

Studies Confirm Exilis Elite's Advantages for Tightening and Shaping



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New Exilis Elite 90 W Applicator with self-monitoring Impedance Intelligence and zero-arc circuitry.

Image courtesy of BTL Industries

By Jeffrey Frentzen, Executive Editor

Of the numerous devices that use radiofrequency (RF)-based energy to non-invasively treat wrinkles, skin laxity and body shaping the Exilis Elite from BTL Industries, Inc. (Framingham, Mass.) stands apart from the pack, utilizing monopolar, focused RF with advanced cooling, which allows for a layering of the energy at different depths. In addition, this device features an effective new treatment protocol resulting in more even distribution of energy over the treatment area.

Notably, the Exilis Elite has been engineered with greater power and includes a delivery system with self-monitoring circuitry to track local skin impedance changes in real time, combined with uniform heating of targeted tissue and smarter technology to avoid arcing. These advancements ensure safe, effective body shaping and skin tightening procedures with scientifically proven results in as few as two sessions. Two recent clinical studies support these claims, yielding impressive results.

One of the studies focused on a new 90 Watt (W) facial tightening applicator¹ that provides nearly twice the power of the earlier 50 W handpiece with improved safety. "The study's conclusion, which was based on blinded grading of images, was a 35% reduction in skin laxity and a 42% reduction in wrinkles," stated Robert Weiss, M.D., an associate professor of dermatology at Johns Hopkins University School of Medicine (Hunt Valley, Md.), and one of the study's co-authors. "The study also showed that the Exilis Elite demonstrated a 33% reduction in the appearance of global photodamage."

Of the study participants, 24 female subjects with an average age of 57 received treatment to the mid-lower face and submentum. Four subjects were selected to receive pretreatment and three-month post treatment skin biopsies taken from the submentum for histological examination. A subset of 12 subjects underwent ultrasound imaging during pretreatment as well as at one and three months post treatment.

Blinded expert graders revealed 79% of subjects had mild improvement in each of the three categories measured (fine lines/wrinkles, skin laxity and overall skin texture). For skin laxity, 92% of subjects showed a minimum of mild improvement at the three-month time point. Ultrasound images from the 50 MHz detector revealed an average of 19% increase in skin density at three months and a statistically significant linear increase in density over the course of the study. Additionally, in two of the four subjects histologic examination of the biopsies showed significant increase in dermal collagen and elastin fibers throughout the dermis.

"The goal of the study was to, number one, validate the fact that this device actually works not just clinically, but histologically; to do biopsies; and to see new collagen and new elastin, which we did observe," Dr. Weiss advised. "We also were trying to see if we could achieve that in two treatments instead of four, and we were able to demonstrate that, as well."

Researchers adopted a protocol that kept the skin temperature at very tolerable ranges. "We don't want the skin temperature to reach above 45° C, because then patients feel it as a painful burning sensation," explained Dr. Weiss. "Up to that

temperature it just feels like a nice, warm massage. We wanted to maintain this for 20 minutes per side. The very tolerable skin temperature was up to just 43°, we tried not to aim any higher than that.”

Histologies confirmed that Exilis Elite’s sustained heating causes full thickness collagen remodeling. “We also saw major elastin production, which is what you essentially need,” Dr. Weiss added. “You need both to see textural improvements in skin tightening. The other important thing about the study was that the average patient age was 57. It was very significant to achieve changes and such good results in that age group because people tend to think, ‘Oh, 50s is too late.’ Some devices study just younger people. We took on the challenge. We were able to achieve these results without inducing pain and without going above 45° C.”

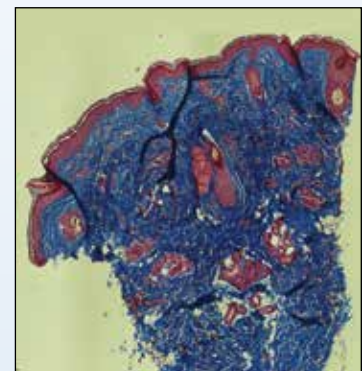
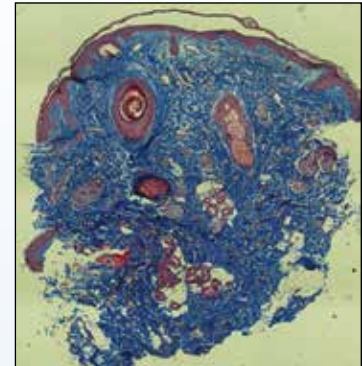
In the end, the studies have indicated that the Exilis Elite in its current configuration pushes the evolution of RF-based procedures. “People want non-surgical treatments now more than ever,” expressed David H. McDaniel, M.D., a dermatologist in Virginia Beach, Va., and co-author of both studies. “One problem has been a lot of these non-surgical devices and treatments showed little or no response, therefore we had a lot of unhappy, disappointed people. There’s a lot more consistency now with the Exilis than we’ve seen with some of the technologies a few years ago. In switching from a researcher to what I do every day in my cosmetic practice, this is a significant piece of my menu of options. It’s meeting the unmet needs without surgery, and that is pretty big.”

