BTL's Vanquish Advances

Non-Invasive Body Sculpting Technology

By Jeffrey Frentzen, Executive Editor

While a lot of energy-based systems make the non-invasive claim, with the release of its new Vanquish™ device, BTL Aesthetics (Boston, Mass.) has succeeded in creating a truly painless, effective fat reduction device. Boasting the largest treatment area in the industry, the Vanquish uses newly developed Selective RF™ energy technology to address fat reduction in these non-invasive treatments. During treatment, the patient lies underneath the device's ergonomically designed panel array (or applicator), which is positioned over the targeted area at least 1 to 2 cm from the skin delivering RF-based energy and affecting induced apoptosis in the fat layers.

According to Robert A. Weiss, M.D., F.A.A.D., F.A.C.Ph., a dermatologist and respected dermatologic researcher at the Maryland Laser, Skin and Vein Institute (Hunt Valley, Md.), "Vanquish is an amazing technological advance, and is unlike any other RF device on the market. You focus the energy by choosing the correct RF frequency specifically for the impedance of the fat. Fat has different absorption properties due to its diminished water content and this device takes advantage of that to selectively heat the fat."

The Vanquish's applicator-generator circuitry delivers energy selectively to tissue layers with specific impedance, focusing the RF energy into fat layers, while restricting the delivery of high heat elsewhere. A multipolar focused field shapes the electromagnetic energy field to optimize penetration and maximize the treatment area, meaning the system automatically tunes the circuitry to selectively deliver the energy with no risk of burning the skin or overheating muscles or internal organs.

Dr. Weiss, who served as the lead researcher in a recently published animal study that verified the Vanquish technology, considers the device to be a radically different approach to the problem of eliminating fat. "Instead of using a point source of RF, which is the typical application method, Vanquish uses a plate array that emits Selective RF energy over a large area," he began. "Rather than moving an applicator around the skin, Vanquish is positioned over the abdomen for a specified time. While other body shaping devices require the operator to apply energy continuously, with Vanquish there is no operator involved and we can treat the entire core in approximately 30 minutes. We monitor the initial rise in temperature of the fat, but then it's basically 'set it and forget it.'

Early adopter Marek Kacki, M.D., an aesthetic medicine expert and owner of VISAGE MedArt in Nashville, Tenn., feels this no-contact approach is nearly revolutionary. "Vanquish is a huge leap forward in terms of design, patient comfort, operation and safety features," he reported, adding that the Vanquish and Exilis – BTL Aesthetics' earlier monopolar, focused RF device – "could

Robert A. Weiss, M.D., F.A.A.D., F.A.C.Ph.
Dermatologist
Dermatologic Researcher
Maryland Laser, Skin and Vein Institute
Hunt Valley, MD

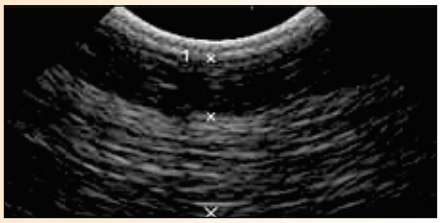
Marek Kacki, M.D.
Medical Director
VISAGE MedArt
Nashville, TN

David McDaniel, M.D., F.A.A.D.
Director
McDaniel Institute of Anti-Aging Research
Virginia Beach, VA

Vanquish Tx

Photo courtesy of BTL

Ultrasound Imaging of Fat Layer

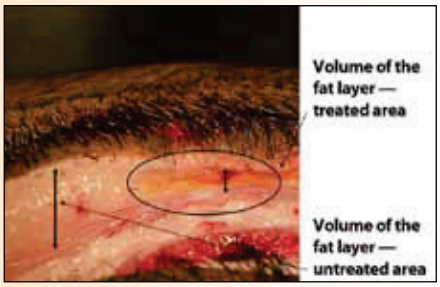


Before Tx the subcutaneous fat tissue thickness measures 7.6 mm

Four weeks after four Vanquish treatments the subcutaneous fat tissue thickness has decreased by 60% to 2.9 mm

