

Simultaneous emission of synchronized radiofrequency and magnetic fields in a single applicator for fat elimination and muscle building

A unique combination of RF and HIFEM[®]

Procedures primarily addressing fat reduction and muscle building non-invasively have been two separate worlds since their inception due to the clinical and technical interferences. EMSCULPT NEO is the first of its kind medical device that generates RF and HIFEM energies simultaneously using dual-field applicators.

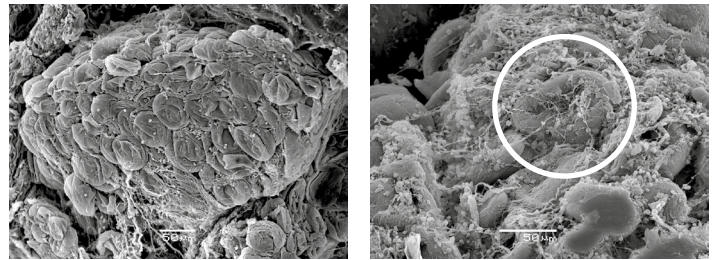
The RF component delivers different levels of heat to underlying structures; skin, fat, and muscle. HIFEM is a procedure based on high-intensity magnetic fields that elicit external muscle contractions of supra-physiological nature. The unique combination of muscle contractions and heating by EMSCULPT NEO has multiple synergistic effects making the simultaneous treatment more effective than any standalone or consecutive application.

Effects on adipose tissue

The unique synchronized radiofrequency in EMSCULPT NEO has shown to heat the adipose tissue to 43–45°C uniformly. Adipocytes exposed to temperatures in this range begin to lose their cellular viability and enter into the apoptotic process, i.e., natural and permanent deletion¹. Consequently, the apoptotic cells lose membrane integrity and are digested by immune cells, which clear the degraded cell debris to maintain tissue homeostasis². As a result, the number of fat cells in the treated area is significantly reduced.

The elevated temperature further results in increased blood flow and acceleration of metabolic activity. In response, the lipids stored in the fat cells are broken down into free fatty acids and glycerol, which are subsequently released to the bloodstream³. This

directly leads to a shrinkage in the size of the remaining fat cells as they lose a large portion of their contents.



SEM evidence of fat cell shrinkage 4 days after treatment (left) and apoptotic fat cell destruction seen 2 weeks after treatment (right). Source: Weiss et al.

Several veterinary and human trials were conducted to investigate the effects of EMSCULPT NEO on subcutaneous fat tissue. Histological and electron microscopy observations of the adipose tissue revealed extensive disruption of fat cells and lipolytic changes. Noninvasive MRI and ultrasound evaluation demonstrated that the simultaneous treatments result in an average reduction of 28.3% – 30.8% in the subcutaneous fat layer.

The muscle contractions further contribute to an even heat distribution. Localized heat accumulation is often associated with thermal treatments and the so-called “hot-spots” can lead to various complications. In EMSCULPT NEO, the muscle contractions work as a natural massager distributing the heat homogeneously across the entire treated area.

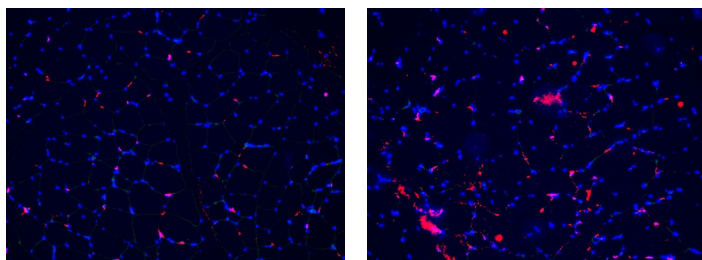
Effect on muscles

Due to the RF, the muscle is heated to 40–41°C, which causes increased blood flow into the

active tissue and thus a significant increase in the oxygen and nutrient delivery to the strained muscle fibers⁴. Increased oxygenation and nutrient supplementation promotes the anabolic processes that take place in an organism and are necessary for faster muscle fiber regeneration and growth.⁵