A second related study² demonstrated the effects of monopolar, focused RF with embedded cooling on subcutaneous skin structures, in order to prove that it can selectively heat fat, causing the disintegration of adipocytes and apoptosis of the subcutaneous fat cells. The authors concluded that the Exilis Elite could also be used for reduction of fat and body shaping.

In this study, the device was used to reduce abdominal fat in a porcine model with treatments administered four times with a week interval between applications. The initial output setting was 95 W with applicator tip cooling set at 10° C. The desired skin temperature was 42.5° C. Minimum exposure temperature level was 39° C and maximum exposure temperature level was 43° C.

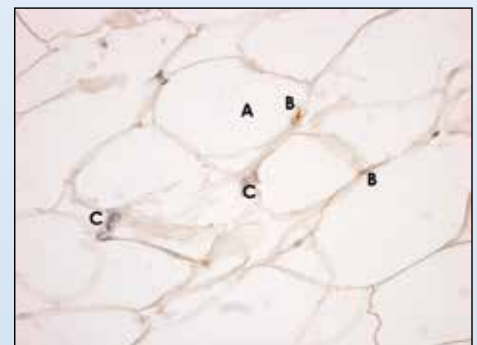
Surface temperature was measured continuously using the Exilis Elite’s cooling system and impedance intelligence, which adjusted the output power according to the temperature measurement. In addition, the internal tissue temperature was periodically measured by a thermal probe during the procedure. Anesthesia was administered during each session and during biopsy. Blood samples, as well as tissue samples for the TUNEL method were taken before the first treatment, after each application, and after the three-month follow-up period. Autopsy and histological samples of skin, liver, kidney and lungs were taken at the end of the recovery phase.

Following treatment, the treated adipose tissue temperature was higher compared to the skin surface. The temperature gradient allowed the surface to remain intact, while subcutaneous layers showed substantial changes. Additionally, the apoptotic index increased from 7% before the first treatment to an average



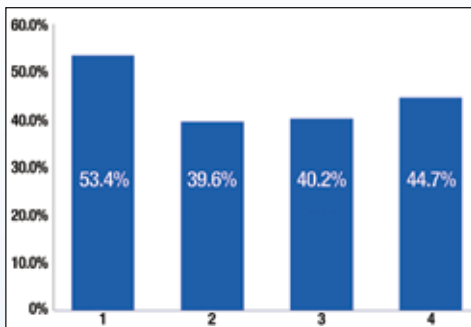
Histology demonstrates before Tx (top) and increased collagen (blue) and density three months after two Exilis Elite treatments with the 90 W applicator (bottom).

Photos courtesy of David McDaniel, M.D., Robert Weiss, M.D., Margaret Weiss, M.D., Chris Mazur, B.S., and Charmaine Griffin, C.C.R.P.



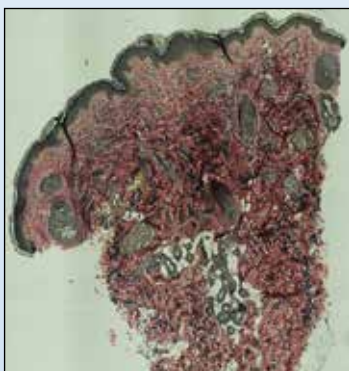
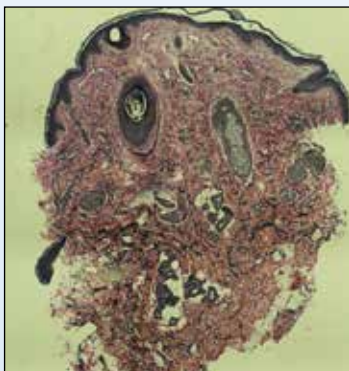
Adipocyte (A) apoptotic nucleus is stained brown (B) and other nuclei are blue (C). The TUNEL method indicates apoptotic cells through color change of nucleus in the histology sample. The cells with a brown nucleus indicate apoptosis while cells with a blue nucleus indicate viable cells.

