who use the 90 Watt Elite skin tightening applicator, Dr. Wexler is able to attain measurable results in as few as two sessions compared to five sessions. "Four or five treatments are very difficult for patients to consistently keep,

especially if they are in high-powered positions or have busy lives," she explained. "Two treatments are much more manageable. Patients are also very excited to achieve visible results within two applications." A typical session lasts one hour, normally spaced 10 to 14 days apart. Having fewer sessions also allows overall treatment to be less expensive for the patient. "It is better for us, too, because we don't have to schedule as many sessions, so we can treat more patients," Dr. Wexler said.

Dr. Wexler also noted that some of her patients find the handpiece to be less painful. Compared to other tightening devices, treatment is less uncomfortable because "we don't have to give any medication." A higher safety profile, due to better contact, is reassuring as well.

"You can treat the full face, neck, décolleté, arms, bra fat, the back, 'love handles,' the upper and lower abdomen and the thighs," Dr. Wexler conveyed. "Exilis is also an anti-aging device because you are changing the texture of the skin." Additionally, treatment can be performed in conjunction with previous liposuction, ultrasound procedures or facial dermal fillers.



Marc Salzman, M.D.  
Plastic Surgeon  
Louisville, KY

At the core of BTL's advanced RF science is a totally revamped Energy Flow Control (EFC) System. "This starts with a double ground pad that helps measure

the impedance of fat and adjusts the current," said Marc Salzman, M.D., a plastic surgeon in private practice in Louisville, Ky. "Based on that resistance, the level of RF is kept constant. Therefore, treatment is safer and has more consistent energy levels, which is going to lead to more consistent results." Plus, Exilis' exclusive grounding pad consists of two grounding electrodes for measuring a loop multi-directionally; hence, enhanced patient safety, which prevents arcing.

Dr. Salzman uses Exilis' smaller applicator to mostly tighten facial and neck skin because there is no cooling, "so you are just heating skin." The smaller handpiece also does not have a temperature measurement, "so we use an external temperature measurement that increases according to patient tolerance, which is typically 41° C at the skin level," he said. The larger handpiece is sometimes used on the neck, but primarily on the body and trunk. It also features the Advanced Peltier Cooling plate, "for adjusting the temperature gap between what the skin can tolerate and where you want the energy – 2 to 2.5 cm down – to heat the fat," Dr. Salzman advised. "Ideally, you would like to heat the fat to the high 40's C, but no one can tolerate that temperature on the skin. The cooling plate allows you to keep the skin at 41° C to 43° C, while the fat can be heated to 44° to 46° C for apoptosis."

Both the large and small handpiece may be used on the neck. "If we are trying to melt fat on the neck, we may use the big applicator first, with cooling, then let some heat radiate before using the smaller applicator just on the skin," Dr. Salzman explained.

It takes Dr. Salzman about 45 minutes to treat larger surface areas, such as an entire belly. For body shaping, he usually schedules four to six sessions, 10 to 12 days apart.

If he did not offer a truly non-invasive approach to tightening and fat reduction, as with Exilis, Dr. Salzman strongly believes he would lose patients. "Patients appreciate having an alternative to a tummy tuck or an arm lift or a face-lift," he said. "Exilis is also a great option for some maintenance of incisional-type therapy to maintain skin tone." Exilis has also allowed Dr. Salzman to attract a younger clientele, such as postpartum patients not yet ready for a tummy tuck.

For patients scheduling a face-lift, Dr. Salzman starts them on Exilis to precondition the skin four months in advance. "We are able to increase that tension in the skin," he noted. "Post-operatively, I think Exilis is great maintenance against the inevitable relaxation that a patient will get during the first year."

As for the competition, in Dr. Salzman's experience, limiting factors of cryolipolysis include a high disposable cost and "is only useful in areas where the fat will fit into predetermined sizes, so there is no way to really feather around," he said. "You are simply taking a lump of fat, freezing it and ending up with a 20% reduction. Also, the apoptosis rate for cryolipolysis is three months versus a reduction in nine to ten days with Exilis. Thus treatment is much faster when you heat fat as opposed to cooling it."

Likewise, cryolipolysis does not tighten skin. "If you are dealing with

skin flaccidity over a lipodystrophic area, you are much better off treating all the layers with heat and creating some injury to the dermis and fat, and getting the skin to compensatorily tighten and take up the slack where the fat was," Dr. Salzman commented. On the other hand, reportedly, one problem with focused ultrasound can be associated pain.

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Dr. Salzman also explained how the physics of electricity dictate the limitations of competing multipolar devices. "The energy is only going to



Before Tx



After four Exilis treatments  
Photos courtesy of Dr. Tang

reach half the distance of the width of the poles (the positive and negative electrode). So if you are trying to reach fat that is 2 cm to 2.5 cm deep, you would need a device that has a 5 cm distance between the poles. Currently, there is no device like that available. It would take too much energy. Monopolar is a more versatile modality because you can treat both deep and superficial."

Finally, Exilis fulfills Dr. Salzman's three Ts to shaping and tightening: time, temperature and tolerability. Time – delivering sustained RF energy for four to six minutes; temperature – high enough to achieve a result; and tolerability for the patient. ■