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IS THE CLINIC THE NEW GYM? NON-INVASIVE PROCEDURES TO INCREASE MUSCLE TONE

Non-invasive cosmetic procedures have increased 217.3% between 2012 and 2017[1], allowing for less risk and downtime than traditional aesthetic surgery. Initially with a focus on the face, these procedures have expanded to body contouring, which is defined as modification of the body's appearance through changes in size or shape. Options for body contouring have expanded beyond liposuction and surgical correction to include many non-invasive energy-based devices, which has resulted in increased patient interest. Statistics from the American Society of Dermatologic Surgery show that the number of treatments for non-invasive body contouring went up by 43% in 2018 in comparison to 2017 and grew four-fold since 2012[2].

Body contouring treatments have conventionally addressed skin, fat and muscle, but there has been a greater focus towards fat reduction. In 2017, liposuction was the second most common surgical cosmetic procedure[1] and subsequent non-invasive modalities for fat reduction include cryolipolysis, laser, radiofrequency, and high-intensity focused ultrasound (HIFU), which all employ heating or cooling as a means to minimize fat. While these devices lead to destruction of adipose cells and overall fat reduction[3], there are limitations to their use. The lipolytic responsiveness of adipose tissue is inversely proportional to an individual's BMI and thus the ideal patient for these devices has a low BMI with isolated discrete bulges of fat[3], leaving a large proportion of patients who are not suitable candidates for these devices. Muscle tissue comprises a larger proportion of human body composition as compared to fat[4] and can play a large role in body contours and appearance. Classically the only way to build muscle mass has been through physical exercise. Recent advances have led to non-invasive body-contouring devices that stimulate muscle contractions using either electromagnetic muscle stimulation (EMMS) (High-Intensity Focused Electromagnetic Technology (HIFEM) and Magnetic Muscle Stimulation (MMS)), or Bio-Electric Current Stimulation. Both electric and electromagnetic stimulation have been used in the past as an adjunct to muscle training, with a focus on functional effect rather than appearance[5,6,7]. The following devices are the first of their kind to utilize these technologies as a means to impact body shape.

High Intensity Focused Electromagnetic Therapy (HIFEM):

High intensity focused electromagnetic therapy is based on the concept of electromagnetic induction first described by Faraday in 1831. The technology uses rapidly changing alternating magnetic fields to induce electric currents in the underlying tissue, which stimulate motor neurons in the area and provoke muscle contraction (Emsculpt, BTL Industries, Marlborough, MA). Motor neurons are selectively activated due to their large diameter and lower resistance. The device operates with intensities up to 1.8 T and frequencies up to 3kHz, and by optimizing the parameters of frequency, pulse width and intensity, is able to produce supramaximal involuntary muscle contractions. Supramaximal contractions occur when the muscle does not have the opportunity to relax fully between contractions, which is not reproducible with voluntary muscle contractions in exercise.[3,8,9,10]

HIFEM is delivered as a series of four 30-minute treatments spaced two to five days apart. The applicator is placed on the skin of the treatment area and the treatment is delivered with increasing intensity until the patient's tolerability threshold is reached **(Figure 1)**. No anesthesia is required.

Figure 1. Patient receiving abdominal HIFEM treatment

Studies have demonstrated the effects of HIFEM technology on the abdomen[8,9,10] and gluteal muscles[11,12], as well as strengthening the muscles of the pelvic floor[13] to treat urinary incontinence. Currently, studies are underway to examine strength and tone in the biceps, triceps and gastrocnemius muscles, with initial results showing improvement in muscle thickness in these areas[14]

Many studies have demonstrated improvement following a series of HIFEM treatments. An examination of 22 patients (avg. BMI 23.8 kg m^{-2}) at baseline and 3 months following a series of four HIFEM sessions of 30 minutes each and spaced apart by 2-3 days, showed an average waist reduction of 4.37 ± 2.63 cm ($P < 0.01$) three months after the last treatment, with 91% of patients stating that their abdominal appearance had improved.[9] In another study, results from MRIs taken at baseline and at the two-month follow up mark demonstrated statistically significant reductions in adipose tissue thickness (-18.6%), increase in rectus abdominus thickness (+15.4%) and a reduction in abdominal separation, or diastasis (-10.4%). The patients' weight did not change significantly through the study period, and the results continued to improve in the four patients randomly selected for six-month follow up.[10] In yet a third study, when the gluteal muscle was treated, seven patients demonstrated a significant increase ($p = .001$) in the size of the examined muscles at 1-month (+10.81 ± 1.6%) and 3-month (+13.23 ± 0.91%) follow-up.[12] Results of these studies further support the role of electromagnetic energy in building muscle tone.