Image courtesy of David McDaniel, M.D., Klaus Fritz, M.D., Alena Machovcova, M.D., Ph.D., M.B.A., and Jan Bernady, Ph.D.



Average minimum and maximum apoptotic index two weeks before therapy, during each therapy and at the three month follow-up. Before Tx the apoptotic index average was 7%. The apoptotic index reached average levels of 53.4%, 39.6%, 40.2% and 44.7%, respectively, in four consecutive treatments from tissue samples taken 1, 8 and 20 hours after Tx. At the three month follow-up the average dropped to 11.7%.

Graph courtesy of David McDaniel, M.D., Klaus Fritz, M.D., Alena Machovcova, M.D., Ph.D., M.B.A., and Jan Bernardy, Ph.D.



Histology demonstrates before Tx (top) and increased elastin fibers (black), as well as a more uniform pattern and distribution of fibers three months after two Exilis Elite treatments with the 90 W applicator (bottom).

of 53.4%, 39.6%, 40.2% and 44.7% respectively for each treatment. Histology, blood biochemistry and hematology samples presented minimal to no signs of inflammation in the treated area.

Owing to its adjustable built-in cooling system, its ability to safely and efficiently deliver maximum power and speed of high frequency radio waves using innovative hardware and software safety features, the Exilis Elite is capable of delivering uniform heating at controlled depths to the subcutaneous tissue.

Also, practitioners have the ability to alter the cooling, "so that you can modulate the depth," expressed Dr. McDaniel. With the Exilis Elite's large handpiece, "If you want to treat fat you can make the tip very cold so it doesn't affect the skin at all, yet it penetrates deeply and causes fat to undergo apoptosis. That has been achieved both in animal experiments and, I believe now, in human skin as well. While this requires a little more skill and experience from the staff, overall, it is a pretty simple system to operate and you get nice results. BTL has been very good about providing the training necessary to obtain consistent results."

According to experts, the histologies from the Exilis Elite 90 W facial study were impressive. "We don't get to see biopsies very often on these studies, and you certainly expect to see a correlation with the clinical results and pathology," said Dr. McDaniel. "If you see improvement, you expect to see some new collagen. But what was really interesting was the development of new elastin fibers. Significantly, we had only one subject that did not show a dramatic result, and she happened to be one of the biopsy subjects. Her lack of clinical results was consistent with her biopsy results, as they did not show a lot of new collagen. There was a very high correlation between what we observed in the biopsies and what we saw clinically, which you'd like to have, but you don't always see so strikingly in clinical studies."

Moreover, Dr. McDaniel did not expect to observe such impressive wrinkle reduction. "I was just expecting to see skin tightening, which we did. From a more clinical standpoint, the skin tightening was pretty consistent, the collagen and elastin fibers sort of matched the story, but then we also observed wrinkle reduction. It's nice in science when things all tie together and do what you think they ought to do," he said. "The pathology and clinical results matched and correlated very well, even with the one patient that wasn't as responsive. This is still useful because it demonstrates cause and effect."

Impedance intelligence, which is an automatic self-adjusting system delivering energy based on measured capacitive, inductive and resistive parameters of the skin-applicator borderline, controls or fine tunes the current energy supply while the circuitry automatically compensates for impedance changes. Energy flow is microprocessor controlled, automatically maintaining the power output equivalence even in areas of higher/lower impedance. In this way, practitioners can use high power settings without compromising safety.

These technology improvements can help eliminate the electrocautery-based issue of arcing when contact with the tissue is insufficient. High-speed feedback

circuitry and a double-grounded electrode ensure that as soon as sufficient contact is lost, no energy can be delivered. The energy output adjusts based on whether you're over soft tissue or bone Dr. Weiss noted. "I tried it on myself. I took the tip and applied it on my forehead and cheeks. There is no way that this would ever spark or arc, which other RF devices are prone to," he said.

For Leif Rogers, M.D., F.A.C.S., a plastic surgeon in Beverly Hills, Calif., the skin impedance and cooling technology work well. "With these, you can obtain higher temperature levels in the deeper tissues," he said. "If the skin gets too hot you could cause burns and blisters that may turn into permanent scars. As previously mentioned, to affect the deeper layers, we must reach a temperature that causes some change in the cells and the collagen molecules. The Exilis Elite tries to hit 45° C, at which point you lose some fat, but you also achieve some collagen change. That really is where this device's value lies."