The HIFEM-induced supramaximal muscle contractions produce a strong response that triggers muscle tissue hypertrophy⁶. During the treatment, muscle fibers are stretched and relaxed with high frequency and intensity, leading to micro-ruptures in the muscle fibers^{7,8}. In turn, signaling molecules (heat shock proteins - HSP) are released to activate regenerative and muscle growth processes to strengthen the muscle.⁸ Satellite cells (SC), the muscle-derived stem cells responsible for **myofiber development, and renewal**⁹ are activated at the same time. When activated the SC's may differentiate to support existing muscle fibers, or to generate new muscle fibers.¹⁰

Both HSP and SC can be activated by intense muscle exercise, but also by heat. Several studies have documented the ability of muscle heating to alter the levels of HSP as well as SC¹¹. Moreover, the simultaneous application of heat and mechanical stress showed the highest levels in the expression of **HSPs** when compared to either heat or mechanical stress alone¹².



Immunofluorescence images. The levels of satellite cells (red) are increased significantly at 2 weeks post-treatment (right) when compared to baseline (left). Adopted from Halaas et al.

Multiple IRB studies have investigated the synergy, and their results have shown a muscle thickening effect of 24-26%. On the other hand, the studies investigating the use of HIFEM without RF heating reported growth in muscle thickness by 16%. This comparison clearly shows that the heat plays an important role in achieving superior clinical efficacy.

Concluding comments

EMSCULPT NEO represents the first-ever technology allowing the application of RF heating and HIFEM energies to the same body area simultaneously. This represents a breakthrough approach to non-surgical body shaping that clinically allows combining RF-induced fat elimination and HIFEM-induced muscle building in a wide range of patients, varying from athletes to high-BMI individuals. This new approach addresses the two biggest patient concerns in a single treatment while unlocking the various synergistic benefits that can only be seen when the energies are emitted at the same time. Multiple clinical studies investigating the synergistic effect of dual emission documented an efficacy superior to any other standalone or consecutive treatment available in aesthetic medicine today.



MRI images taken at baseline (left) and 3 months post-treatment (right). Adopted from Jacob et al.

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SYNCHRONIZED RF & HIFEM: FAT HISTOLOGY & SCANNING ELECTRON MICROSCOPY STUDY

SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY FOR FAT DISRUPTION: HISTOLOGICAL AND ELECTRON MICROSCOPY PORCINE MODEL STUDY

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HIGHLIGHTS

- Both **histology** and **scanning electron microscopy** showed **damaged adipocytes** post-treatment due to apoptosis and lipolysis.
- **Adipocyte size** was **decreased by 31.1%** at 2 weeks post-treatment.
- The **temperature** in fat tissue was maintained **just below 45°C** for the entire treatment.
- **No necrosis** was seen in the tissue.



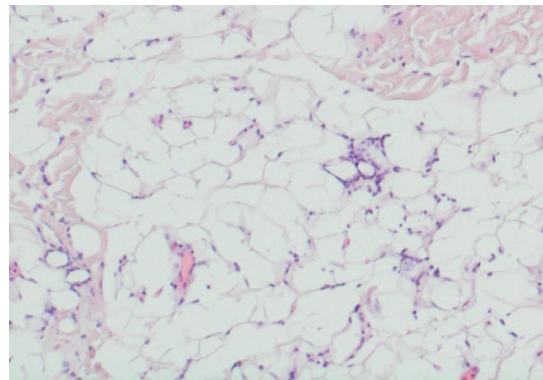
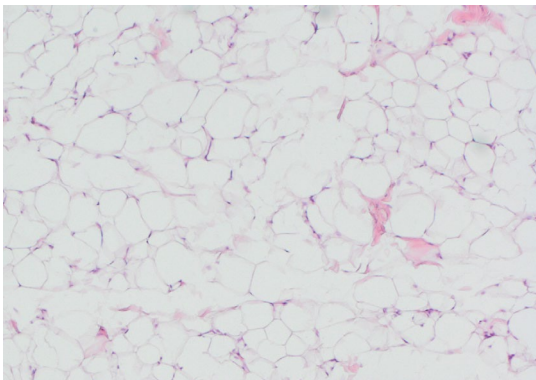
Healthy fat cells with well-defined shape at the baseline (left); shrunk adipocytes with noticeable membrane ruptures occurred at 4 days (center); disrupted adipocytes with extrusion of lipid droplets at two weeks (right)

STUDY DESIGN

- 7 Large White pigs (approximately 6 months old).
- All animals received three 30-minute treatments applied to abdomen.
- Biopsy specimens of fat tissue were collected at baseline, 4 days, 2 weeks, 1 month and 2 months post-treatment for each animal.
- Control specimens were collected from the site opposite to the treatment site.
- Evaluation included scanning electron microscopy and histology.