In an effort to validate that the results demonstrating muscle growth were related to muscle hypertrophy and not simply swelling or increased water content in the muscle, Duncan and Dinev performed histologic examination of muscle from Yorkshire pigs following four 30-minute HIFEM treatments[15] and showed both hypertrophic and hyperplastic changes to the muscle along with an increase in muscle mass density of 20% compared with baseline, further providing evidence that HIFEM builds muscle tone.

While the initial treatment objective of HIFEM was to induce muscle thickening, studies have shown a secondary increase in apoptosis of fat cells, demonstrating that fat reduction is possible using non-thermal means. Weiss and Bernardy examined the apoptotic index of fat in pigs receiving one treatment with a HIFEM device and showed evidence of adipocyte apoptosis.[16] It is believed that the induction of supramaximal contractions leads to increased metabolic activity in the treatment area, leading to subsequent lipid breakdown. A study involving 33 patients measuring subcutaneous fat thickness with ultrasound of the abdomen following four sessions of HIFEM demonstrated a statistically significant reduction in subcutaneous fat on ultrasound averaging 19.0% / 4.47 +/- 3.23 mm ($p < .01$) at 1 month after treatment and 23.3% / 5.78 +/- 4.07 mm 3 months after treatment.[17] Interestingly, there was no effect demonstrated on gluteal fat after MRI following four treatments with HIFEM in seven subjects[12], which differs from the results shown in the studies of abdominal fat. It is unclear why this difference exists, and further study is warranted.

The longest follow up of the HIFEM procedure is currently one year[8], in which twenty-one subjects from the original cohort of forty-four were recalled for a follow up CT or MRI at one year. Repeat imaging of nineteen of these twenty-one subjects demonstrated that subcutaneous fat thickness remained reduced, rectus abdominus muscle thickening was maintained at one year in all subjects, and the overall difference in muscle thickness between 6-weeks and 1-year following treatment was not significant. No treatment related adverse events were reported at either the six week or one year follow up mark.

High Intensity Focused Electromagnetic Therapy with Radiofrequency:

The second generation of HIFEM device includes the addition of radiofrequency (Emtone, BTL Industries, Marlborough, MA) which is a combined device emitting synchronized RF and HIFEM energies at the same time, allowing for muscle heating prior to contraction. The addition of radiofrequency also allows for the heating of subcutaneous fat in the area of treatment, leading to fat cell apoptosis. Studies are underway to examine the effects of combined HIFEM and RF[18,19], and determine if the combination of these two modalities will allow for greater improvement to muscle tone and fat apoptosis than either modality alone.

Magnetic Muscle Stimulation (MMS):

Similar to HIFEM, magnetic muscle stimulation utilizes a magnetic field to generate a current to induce involuntary muscle contractions (CoolTone, ZELTIQ Aesthetics, Pleasanton, CA) and is indicated for use on the abdomen, thighs and buttocks. Treatment consists of four 30-minute sessions in a two-week period, with each treatment spaced at least 48 hours apart.

Interim results of a study examining the use of MMS in 110 patients found that after four treatments to the abdomen, buttocks or a combination of both areas, improved scores on the body satisfaction questionnaire and subject-rated Global Aesthetic Improvement Scale at the 4-week follow up visit were noted.[20] Improvements were greater for patients receiving treatment to the buttocks, which may reflect differences as a result of the amount of fatty tissue overlaying the treated muscle group. Primary endpoint results from this study at 12 weeks are pending.