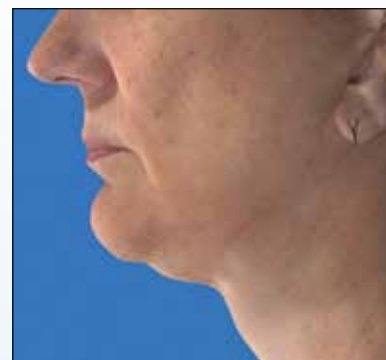
Nonetheless, in some situations, the clinician performs the procedure without cooling. "When you're using the body applicator for skin tightening, you shut off the cooling so that you're just heating the skin and not the fat underneath," Dr. Weiss explained. "We use it around the knees, to tighten up the common areas that people would like to have addressed, and around the elbows, though sometimes we'll use the facial applicator for this area."

With the 90 W applicator the temperature rises very quickly, Dr. Weiss pointed out. "As the skin heats up we turn the wattage down. We can reach the therapeutic temperature within a minute or two, which is a big advance. Unlike some other devices that are used for this purpose, there is no anesthetic required, no consumable costs and no pain meds taken orally. There is a grounding pad that costs about three dollars."

Interestingly, this grounding pad, which is situated underneath the patient during treatment, is a significant component in the safety system, Dr. Weiss stated. "That pad is not just a simple grounding pad. It actually has two different grounding points, and it can measure the impedance or the resistance across the pad. It is an intelligent device that checks itself several hundred times per second. If it detects any spikes or anomalies, it stops transmitting the RF."

With the Exilis Elite, practitioners can start rethinking skin tightening in general, expressed Jeanine B. Downie, M.D., a cosmetic dermatologist in Montclair, N.J. "It's a two treatment protocol for skin laxity using the 90 W applicator. Applying tolerable temperatures over the treatment area, of 42° to 43° C, you get full thickness collagen remodeling, full thickness elastin production and you achieve proven results with a lower temperature," she said.

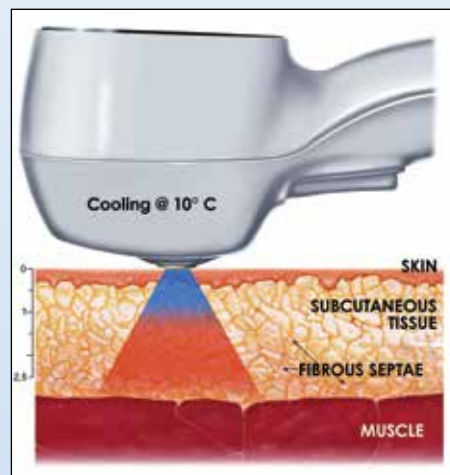
As Dr. Rogers stated, "Compared with other RF-based energy devices, I prefer the Exilis Elite for a number of reasons. First and foremost, the device actually does tighten the skin effectively. Whereas with any of the energy-based devices some patients respond better than others, I've had patients achieve dramatic non-surgical outcomes after Exilis treatments, with very obvious improvements and significant results."



Before Tx



After two Exilis Elite treatments with the 90 W applicator
Photos courtesy of David McDaniel, M.D., Robert Weiss, M.D., Margaret Weiss, M.D., Chris Mazur, B.S., and Charmaine Griffin, C.C.R.P.



Large applicator provides cooling with corresponding depth of heat penetration.
Image courtesy of BTL Industries



Before Tx



After two Exilis Elite treatments with the 90 W applicator
Photos courtesy of David McDaniel, M.D., Robert Weiss, M.D.,
Margaret Weiss, M.D., Chris Mazur, B.S., and Charmaine Griffin, C.C.R.P.

For practitioners, the impressive cost-to-benefit ratio and lack of consumables also constitute a big advantage. "The absence of consumables is a big factor," said Dr. Weiss. "Some other devices may charge several hundred dollars per tip, and it's timed out at two hours, making it a much more expensive treatment. With no consumable expenses, things really open up for our practice. We are able to offer this treatment to many more patients, at a much more reasonable cost."

In both studies the authors clearly state that patient selection is possibly the most important aspect of using this device. "If you try to treat someone that needed a face-lift five years ago and they have tremendous skin laxity, even if the before and after pictures look better, they are still not going to be pleased," noted Dr. McDaniel. "Therefore, this is a really good option for people with early changes, yet it is too soon for a face-lift. It is also an option for people who may need something down the road, but want to defer to a later date."