CONCLUSION

- The procedure elevates the **temperature** in subcutaneous fat to levels **necessary** for **apoptosis induction**.
- **Efficacy** of the procedure for **adipocytes deletion** was documented in **252** analyzed tissue slices.
- Mild inflammatory response was present to promote the **apoptotic death cells removal**.
- The procedure was **safe, no burns, no necrosis** or other adverse events were documented.



Baseline histology (left) showed adipocytes without any damage. At 2 weeks (right), flattened adipocytes with delaminated membranes are seen along with immune cells clearing the damaged tissue.

SYNCHRONIZED RF & HIFEM: MULTI-CENTER ABDOMINAL MRI STUDY

EFFICACY AND SAFETY OF SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY FOR ABDOMINAL FAT REDUCTION AND MUSCLE TONING: A MULTI-CENTER MRI EVALUATION STUDY

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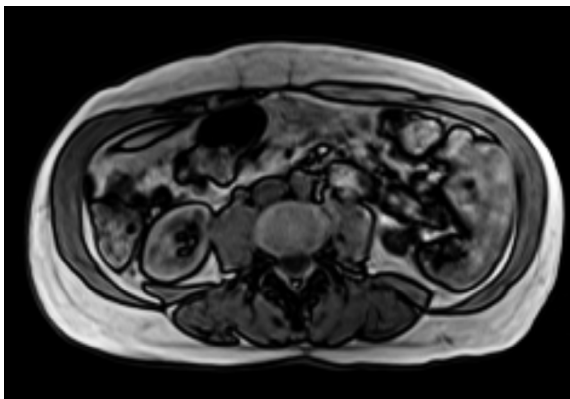
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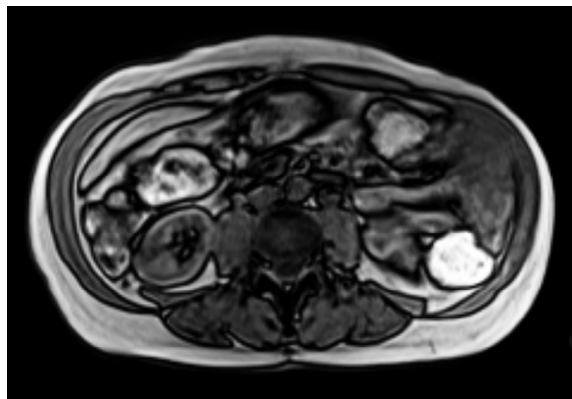
HIGHLIGHTS

- Study included **41 subjects** (22-62 y/o, BMI 21.2-34.3 kg/m²).
- MRI assessment showed **30.8% reduction in subcutaneous fat** and **26.1% increase in muscle thickness at 3 months**.
- **Abdominal separation decreased by 19.8% at 6 months**.
- **Waist circumference was reduced by 5.9 and 6.7 cm at 3 and 6 months**.

BASELINE



3 MONTHS AFTER



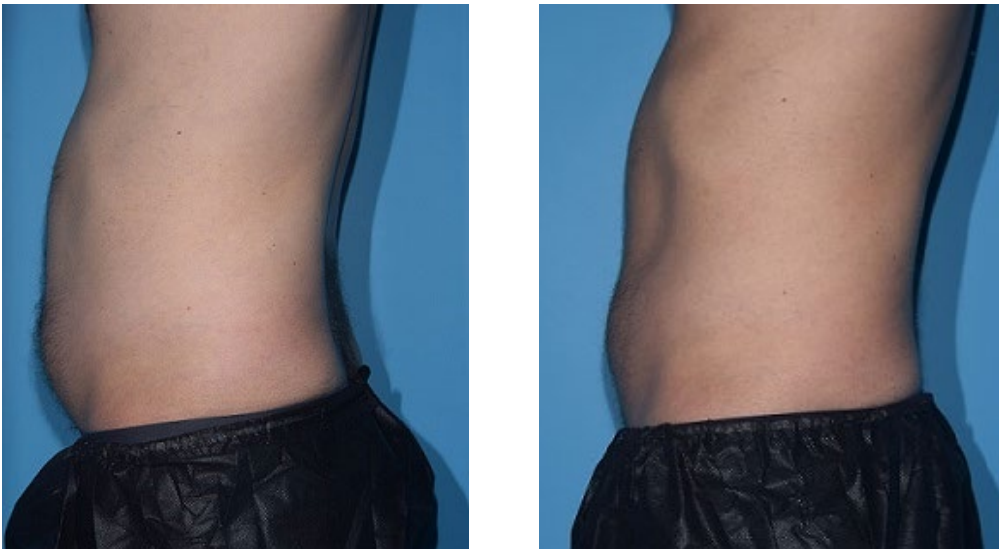
MRI scans of a 62-year old female showing 30% muscle thickening, 29.2% reduction in abdominal separation, 45.6% fat reduction and 5.8 cm reduction in waist circumference.