Bio-electrical Muscle Stimulation:

Direct electrical muscle stimulation utilizes electrical impulses delivered through electrodes placed on the skin to mimic an action potential and thus stimulate muscles to contract. The waveform targets skeletal muscle with a frequency that creates an action potential to the entire muscle group being treated. These devices deliver 10 to 30 mA of energy to motor neurons, creating different types of torsional contractions by changing the polarity of the electrodes (truSculpt flex, Cutera, Inc. Brisbane, CA). The variety of contraction sequences throughout the treatment is meant to simulate a traditional workout. Muscles are initially stimulated in a twisting motion to warm up, then contracted sequentially to the point of exhaustion, and then finally stimulated with faster, deeper contractions to increase the basal metabolic rate.[21]

Treatment with bio-electrical muscle stimulation consists of a series of up to six 45-minute sessions, each spaced 2-4 days apart. Areas for treatment include the abdomen, buttocks, and thighs with the capacity to treat up to eight areas at once. No anesthesia is required.

Studies on the effects of bio-electrical muscle stimulation are currently underway and will inform the degree of impact to muscle tone in the treated areas.

Safety:

The safety of muscle stimulation procedures has been demonstrated through the existing peer-reviewed literature, all of which shows no significant adverse events, with some patients experiencing mild redness immediately following treatment, as well as muscle fatigue to the treated area in the days following. The World Health Organization has examined the relationship between electromagnetic exposure and adverse events such as childhood cancers, adult cancers, depression, cardiovascular disorders, reproductive dysfunction, immunological modifications and neurodegenerative disease and found no association. A possible link between childhood leukemia and long-term exposure to residential power-frequency magnetic fields has been found. However, since animal studies have been largely negative and there were methodological problems with the studies linking the two, the evidence for electromagnetic exposure and childhood leukemia was deemed not strong enough to be causal.[22] However, published data highlights the importance of monitoring the total dosage of electromagnetic energy being generated per treatment as a precaution.[23]

Discussion:

Devices to stimulate muscle tone expand our current modalities for body contouring beyond fat reduction, and for the first time, allow for stimulation of muscle growth outside of traditional exercise. With increased options for non-invasive body contouring, patient selection is key in optimizing treatment outcomes. Currently, it seems that patients with lower BMIs at baseline and less than 2.5cm of pinchable fat have the best outcomes[9,10], with further studies soon to provide greater clarity on the ideal candidates for these treatments. For many patients, the best outcome will be achieved from a combination of different body contouring procedures versus treatment with one modality alone. A study comparing patients treated with EMMS alone, cryolipolysis alone, and EMMS and cryolipolysis in combination found that the multimodal approach of cryolipolysis and EMMS was safe and more effective than either modality alone.[24] Further studies are needed to delineate the safest and most effective method of combining these procedures. While initial data support muscle stimulation treatments as safe and effective, long-term data will continue to guide our treatments with these novel devices.

References

1. The American Society for Aesthetic Plastic Surgery. Procedural Statistics; 2017. https://www.surgery.org/sites/default/files/ASAPS-Stats2017.pdf

2. 2018 ASDS Survey on Dermatologic Procedures.; 2018. Available at: https://www.asds.net/skin-experts/news-room/press-releases/asds-members-performed-more-than-125-million-treatments-in-2018. Accessed December 20, 2020

3. Mazzoni D, Lin MJ, Dubin, DP et.al. Review of non-invasive body contouring devices for fat reduction, skin tightening and muscle definition. Australasian J Dermatol 2019;60: 278-283

4. Brierly ME, Brooks KR, Mond J, et.al. The body and the beautiful: Health, attractiveness and body composition in men's and women's bodies. PLoS ONE 11(6):e0156722

5. Langeard A, Bigot L, Chastan N, Gauthier A. Does neuromuscular electrical stimulation training of the lower limb have functional effects on the elderly?: A systematic review. Exp Gerontol. 2017;91(suppl C):88-98.