Photos courtesy of Robert A. Weiss, M.D., F.A.A.D., F.A.C.Ph. / Vanquish Porcine Study

Vanquish Treated Fat Layer



After four Vanquish treatments

Photo courtesy of Robert A. Weiss, M.D., F.A.A.D., F.A.C.Ph. / Vanquish Porcine Study

become the gold standards in the industry. Right now, Vanquish currently treats the abdomen and flanks, and as different applicators are developed for the device it will greatly expand the possible areas it can be used. All devices evolve over time, and with Vanquish we are just beginning to see what it can do."

In Dr. Weiss' animal study Vanquish proved to be safe and effective in subcutaneous fat reduction in a porcine model. In this study, the adipose tissue was gradually heated to approximately 45° to 46° C, while the skin temperature averages only 41° C. Post-procedure ultrasound revealed approximately 60% reduction of fat layer from 7.6 mm to 2.9 mm. A histologic evaluation indicated the epidermis, dermis and adnexal structures such as hair follicles were unaffected by the treatment, but adipocytes had been significantly affected. In terms of follow-up human studies, "all signs indicate that we will be able to confirm these results with a reduction in circumference (in the ultrasound thickness of fat in humans), and potential weight loss after using this device," explained Dr. Weiss.

According to David McDaniel, M.D., F.A.A.D., director of the McDaniel Institute of Anti-Aging Research (Virginia Beach, Va.), who has also been designing IRB-sanctioned human studies for the Vanquish, "looking back, it is not surprising that the original animal studies used for the Exilis had already indicated the best depth of RF penetration with a monopolar device. The original Vanquish animal studies were very well done," he said. "To look at the skin temperature, the researchers used external probes, as well as internal probes placed in the fat. They obtained some very nice data showing that the fat temperature was higher than the skin temperature, which we tend to expect."

"I think it is widely recognized that the surface temperature is usually lower than that of the fat, assuming the RF is focused in the proper area of the fat," Dr. McDaniel continued. "The researchers' histologies show about a four-fold increase in apoptosis using TUNEL technique staining, which is good as a mechanism of action. As far as the inflammatory response, the histology I've seen so far doesn't show a really profound response. There is some thermal camera imaging that looked primarily at the skin's surface and you do see a fairly homogenous temperature rise."

Based on results so far, Dr. McDaniel explained that this type of Selective RF delivery does not seem to produce the same level of patient pain and discomfort that you might see with some of the sonic type methods. "We have had some success with cryolipolysis, but it has limited applications," he advised. "Patients have to come back for multiple treatments, which is a good thing certainly from a business standpoint, but they also have to take time off from work. Each set of applicators is a couple of hours, which also ties up their time, our room and staff."

"Probably more important than that, to treat large areas across the abdomen with cryolipolysis you have to do an overlap or 'roof shingling' in order to achieve a uniform effect. Therefore, Vanquish's ability to treat the entire abdomen in a single session without contact is a major new development as far as treatment options."

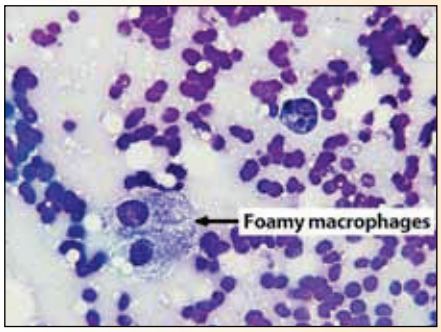
In a clinical study of Vanquish conducted in Europe, researchers validated the safety and efficacy of the system for body contouring and circumferential reduction of the abdomen and flanks. Dr. Kacki expects further clinical testing to demonstrate its ability to induce enough apoptosis to show measurable results. "We have already done several treatments, but only checking peripheral temperature, temperature on the surface after treatment and oral temperature, which reflects the body's core temperature," he noted. "The next step is to measure temperature deep inside the fat," he stated.