STUDY DESIGN

- All subjects received three 30-minute treatments on abdomen.
- MRI images were taken at baseline, 1M, 3M and 6M post-treatment.
- Waist circumference, subject satisfaction and therapy comfort were assessed.

CONCLUSION

- **Simultaneous application of RF and HIFEM enhances the fat reduction and boosts up the muscle thickening effect.**
- **Simultaneous application is more effective than using only HIFEM energy.**
- **The treatments were comfortable.**
- **94% of subjects were satisfied with treatment results.**



Digital photographs of a 34-year old male, taken before (left) and after (right) the treatment.

SYNCHRONIZED RF & HIFEM: MULTI-CENTER ABDOMINAL ULTRASOUND STUDY

RADIOFREQUENCY HEATING AND HIFEM DELIVERED SIMULTANEOUSLY - THE FIRST SHAM-CONTROLLED RANDOMIZED TRIAL

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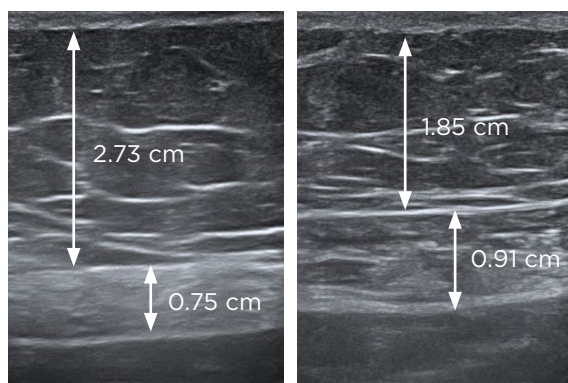
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Accepted for publication in Plastic and Reconstructive Surgery journal, 2021

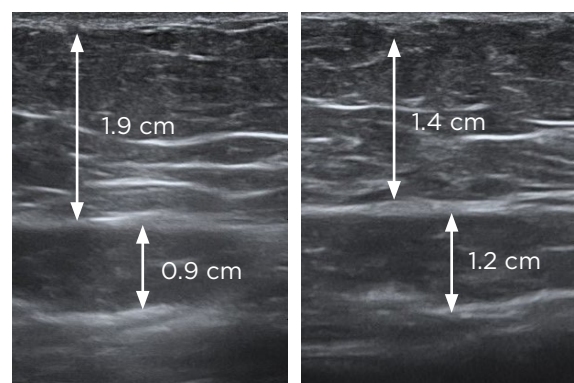
HIGHLIGHTS

- A total of 72 subjects allocated into two groups (Active: N=48, BMI 19.5–34.3 kg/m²; Sham: N=24, BMI 18.8–32.5 kg/m²).
- Active group showed **28.3% reduction in subcutaneous fat at 3-month** follow-up visit.
- **Muscle thickness increased by 24.2% at 3-months** post-treatment in **active group**.
- The results were maintained up to **6 months**.

