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Extreme Commitment to Science Catapults BTL Forward

By Kevin A. Wilson, Contributing Editor

Ideally, when a medical device is launched, the company and its core of researchers and affiliated physicians assemble a strong body of clinical information about the safety, efficacy and mechanism of action of a treatment. This is not always the case, but when a company invests in science, the payoff is profound. In this, BTL Aesthetics (Boston, Mass.) sets a high standard.

"Often a company won't spend the time or money to get down to the basic science and really understand how their product is functioning, as well as the full ramifications of treatment," said Yael Halaas, MD, a facial plastic surgeon in New York City, N.Y.

"A lot of times they're trying to get a new technology out there, but they sacrifice in the long run by not knowing as much as they could to truly develop the technology to its fullest potential the first time out and letting the community help them build from there," she stated. "It is easier to do some patient satisfaction surveys with good before-and-after pictures. By going deeper into the science, we educate the community and invite their participation as well as provide the best, safest therapies for patients."

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David E. Kent, MD, a dermatologist in Macon, Ga. agreed. "One of the most important questions in aesthetic medicine is how much science do we have about a product before it is launched?" he posed.

"The road to device claims by companies is littered with empty promises made by those who didn't do their homework," he noted. "Results are inconsistent and not well understood. Patient and physician satisfaction in those cases is weak at best. I've worked with a variety of companies in the past who did good work, but BTL's commitment to peer-reviewed science and thorough research is exceptional. Their track record is the proof. It is refreshing and sets an example for others."

"A great example of this is the science that surrounded EMSCULPT before, during and after launch," said Dr. Halaas, lead investigator for an animal tissue study with the device.

"We saw the release of more studies done prior to launch than we typically see in the industry," she reported. "Through studies using CT, MRI, ultrasound, animal histology and more, BTL has an unprecedented volume of knowledge about the energy, as well as how to manipulate and use it – the device itself, and possible new ways to apply the technology. They are so far ahead of the competition that by the time the copycat devices come out, BTL will be far into the next iteration."

The high intensity focused electromagnetic (HIFEM) device uses focused electromagnetic current at varying intensities and algorithmically controlled pulses to induce muscular hypertrophy. Thousands of supramaximal contractions in a single session, well beyond what one could perform with exercise, build muscle in both large and small muscle groups, in a well-rounded fashion. The local demand for energy upregulates local metabolism for a slimming effect as well. New applicators for the device, based on continued research, are in the works.

Dr. Halaas led the investigation presented at the 39th annual *American Society for Laser Medicine and Surgery* (ASLMS) conference in Denver, Colo. (March 2019). This study looked at mechanisms of apoptosis after treatment in live porcine subjects, examining punch biopsy specimens taken before, immediately after and eight hours after a single 30-minute application, with controls from the abdomen at baseline and eight hours after treatment.

Before and after treatment with EMSCULPT

Photos courtesy of David E. Kent, MD

Before and after treatment with EMSCULPT

Photos courtesy of David E. Kent, MD

"We noted local increases of approximately 127% and 134% immediately and eight hours after treatment, respectively, suggesting a profound metabolic response in the fatty tissue," Dr. Halaas reported. "Four of five pro-apoptotic markers measured showed significant increases, which is strong evidence of enhanced apoptosis in local subcutaneous fat. Also, average fat pH decreased from about 7.3 to approximately 6.6 right after treatment, measuring about 7.2 at eight hours. This demonstrates not only the local metabolic reaction triggering the cascade leading to apoptosis of adipocytes, it strongly supports the proposed mechanism of action of the device and correlates with findings seen in humans during previous studies." Publication of the study in a peer-reviewed journal is pending.

Dr. Kent also presented a study at ASLMS showing long-term follow-up data for patients with EMSCULPT for the abdomen. MRI and CT scanning were employed to measure muscle growth and fatty layer reduction. "We had 21 subjects after a course of four to eight 30-minute treatments with initial evaluation at baseline and six weeks. This represented an additional follow-up at one year," he said.

Subcutaneous fat thickness, abdominal muscle thickness and changes in abdominal separation were measured; weight was also recorded. "We saw an average thickness reduction of almost 15% in the fatty layer, which was slightly declined from the six-week evaluation numbers (close to 18%)," he reported.

"Measurements of muscle thickness showed preserved and slightly improved numbers (almost 18% improvement at six weeks versus 19% at one year). The average reduction of about 11% in abdominal separation at six weeks was maintained at one year. Weight changes were insignificant," Dr. Kent continued. The investigation is under consideration for publication pending review and is a follow up to the original study published in *Journal of Drugs in Dermatology*.[1]

For any treatment patients want to know three things," Dr. Kent shared. "Is it safe, does it work and how long does it last? This study, together with its predecessor, support the findings of others for this technology and also demonstrates the longevity of results after a single course of treatment, without maintenance procedures."

"BTL is not resting on its laurels," Dr. Halaas said. "Dr. Kent and I, and others involved, are impressed with how the company continuously demonstrates their dedication to science, educating the market and development of new safe, effective products and applications."

The company's overall commitment is also demonstrated in the manufacturing," Dr. Kent added. "Companies will often outsource parts of the production process. At BTL, 100% of their products are manufactured in-house. Quality, standardization, supply chain issues; these are not a problem." And, according to Dr. Kent, quality control testing is akin to that of the U.S. automotive industry. "BTL is on top of it every step of the way. Nobody else does that."

Reference:

1. Kent DE, Jacob CI. *Simultaneous changes in abdominal adipose and muscle tissues following treatments by high-intensity focused electromagnetic (HIFEM) technology-based device: computed tomography evaluation. J Drugs Dermatol* 2019;18(11):1098-1102.