6. Matsuse H, Hashida R, Takano Y, et al. Walking exercise simultaneously combined with neuromuscular electrical stimulation of antagonists resistance improved muscle strength, physical function and knee pain in symptomatic knee osteoarthritis: a single-arm study. J Strength Cond Res. 2017;31(1):171-180

7. Lin VW, Hsieh C, Hsiao IN, Canfield J. Functional magnetic stimulation of expiratory muscles: a noninvasive and new method for restoring cough. J Appl Physiol Bethesda Md 1985. 1998;84(4):1144-1150

8. Kinney BM, Kent DE. MRI and CT assessment of abdominal tissue composition in patients after high-intensity focused electromagnetic therapy treatments: one-year follow up. Aesthetic Surg J 2020; 40(12):686-693

9. Jacob CI, Paskova K. Safety and efficacy of a novel high-intensity focused electromagnetic technology device for noninvasive abdominal body shaping. J Cosmet Dermatol. 2018;17:783-787

10. Kinney BM, Lozanova P. High intensity focused electromagnetic therapy evaluated by magnetic resonance imaging: Safety and efficacy of a dual tissue effect based on non-invasive abdominal body shaping. Lasers in Surgery and Medicine 2019;51:40-46

11. Jacob C, Kinney B, Busso M. et.al. High intensity focused electro-magnetic technology (HIFEM) for non-invasive buttock lifting and toning of gluteal muscles: A multi-center efficacy and safety study. J Drugs Dermatol. 2018;17(11):1229, 1232

12. Palm M. Magnetic resonance imaging evaluation of changes in gluteal muscles after treatments with the high intensity focused electromagnetic procedure. Dermatol Surg. 2020 Sept 15. Doi:10.1097/DSS.0000000000002764. Online ahead of print

13. Samuels JB, Pezzella A, Berenholz J. Safety and efficacy of a non-invasive high-intensity focused electromagnetic field (HIFEM) device for treatment of urinary incontinence and enhancement of quality of life. Lasers in Surgery and Medicine. 2019;51(9):760-766

14. Katz BE, Duncan D. Non-invasive arm lifting and calf toning using high intensity focused electromagnetic field (HIFEM) procedure: ultrasound assessment. E-poster abstract 2020 ASDS

15. Duncan D, Dinev I. Noninvasive induction of muscle fiber hypertrophy and hyperplasia: Effects of high-intensity focused electromagnetic field evaluated in an in-vivo porcine model. A pilot study. Aesthetic Surgery Journal. 2020;40(5):568-574

16. Weiss RA and Bernardy J. Induction of fat apoptosis by a non-thermal device: Mechanism of action of non-invasive high-intensity electromagnetic technology in a porcine model. Lasers in Surgery and Medicine. 2019;51:47-53

17. Katz B, Bard R, Goldfarb R, et.al. Ultrasound assessment of subcutaneous abdominal fat thickness after treatments with a high-intensity focused electromagnetic filed device: A multicenter study. Dermatol Surg 2019;45:1542-1548

18. Jacob C et al. Abdominal toning and reduction of subcutaneous fat with combination of novel radiofrequency and HIFEM procedure – MRI scan study. Presented at the Annual Meeting of the American Soc for Derm Surg., 2020 Virtual Meeting

19. Denkova, R. Ultrasound evaluation of the simultaneous RF and HIFEM treatments on human fat tissue. Source: U.S. FDA. 510(k) Premarket Notification: K192224. Published online Dec 5, 2019.

20. Fabi SG, Dover JS, Tanzi EL, Bowes LE. Et al. Electromagnetic Muscle Stimulation for Abdominal and Gluteal Muscle Toning. Lasers in Surgery and Medicine. 2020. 52:S5-S82

21. Nye R, Hoffmeister A. The process of muscle hypertrophy utilizing a novel bio-electrical muscle stimulation device. 2020. Cutera Inc.

22. WHO – World Health Organization. Exposure to extremely low frequency fields. 2007. https://www.who.int/peh-emf/publications/facts/fs322/en/. Accessed January 2, 2021

23. Alexiades M. High intensity focused electromagnetic field (HIFEM) devices in dermatology. 2019;18(11):1088

24. Kilmer SL, Cox SE, Zelickson BD et.al. Feasibility study for electromagnetic muscle stimulation and cryolipolysis for abdominal contouring. Dermatol Surg. 2020;46:S14-S21.