A 64-YEAR OLD FEMALE



A 51-YEAR OLD FEMALE



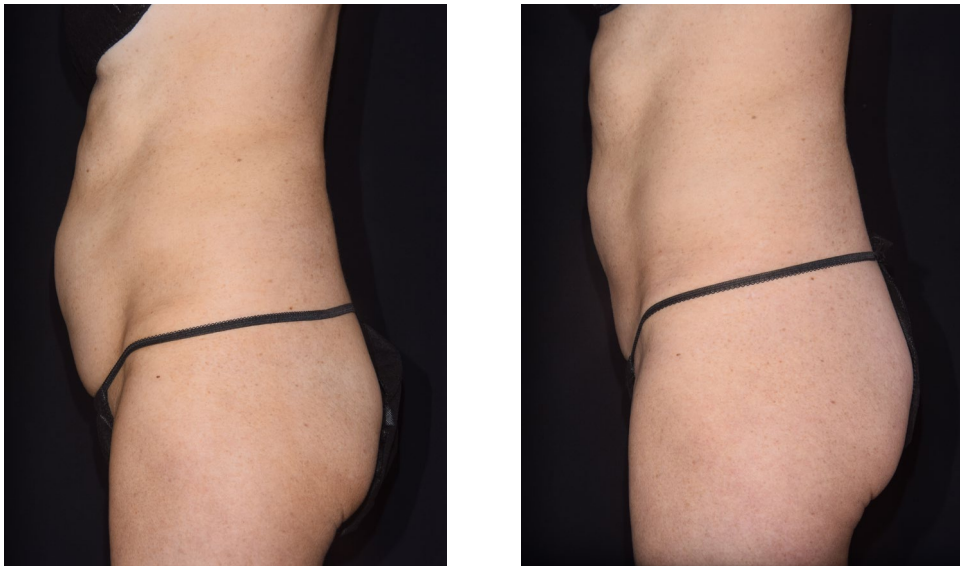
Ultrasound images of patients in active group taken before (left) and 1 month after (right) the treatments.

STUDY DESIGN

- Both groups received three 30-minute treatments on abdomen (active: maximum tolerable intensities, sham: intensities of 5%).
- Ultrasound images were taken at baseline, 1M, 3M and 6M after the last treatment.
- Evaluation included measurements of subcutaneous fat and muscle mass thickness.

CONCLUSION

- **Dual field technology** showed **high efficacy** for subcutaneous fat **reduction** and thickening of **rectus abdominis muscle**.
- **93.9%** of patients reported satisfaction with the results.
- **Sham treatments did not induce any significant changes.**
- **The procedure** combining HIFEM and RF energy **was safe** and did not cause any adverse events.



Digital photographs of a 55-year old female, taken before (left) and 3 months after (right) the treatments.

SYNCHRONIZED RF & HIFEM: ACTIVATION OF MYOSATELLITE CELLS

ACTIVATION OF SKELETAL MUSCLE SATELLITE CELLS BY A DEVICE SIMULTANEOUSLY APPLYING HIFEM TECHNOLOGY AND NOVEL RF TECHNOLOGY: FLUORESCENT MICROSCOPY FACILITATED DETECTION OF NCAM/CD56

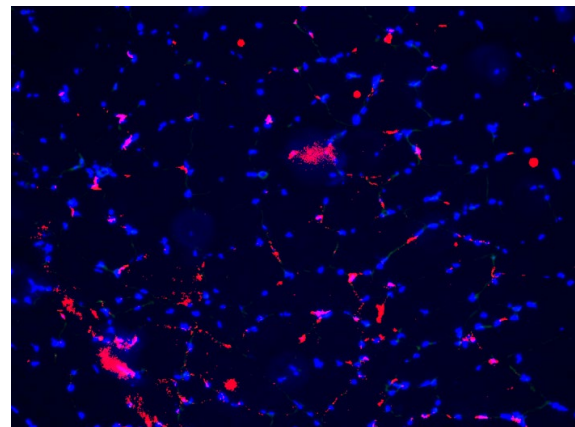
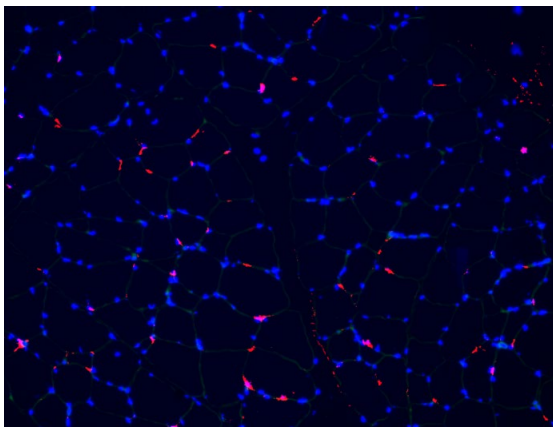
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Stara Zagora, BG

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HIGHLIGHTS

- The study was primarily focused on **Satellite cells** (muscle stem cells) that differentiate to **form new muscle fibers** or new myonuclei **supporting growth** of existing fibers.
- The levels of **satellite cells** increased by **30.2%** at 2 weeks FU.
- Histology images showed **hypertrophic fibers** and **newly formed myofibers**.
- The **muscle temperature** was between **40 - 41°C** during the whole procedure.
- The observed **results** are equivalent to **12-16 weeks of intense** exercise programs.



