A full-page photograph of a muscular Black man, shirtless, posing for a magazine cover. He is looking down and to his left, with his hands resting on his hips. The background is a plain, light grey color. The title 'THE AESTHETIC GUIDE' is overlaid on the top half of the image in a white, serif font. The word 'THE' is smaller and positioned above 'AESTHETIC'.

THE AESTHETIC GUIDE

The Shocking Ascent
of Muscle Stimulation
Technology - pg. 3

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HIFEM Technology Excels in Delivering Aesthetic and Wellness Benefits

By Kevin A. Wilson, Contributing Editor

In an industry that regularly faces issues with marketing hype and excitement versus scientific substance, few technologies have so rapidly shot to the stratosphere like muscle stimulation. Touting the ability to build, firm and tone muscle outside of the gym setting, the combination of aesthetic and wellness benefits available has been attracting more and more patients seeking improved appearance and quality of life.

Beginning with the development of tools to augment athletic training and physical therapy, various OTC and prescription or practice-based devices have been approved for therapeutic uses including maintenance and improvement of range of motion, muscle re-education, increasing local circulation, prevention or treatment of disuse atrophy, relaxation of muscle spasms and prevention of venous thrombosis, among others.

High Intensity Focused Electromagnetic (HIFEM) energy has taken this concept and run with it, evolving into something much more profound. “This technology simply mimics the action potential of nerves that cause muscle contractions, in a thoroughness and intensity that you could not physically perform through voluntary exercise,” said urologist Judson Brandeis, MD, an expert in sexual medicine and male rejuvenation in San Ramon, Calif. “As we use it, the technology has functional as well as aesthetic consequence. Core strength is the foundation of overall physical strength, and for areas such as the pelvic floor this has significant therapeutic benefits such as improvement in both male and female incontinence.”

The numerous wellness benefits that come with core strength and health are made more accessible by HIFEM technology. The effect on quality of life is unmistakable and where the real demand may come from as the technology evolves, according to dermatologist and cosmetic surgeon Suneel Chilukuri, MD, medical director of Refresh Dermatology in Houston, Texas.

“Everyone wants to look and feel better and stronger. By strengthening and toning the core musculature using this kind of technology, patients come in to improve their appearance, but their ability to function improves because core strength is at the heart of overall physical functionality,” he explained. “In my own case I saw reduction in back pain so my personal physician explained how my core, including abdominals and buttocks, being worked when I’m not physically active in my job, works together to improve my posture even when sitting. As a result, my posture has improved.

“My patients who sit at a desk all day have reported the same effect with improvement of back pain,” Dr. Chilukuri continued. “Bear in mind that this isn’t an FDA cleared indication itself but rather an obvious, known consequence of core muscle improvement. And with COVID-19 keeping people out of the gym, more and more individuals are reaping the benefits of improved core strength using this kind of technology.”

Since entering the aesthetic industry in 2002, Carolyn DeLucia, MD, an obstetrician/gynecologist and medical director of ViVa Rejuvenation Center (Hillsborough, N.J.) has witnessed firsthand the growth of non-invasive body contouring. “So many devices have come and gone and I have owned some of them,” she said. “Muscle stimulation technology has quickly become a lynchpin of practices everywhere desiring to offer a truly comprehensive body sculpting armamentarium. The potential for improving physical function and quality of life, as well as enhancing the appearance is rapidly becoming essential.”

Doubtlessly, the leader in the charge has been BTL Industries, Inc. (Boston, Mass.), with more than 20 years of knowledge and success in the physiotherapy space. The unveiling of HIFEM technology – the wunderkind of BTL’s experience – first became apparent with the September 2017 launch of Emsella, but truly took hold with the launch of Emsculpt in April 2018. The scientific foundation of the



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technology, with a flourishing body of work that exceeds 25 clinical studies and counting, is part of the appeal to practitioners, said dermatologist David E. Kent, MD (Macon, Ga.). “The hype-over-substance issue rampant in aesthetic medicine leads to product launches with inconsistent outcomes, weak science, empty promises and at worst, questionable safety,” he said. “The exceptional commitment to science BTL has repeatedly demonstrated is made even more refreshing in this context.”

“BTL goes beyond anecdotal evidence, hand-picked before-and-after pictures, and patient satisfaction surveys,” said facial plastic surgeon Yael Halaas, MD (New York City, N.Y.). “The launch of Emsculpt represented an outstanding example of a well-backed device with more science behind it than usual, by far, using an unprecedented range of measures to demonstrate the safety and efficacy of their product, as well as the ins-and-outs of the technology and its mechanisms of action. This rock-solid foundation suggests that BTL will remain far ahead of the competition for quite some time.”