As Dr. Kacki pointed out, "The beauty of BTL's RF devices is that they are basically color blind. For example, lasers always target certain things, such as the pigment of the skin or pigment of blood, but RF energy penetrates and heats different tissues," he continued. "At certain frequencies – especially the high frequency that Vanquish is generating – it seems as if energy just passes easily through skin and well-hydrated tissue, including muscles. Success depends on the hydration of the skin – the more water content in the skin, the easier the RF energy can pass through without being stopped at this level; therefore, the skin is bypassed by this thermal effect. Thus, as with the patient who receives an Exilis treatment, Vanquish patients should be well hydrated."

While tests and animal studies are showing positive results, it is also important to obtain evidence from real world use. Dr. Weiss anticipates the basic treatment regimen will be four treatments of 30 minutes each, spaced a minimum of one week apart. "Of course, with any clinical device there will be a variation in how patients respond. Some will be happier with fewer treatments; some people will require more," he noted.

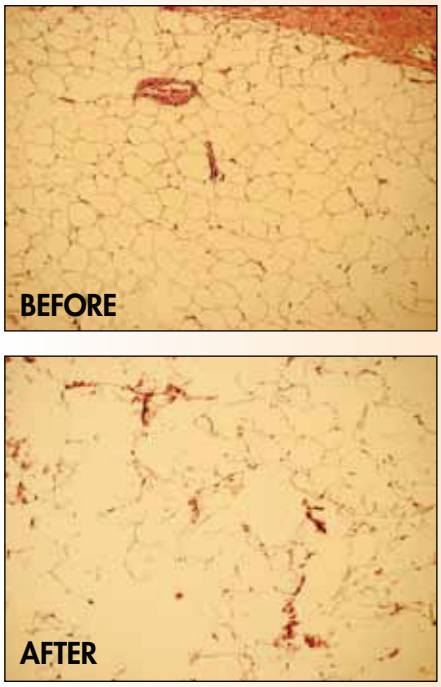
For instance, with three treatments, one of Dr. Weiss' Vanquish patients noticed a significant, two to three inch circumferential reduction in her abdomen over two and a half weeks, without any diet or exercise changes. "She felt and saw a change after only two days," he reported. "It is fast. That is why I am so enthusiastic about this device."

So far, Dr. Kacki has treated 15 patients with the Vanquish, "and over 200 with the Exilis. These devices are like brother and sister. Vanquish will do certain things that Exilis will not, and vice versa," he said. "We see our Vanquish patients once a week to maintain the same protocol. Also, we are trying to determine the limits in terms of patient expectations, satisfaction and their



Apoptosis / pseudoinflammation of the fat cells following Vanquish Tx

Photo courtesy of Robert A. Weiss, M.D., F.A.A.D., F.A.C.Ph. / Vanquish Porcine Study



Histology shows fat cells before Tx and significant proof of induced apoptosis after fourth Vanquish Tx

Images courtesy of Robert A. Weiss, M.D., F.A.A.D., F.A.C.Ph. / Vanquish Porcine Study

Before Tx

13 cm circumferential reduction after four Vanquish Tx sessions

Photos courtesy of BTL

"We have also had great success using the Vanquish on other body areas, such as on backs and outer thighs. With small modifications, and a few different sized applicators, we will even be able to treat the arms."

tolerance of treatments. If someone is interested in body sculpting and fat reduction, the Exilis and Vanquish are the tools to use. From a scientific point of view, both are well developed and absolutely well documented. We have also had great success using the Vanquish on other body areas, such as on backs and outer thighs. With small modifications, and a few different sized applicators, we will even be able to treat the arms and the legs."

Likewise, Dr. Weiss, who is the first to admit he seldom gets excited about new systems, is enthusiastic about the technological advancements that have flowed from the original Exilis to the Vanquish. In his opinion, the Vanquish, "is a remarkable piece of engineering that I really didn't think was even possible. Not only is it possible, but it works well and is comfortable; patients feel a little warmth around the abdomen. Our initial clinical results have been quite remarkable."