Immunofluorescence images captured at baseline (left) and 2 weeks post-treatment (right) showing an increase in the satellite cell levels. The satellite cells are stained by red color. Blue color represents the myonucleus.

STUDY DESIGN

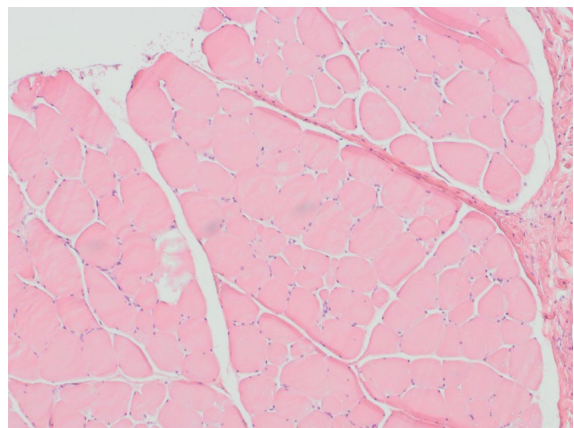
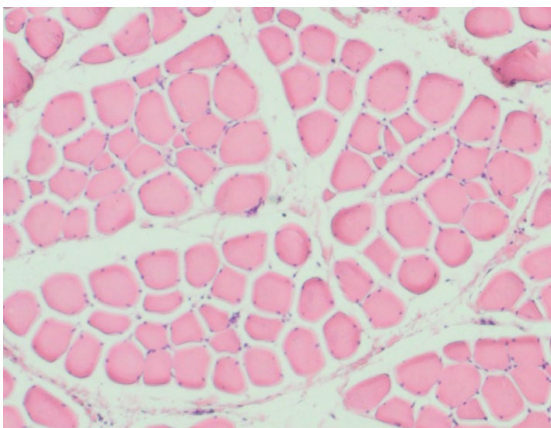
- 5 Large White pigs (approximately 6 months old).
- All animals received **three 30-minute** treatments applied to **half** of the abdomen (1 tx per week).
- The **opposite site** of the abdomen was used as a **control area**.
- A total of **275 histological** slices were processed.



1 biopsy specimen ($\phi 6\text{mm}$) was collected from the treatment site and 1 from control site at baseline, 4 days, 2 weeks and 1 month after the last treatment

RESULTS

- **Increased levels** of satellite cells suggested **formation of new muscle fibres** and corresponded to the **hypertrophic changes**.
- **Procedure** based on stimulating and heating muscle tissue is **effective, safe and does not cause any muscle damage**.



Tissue images collected 1 month after treatments (right) showing pronounced thickening of muscle fibers and increased density of muscle tissue when compared to baseline (left).

SYNCHRONIZED RF & HIFEM: VISCERAL FAT STUDY

VISCERAL FAT REDUCTION WITH SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY ENERGIES RETROSPECTIVELY ASSESSED FROM MRI SCANS

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Accepted at American Society for Laser Medicine and Surgery 2022, San Diego, CA

HIGHLIGHTS

- 40 patients (22-62 years, BMI 21.2-34.3 kg/m², Skin types I-VI) underwent three 30-minute treatments over the abdomen
- The MRI evaluation showed an average **reduction of -17.8%** (15.8 cm²) in visceral adipose tissue (VAT)
- The reduction in visceral fat was **homogeneous** throughout the abdomen and there were no non-responders
- The effect was maintained up to a 6-month follow-up **(-17.3%)**

