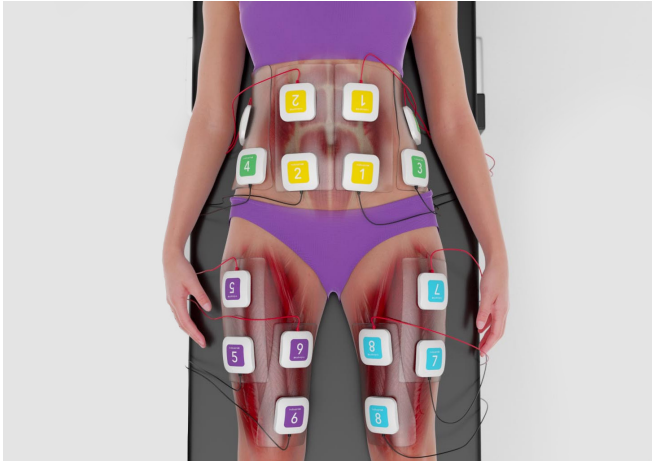


A NOVEL BIO-ELECTRIC CURRENT STIMULATION DEVICE FOR IMPROVEMENT OF MUSCLE TONE: THE TRUSCULPT FLEX

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WHAT IS THE TRUSCULPT FLEX?



Direct electrical muscle stimulation (EMS) devices stimulate muscles to contract and has been used for toning, reshaping, and maintaining muscle definition. Electrical impulses are generated by a device and are delivered through electrodes placed on the skin over the muscles to be stimulated and mimic the action potential initiated by the nervous system, causing the muscles to contract. These devices have been used for muscle rehabilitation following injury and use has been extended for the improvement of physical appearance by increasing muscle tone and firmness.

The truSculpt flex is a bio-electric current stimulation device cleared by FDA for improvement of abdominal tone, for strengthening abdominal muscles, and for development of a firmer abdomen. In addition to strengthening, toning, and firming of the buttocks and thighs. The device consists of a touch screen LCD user interface and four core electrode cables which power sixteen handpieces. The handpieces are placed on the body to allow simultaneous treatment of up to eight areas. The electrical muscle stimulator has multiple intensity settings that contract muscles rhythmically, stimulate metabolism and blood flow.

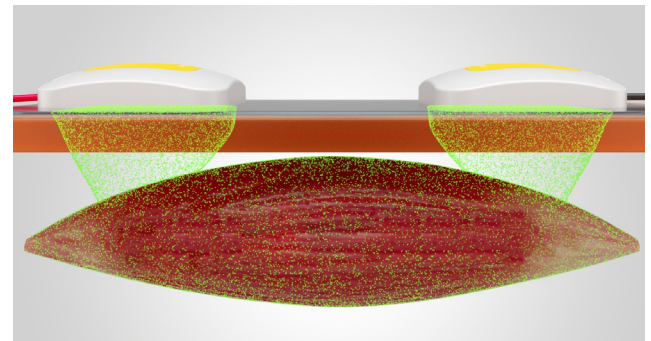
The truSculpt flex differs from other devices that use electromagnetic or magnetic stimulation in that it provides equal distribution of electrical current directly into specific and targeted muscles. truSculpt flex delivers 10 to 30 mA of energy to stimulate motor neurons, and different types of torsional contractions can be achieved by changing polarity of the electrodes in real time. Transcutaneous Electrical Nerve Stimulation (TENS) and Traditional Electrical Muscle Stimulation (EMS) technologies produce

flinching-like responses in the motor neurons, and the amount of energy conducted through the skin is limited to below 10 mA to prevent sharp pain and skin injury. Magnetic stimulation is achieved with very large magnetic fields placed over one muscle group at a time. These devices have no polarity and only single axis contractions are possible.

TREATMENT WITH TRUSCULPT FLEX

There were 28 patients treated with the truSculpt flex device and received up to six treatments spaced 1-2 weeks apart. Patients returned for follow-up assessments at 4, 8, and 12 weeks post treatment. Digital photos and ultrasound measurements were obtained at baseline and at each follow-up visit. The electrodes were placed on the abdomen, flanks or obliques in the pattern shown. These areas were treated for 45 minutes with varying intensities of energy.

Patients were not treated if they had contraindications to the truSculpt flex, including cardiac pacemaker, known myocardial arrhythmia, swollen, infected, or inflamed skin, or cancer. Additionally, patients were excluded if they had any electronically, magnetically, or mechanically activated implant; if they had any metal implant; skin abnormality; cancer treatment within the prior three months; history of seizure disorder or epilepsy, or pregnancy.



RESULTS

There were 17 females and 11 males treated in the study, ranging from 23 to 64 years old. Racial distribution was diverse with nine Caucasian, nine Asian, five African American, and five Latino or American Indian. Patients reported pain of 2.27 out of 10 during the procedure and there were two reports of minor erythema following the treatments. Preliminary results indicate that at the 12-week follow-up, there were three patients with complete Ultrasound data. Digital before and after photos for three representative patients are shown.