In Dr. McDaniel's opinion, the original version of the Exilis was a good product, but the recent upgrades in the Exilis Elite pushed the technology to the cutting edge. "When the BTL engineers increased the power in subsequent Exilis versions, they also worked on matching the impendence, which helped to adjust for subtle changes in the RF field. In addition, they developed a safety feature that immediately turns the device off if contact is interrupted. It uses an in-motion technology based on contact, versus the non-contact field effect of the Vanquish. In some ways, they are quite different systems, but with some of the same advanced RF engineering behind them."

According to Dr. Kacki, this intelligent engineering has put a spotlight on BTL Industries for advancing RF-based approaches for the face and body. "In terms of non-invasive procedures, RF is number one," he stated. "Then you have focused ultrasound and cryolipolysis. For quite some time, I had a chance to follow some of the devices that are available in Europe, but not the U.S. Interestingly, I started to look for the science behind these technologies and the claims. Manufacturers will advertise right and left about how successful their treatments are, but when you look at the supporting data you see some suggests that perhaps apoptosis can be achieved. It has always been a question of which device can lead to apoptosis. Now, we know."

As suggested by Dr. McDaniel, the next stage in testing the abilities of both the Exilis and Vanquish will be in new human studies. With the Exilis, he helped design a recently completed animal study using the unit's body applicator to confirm true induced apoptosis. He also discussed another new BTL sponsored study just underway: "It is a multi-center trial to evaluate the jawline and chin strap area using the new Exilis Elite 90-Watt facial applicator for skin tightening. This is also an IRB-sanctioned and supervised study, in which we're actually doing some histopathology from biopsies, as well as using three-dimensional (3D) photography and other metrics."

In addition to finalizing the animal studies to confirm the results and safety of Vanquish, Dr. McDaniel is preparing the protocol for a new circumferential reduction study using Vanquish. "We plan to use high-resolution ultrasound to measure and hopefully obtain some histology on human subjects," he said. "We'd like to check some of the things we observed in the porcine studies and see if they do indeed parallel as far as apoptosis is concerned. We want to define the benefits, optimize the treatment and also create teaching materials for physicians and educational materials for the patients."

Incidentally, he added, when many physicians see the term circumferential reduction today, it is like a red flag. "Physicians automatically assume that your metrics are invalid because over the last few years, so many studies on cellulite and fat reduction have relied on tape measurements to document circumferential reduction of thighs or the abdomen. The reliability of circumferential measurements has become very suspect. However, for our study, we will be using regular and 3D photography, in addition to remarkable, new ultrasound technology for our metrics. The findings should be definitive."

Looking ahead, more studies are planned with the goal of providing clinically significant results using these treatments, Dr. Weiss noted. "We are looking forward to collecting more clinical data. This is an exciting time of working with a new technology and BTL has demonstrated a commitment to science," he said.

As Dr. McDaniel pointed out, it is important for researchers and early adopters to articulate where the Vanquish system fits into the medical aesthetic landscape. "We still use and have used many devices intended for body shaping and eliminating fat," he stated. "Some are ultrasound devices; there is cryolipolysis and lasers. We have broad experience with these systems. Each one has unique pros and cons but the Vanquish system looks to usher in a new era of treating large areas safely, reasonably comfortably and fairly rapidly. While the science behind Vanquish interests me, I like the simplicity of being able to treat large areas in a shorter period of time, with limited discomfort, ease of use and no consumable costs."

"There is no question about it," added Dr. Kacki. "With Vanquish, the treatments are safe and we can pretty much guarantee good results. For my practice, that is absolutely wonderful news." ■

Before Tx

8 cm circumferential reduction after four Vanquish Tx sessions

Photos courtesy of BTL

"While the science behind Vanquish interests me, I like the simplicity of being able to treat large areas in a shorter period of time, with limited discomfort, ease of use and no consumable costs."