The trickiest group, according to Dr. McDaniel, "Include those who are too early in life for a face-lift, or they are indicated for face-lifts, but don't have excessive laxity and for various reasons don't want to have surgery. This latter group probably has a little bit of variation in results. I had a woman in my office that wanted to have a third treatment because she really liked the results. She had mild laxity and her results were really stunning, but she inquired about maintenance if it starts to sag. She was a good example of someone that maintenance might keep looking good for a very long time if she doesn't go through some major health change. In my experience, people that respond like this tend to continue to respond well in the future. We are starting to see a few people that are fairly perfectionistic and want to know if they can do another treatment to maintain things. It is certainly safe to do that."

With nearly all cases, though, two sessions are all that is needed. "Most of the people we treat are pretty happy after the two sessions," Dr. McDaniel shared. "Occasionally, we'll have somebody that wants an additional treatment. We've had a few people come in after they've had eight to twelve pounds of weight loss and they notice a little bit of laxity, so they were re-treated. If you lose six, eight or ten pounds, it usually shows in your face. So, if the patient is in their 40s or 50s, as long as they don't have really saggy skin the results should be good."

In Dr. Rogers' experience, the Exilis Elite treatment is most effective in age groups between 30 to just under 60 years old. "With anyone over 60, you can still see a result, but at some point your collagen rate goes down. If their skin quality is poor, then a small difference in appearance after treatment is not really noticeable, and / or the treatment is unable to stimulate enough collagen synthesis," he advised.

Exceptional results on the face or body are possible in any age group, using combination procedures that include the Exilis Elite, Dr. McDaniel added. "However, there are big challenges for me when it comes to patients that want to have total facial rejuvenation without surgery," he stated. "They either want to avoid surgery

or they don't want to do it at this time. The two areas that have been really difficult to improve non-surgically are the sagging mid-lower face and neck, and the loss of the jawline. These are really a combination of skin laxity and volume loss."

Dr. McDaniel combines the Exilis Elite and Juvéderm Voluma™, a dermal filler used to volumize the cheeks from Allergan (Irvine, Calif.). "With Juvéderm Voluma, we can now restore mid cheek volume loss, leaving us with the jawline and skin tightening," he noted. "When you combine Exilis with volume correction, we see very natural, significant and long lasting results. Prior to this, some physicians would do fat grafting, in which you had to have anesthesia and a bigger procedure."

People may get a little filler, some volume and fine line correction, along with some resurfacing and Exilis," Dr. McDaniel shared. "If people have tremendous facial laxity, they still need surgery. Still there's a big section of the population that needs volume filling and skin laxity correction, and that's what's we do mostly with Exilis. It is one of the missing pieces of the non-surgical skin rejuvenation puzzle."

Dr. Rogers agreed that Exilis works well in conjunction with other types of devices. "We have used Coolsculpting from Zeltiq (Pleasanton, Calif.), which is effective at removing fat, but not in tightening skin," he said. "We have started offering it and Exilis Elite together. First, we do a Coolsculpting treatment followed by Exilis every week or so. We are seeing improved results, not just with the loss of fat, but with tightening of the skin as well. We have also used the Exilis for edema and clearing ecchymosis. By increasing blood flow it decreases edema, and increases the rate of ecchymosis clearing."

The Exilis allows practitioners to treat areas that have been historically difficult to approach. For example, as Dr. Downie noted, it does a good job of treating chin fat. "Coupling the technology in Exilis Elite with other treatments and modalities pushes the evolution of non-invasive skin tightening to a new level."

Dr. Weiss agreed. "This technology shows what RF-based aesthetic treatments can be. We obtain really good, consistent results on most patients, and pretty high satisfaction because of two things: proper screening of patients and consistent treatments. Screening properly helps to minimize the non-responders, and having treatment protocols helps to maximize the uniformity of the results. "

According to Dr. Rogers, "This is a comfortable treatment and it's relatively affordable owing to the lack of those several hundred dollar tips. Most importantly, there's science to back it up, so it's been great addition to our practice."

References:

1. *Two-Treatment Protocol for Skin Laxity Using 90-Watt Dynamic Monopolar Radiofrequency Device With Real-Time Impedance Monitoring*, David McDaniel M.D., Robert Weiss M.D., Margaret Weiss M.D., Chris Mazur B.S., and Charmaine Griffin CCRP. Sept 2014, *Journal of Drugs in Dermatology*. Vol. 13:9. Pages 1112-1117
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Before Tx



After two Exilis Elite treatments with the 90 W applicator
Photos courtesy of David McDaniel, M.D., Robert Weiss, M.D., Margaret Weiss, M.D., Chris Mazur, B.S., and Charmaine Griffin, C.C.R.P.