Some examples: Busso and Denkova (2019)¹ shared data that suggested significant improvement in shape and volume of the buttocks in a study of 21 women after four 30-minute sessions, associated with high levels of reported treatment comfort and overall satisfaction. Histology study in 2020² revealed significant muscle hypertrophy and hyperplasia at two weeks post-treatment. A 2019 study in *Lasers in Surgery and Medicine* (Kinney and Lozanova)³ used MRI to establish the safety and efficacy of muscle stimulation technology in human subjects (n=22), showing greater than 15% average increases in abdominal muscle thickness coupled with 10.4% average reduction in rectus abdominus separation and subumbilical circumference reductions averaging 3.8 cm.

The safety, ease-of-use and general appeal of the technology has been an impetus for a growing list of competitors to bring their own devices to the market, and understandably so. Emsculpt nonsurgical body sculpting currently holds a 91% ‘Worth It’ rating on Realself.com.⁴ Over the first ten months of 2019 RealSelf reported an astounding 450% increase in interest (from 2018) among users researching technologies on the site.⁵

And who wouldn’t be interested in non-invasive, exercise-free muscle building that



Before and three months after treatment with Emsculpt
Photos courtesy of Carolyn DeLucia, MD

can seemingly do more for your core in a series of relatively short treatments than weeks’ worth of crunches? The potential of this technology has been summed up best by cosmetic dermatologist Paul J. Frank, MD, medical director of PfrankMD in New York, N.Y. “I expect this technology will do to the body contouring market what Botox Cosmetic did to the facial rejuvenation market in the new millennium.”⁶

BTL’s Emsculpt and Emsella are prime examples of muscle stimulation technology at work, yoking the power of HIFEM technology to provide ‘core-to-floor’ treatment to non-invasively strengthen and tone muscle, with resultant physical functionality benefits, running on traditional 110V power. BTL’s leading entries in the global game are backed by research as well as more than 35 patents or patents pending. The technology is regularly featured in mainstream and social media and has shown appeal to millennials and men, two rapidly growing market segments. The devices are so safe, effective and easy to use that they are delegated to staff with confidence; Emsculpt is easy to apply and monitor, while Emsella requires no operator time once treatment has begun.

Both employ programmed and algorithmically directed non-invasive electrical stimulation of the musculature to induce tens of thousands of supramaximal contractions in the treatment zone. Treatment is amazingly thorough. “The algorithms manipulate the delivery of current during treatment and hits even the small muscles that you just cannot easily train otherwise,” Dr. Brandeis explained. “Speed and intensity are always changing. This assures the comprehensive

stimulation of target musculature, in ways that are impossible to achieve through manual voluntary exercise. We must understand that each region is not just one muscle, but a system of muscles that work to stabilize as well as move the body. Nothing stimulates the whole musculature of the target like Emsculpt.”

In four 30-minute treatment sessions (at two-week intervals), Emsculpt provides proven outcomes for muscle as shown in numerous peer-reviewed clinical trials. Muscular hypertrophy and hyperplasia were demonstrated in a porcine study by and Duncan and Dinev². At two weeks, post-treatment muscle mass density had increased more than 20% over baseline with corresponding rises in muscle fiber density and mean size of muscle fibers. Across studies measuring via CT, MRI and ultrasound scanning as well as histology, notable improvements in muscle mass (16%) and fat reduction (19%) were seen with Emsculpt.^{3,7,8}

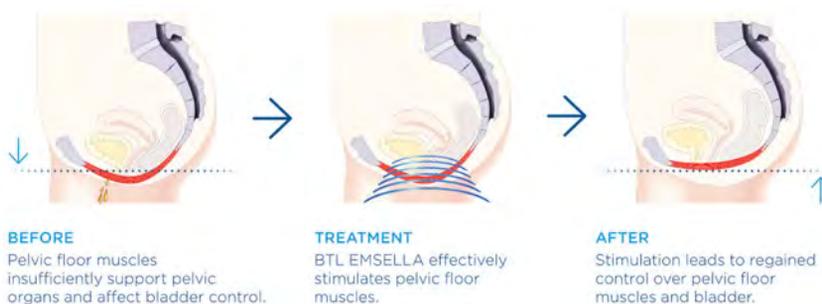
Emsculpt also features a smaller applicator so that physicians can harness HIFEM for skeletal muscles of the extremities to tone arms and legs. “The addition of new applicators makes it the most complete body shaping device available,” said Dr. DeLucia. “Emsculpt allows us to provide a full body transformation that affects appearance as well as functionality and medical issues as well.”

Originally developed to address women’s health issues, Emsella’s ability to restore and maintain pelvic floor and deep core function represents an ideal therapy for both male and female urinary incontinence, which affects hundreds of millions around the world.⁹ In a recent clinical study more than 67% of patients enjoyed reduced need for hygienic pads after Emsella treatment,¹⁰ and its effects have been revealed through pelvic floor ultrasound¹¹ as well. “Improvement of pelvic floor function with Emsella can treat any form of urinary incontinence,” Dr. DeLucia explained, “whether it is sudden leakage due to sneezing or laughing, or difficulty holding one’s bladder temporarily during the day or night.”