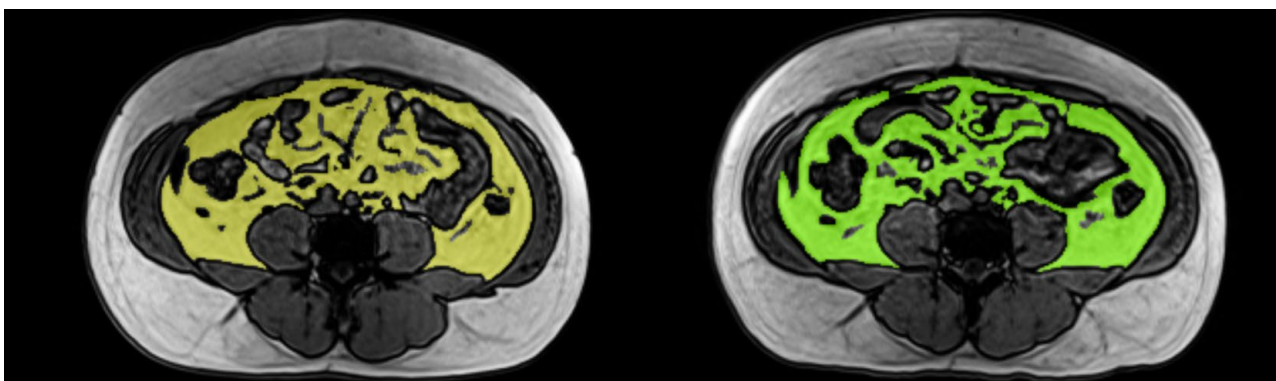


Figure 1: Visualization of visceral fat reduction, MRI image of a 34-year-old male taken at baseline (left) and at 3-month follow-up (right, a 16.4% reduction of VAT).



Figure 2: A digital photographs of 34-year-old male were taken at baseline (left) and 1-month follow-up (right, a 14.5% reduction of VAT).



Figure 3: A digital photographs of a 57-year-old male with a BMI of 32.8kg/m² taken at baseline (left) and a 1-month follow-up visit (right, an average VAT reduction of 17.0%).

SYNCHRONIZED RF & HIFEM: FULL BODY REMODELING

CONCOMITANT USE OF RADIOFREQUENCY AND HIGH INTENSITY FOCUSED ELECTROMAGNETIC FIELD ENERGIES FOR FULL-BODY REMODELING: MRI-EVIDENCE BASED PREFATORY TRIAL

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Accepted for publication in Journal of Cosmetic Dermatology, 2022

HIGHLIGHTS

- **Four HIFEM & RF procedures** were consecutively applied to abdomen, lateral and inner thighs, and buttocks during each treatment visit
- Substantial **reduction in fat thickness** was found in abdomen (-10.7 mm), lateral thighs (-17.6 mm), and inner thighs (-12.4 mm) at 3-month follow-up
- Abdominal and gluteal muscles showed **significant thickening** by +3.0 mm and 7.4 mm, respectively
- Treatments were comfortable and no AE occurred throughout the study

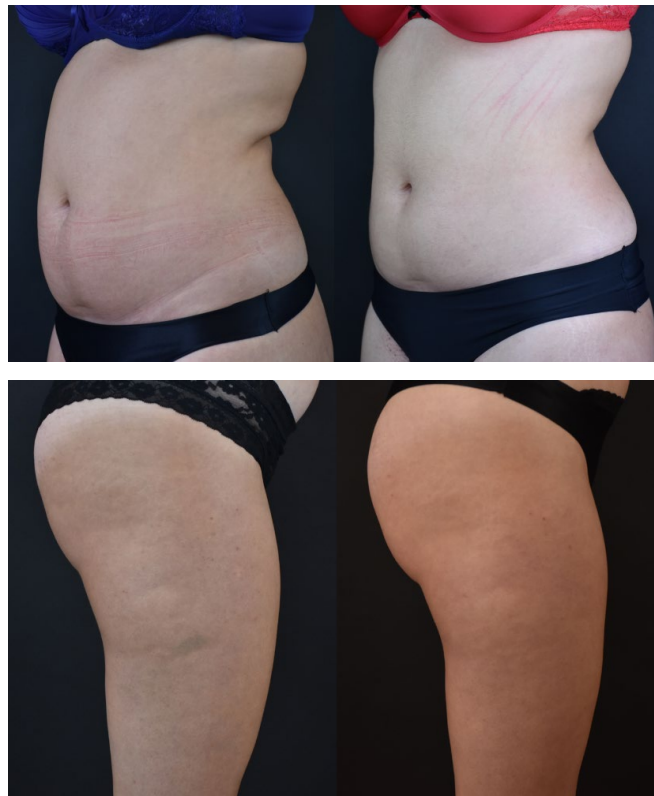


Figure 1: Digital photographs taken at baseline (left) and 3 months (right) illustrates the gradual progress in the shape of abdomen (up) and buttocks (down).