Photos courtesy of S. Ronan, M.D.

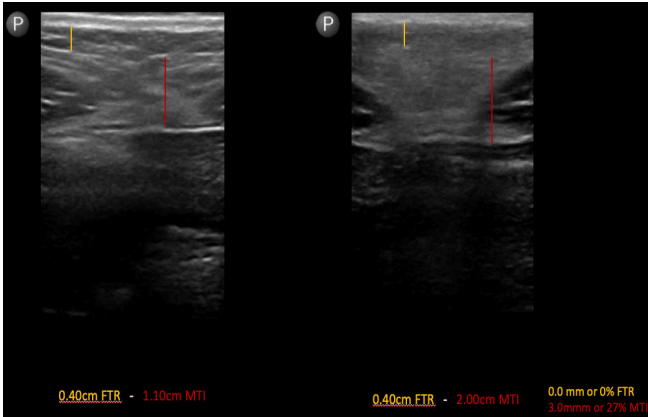


Figure 1. This was a 36-year-old female of Asian descent who received four treatments on her abdomen and flanks. The left ultrasound shows the baseline and the right ultrasound shows results at 12 weeks follow-up on her abdomen. She had a 27% Muscle Thickness Increment.



Photos courtesy of S. Ronan, M.D.

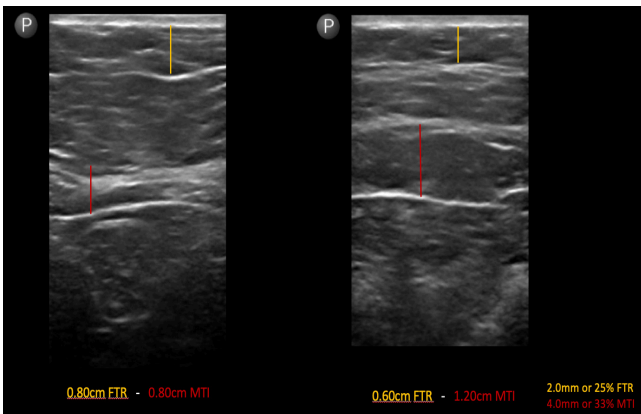


Figure 2. This was a 27-year-old Latino male who received six treatments on his abdomen and flanks. The left ultrasound shows baseline and the right ultrasound shows 12 weeks follow-up of the treated abdomen. He had 33% Muscle Thickness Increment and 25% Fat Thickness Reduction.



Photos courtesy of S. Ronan, M.D.

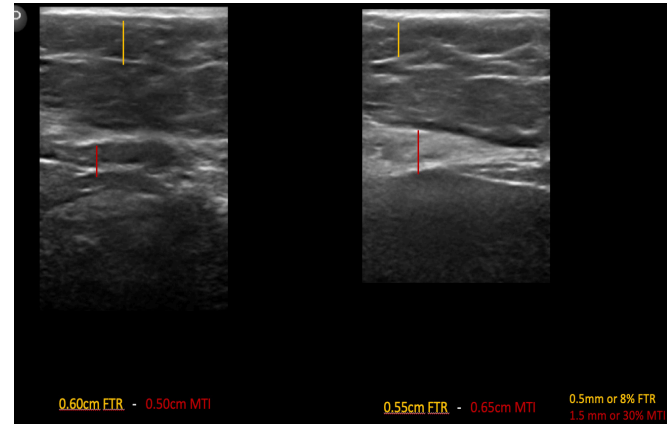


Figure 3. This is a 54-year-old Caucasian female who received six treatments on her abdomen and flank. The left ultrasound shows baseline and the right ultrasound shows results after 4 weeks follow up of the treated abdomen. At 12 weeks follow-up, she had a 30% Muscle Thickness Increment and 8% Fat Thickness Reduction.

CONCLUSION

Preliminary data on treatments with the truSculpt flex device shows an average of 30% increase in muscle mass and a modest reduction in fat thickness. All patients tolerated the procedure well. Pain during the treatment was minimal and only minor erythema was reported by two patients following the treatments. truSculpt flex resulted in a safe and efficacious treatment to strengthen, firm, and tone the abdominal muscles.

¹Kinney BM and Lozanova P. High Intensity Focused Electromagnetic Therapy Evaluated by Magnetic Resonance Imaging: Safety and Efficacy Study of a Dual Tissue Effect Based on Non-Invasive Abdominal Body Shaping. LSM. 2019, 51:40-46.

²Lai, H.S., DeDomenico, G & Strauss, G. The Effect of different EMS training Intensities on Strength Improvement. Australian Journal of Physiotherapy. 1988, 34,3, 151-164.

³DeDomenico, G. Strengthening of the Abdominal Muscles with Electrical Stimulation. San Antonio Medicine: Journal of the San Antonio Medical Society. 2003, 56,(5), pp 26-29.