Strength of contractions is related to strength of induced current. While the patient is sitting in the applicator ‘chair’, Emsella delivers up to 2.5 Tesla of magnetic induction at the coil surface. “Pelvic floor muscles are difficult to strengthen, and few people are able to do Kegel exercises properly, so Emsella’s ability to isolate and



Before and after treatment with Emsculpt
Photos courtesy of David E. Kent, MD



strengthen these muscles have made it a frontline treatment. By providing durable improvement to the pelvic floor, we can restore and even improve sphincter function for the male population as well,” added Dr. Brandeis. “I use it to treat aging-related uncontrolled urinary leakage as well as incontinence after prostate surgery.”

The two devices are available separately, but the development of the Emsella applicator provides practitioners with increased versatility to those already owning the Emsculpt system. The two are perfectly complementary, according to Dr. Brandeis. “They do basically the same thing, and together represent a thorough regimen than can treat most of the musculature thoroughly and in ways one could not otherwise achieve. Even a comprehensive training program targeting these areas would require a range of exercises and a lot of time that makes the prospect prohibitive, and still you would not obtain the kind of benefits we’ve come to expect from Emsculpt and Emsella.”

The tandem therapy is excellent for nonsurgical improvement of abdominal separation, stated Dr. DeLucia. Emsculpt’s



Before and three months after treatment with Emsculpt
Photos courtesy of Carolyn DeLucia, MD

“We noticed the visibly elevated mood of our patients after HIFEM treatment. Using a survey with validated Subjective Happiness Scale, 87% of subjects reported happiness after the treatment.”

effect on the condition has been shown in clinical trials.^{6,7} “With approximately two-thirds of women experiencing abdominal separation post-childbirth, most of whom also have pelvic floor disorder, plus the proven correlation between the two and the naturally contiguous musculature, the expected benefit is readily apparent. After a course of therapy using Emsculpt and Emsella my patients experience substantial improvement in quality of life with a restored sense of normalcy, and can enjoy activities that were negatively impacted by these conditions.”

The potential for Emsculpt and Emsella to provide hassle-free quality of life enhancement, in the end, is what separates BTL’s HIFEM not only from direct competitors, but from the bulk of the aesthetic armamentarium. “In addition to the physical benefits or efficacy of HIFEM therapy, the safety and convenience of these technologies is remarkable,” said Dr. Chilukuri. “There are no major pre- or post-treatment protocols and there is no pain. Patients come in, get treated, and go about their business, feeling over the next day or so as if they’d worked out, at most. There is nothing intimidating about treatment. With approximately 400,000 treatments worldwide to date, we’ve had zero complications. None. It is no surprise that patients are so interested in what technologies like Emsculpt and Emsella have to offer. COVID-19 has encouraged me to offer a ‘medical gym’ membership within our practice to allow people to safely return to their normal exercise routines.”

As pointed out by plastic surgeon Steven Dayan, MD (Chicago, Ill.), there is plenty of evidence that exercise improves mood. “Most of us who work out know that feeling, and exercise is a proven treatment for mood disorders,” he elaborated. “We noticed the visibly elevated mood of our patients after HIFEM treatment. It affected our patients, and that affected our staff because this good mood is contagious, so we did a study that has been submitted for publication. We had women (age range 26 to 46 years) rate their happiness before and two weeks after undergoing four treatment sessions. Using a survey with a validated Subjective Happiness Scale, 87% of subjects reported happiness after the treatment. This was a welcomed improvement, and I think that is one of the reasons people keep coming back for treatment. It is definitely an avenue for more intensive study.”



Before and after treatment with Emsculpt
Photos courtesy of David E. Kent, MD

Another way that BTL is leading the charge is with their response to the COVID-19 crisis. BTL has partnered with RealSelf and others to help the industry weather the “new normal” by launching the Sculpt Your Practice online education platform. The focus of this platform is to ensure practice success and provide 24/7 access to knowledge, training and downloadable resources. Featuring virtual demos and webinars on existing and emergent technologies, clinical trial information, best practices, practice management and more in six virtual ‘booths’, makes it the most comprehensive program available.

BTL will also launch the Emsculpt North American Tour, with two coach buses each equipped with Emsculpt and Emsella devices to share the fun and exciting world of HIFEM. The public will take part in challenges, obtain swag and win prizes, share their personal stories and more, starting in early July 2020.

With years of experience in the fields of physiotherapy and aesthetic medicine, along with an established reputation for science and innovation, the future looks bright for BTL and the next generation of HIFEM applications and upgrades that are most assuredly to come.

Editor’s Note:

Emsculpt is intended for improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. Strengthening, toning and firming of buttocks, thighs and calves. Improvement of muscle tone and firmness, for strengthening muscles in arms.

BTL Emsella is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.

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