SYNCHRONIZED RF & HIFEM: HUMAN FAT HISTOLOGY & TEMPERATURE MEASUREMENT

ADIPOCYTE APOPTOSIS INDUCED BY SYNCHRONIZED RADIOFREQUENCY WITH HIFEM PROCEDURE: HUMAN HISTOLOGICAL STUDY

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Presented at the Annual Meeting of the American Society for Dermatologic Surgery, 2020 Virtual Meeting.

HIGHLIGHTS

- Documented **disrupted** adipocytes due to **elevated apoptosis**.
- **Elimination** of adipocytes and **significant reduction in size** of fat cells resulting in **overall reduction** of fat tissue.
- **Effective temperature** needed for apoptotic processes was reached in **4 minutes**.
- **Waist circumference decreased** on average by **2.2 cm (maximum of 5.4 cm)**.
- Procedure was **safe and comfortable** with high satisfaction.

BASELINE



1 MONTH AFTER



A 57-year old female at baseline and 1 month post-treatment showing prominent aesthetic improvement.

STUDY DESIGN

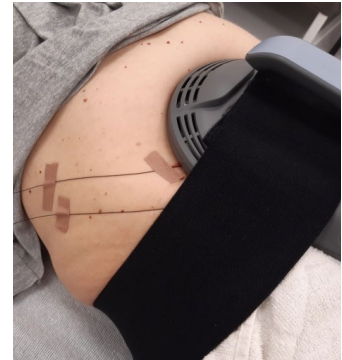
- Four treated subjects, fifth received sham treatments and served as a control.
- Three 30-minute treatments on abdomen.
- Collected biopsy specimens were histologically examined.
- Evaluation was performed at baseline, 1 week and 1 month post-treatment.



Punch biopsies (Ø 6mm) were taken from the treated area, sectioned to 5-10 µm thick slices and stained by H&E.

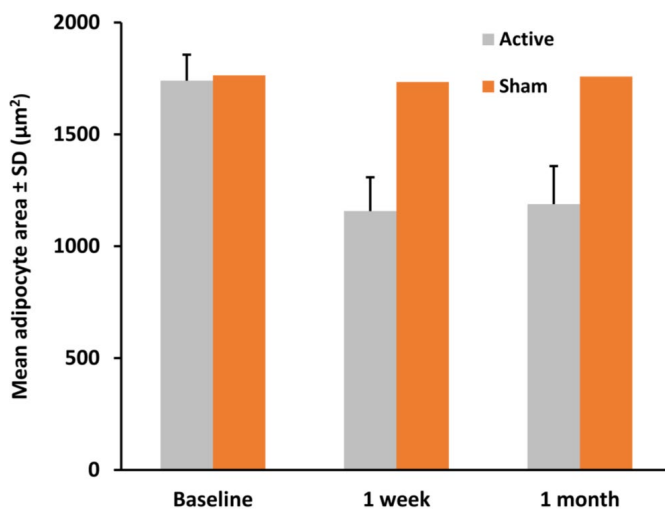


Optical probes were inserted into the subcutaneous layer under ultrasound guidance for in-vivo monitoring of temperature during the 30-minute.

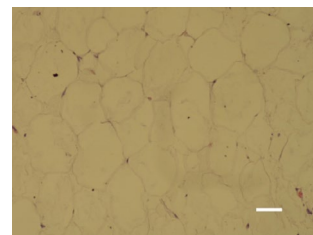


RESULTS

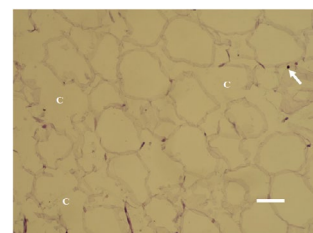
- Adipocyte size was reduced by up to **33.5% at 1 week post-treatment**.
- **Baseline and control (sham) samples did not show any changes in fat tissue.**



Adipocyte size measurement



Baseline histology, bar = 40 µm



1 month, bar = 40 µm; Apoptotic nuclei (arrow) and cystic spaces due to the membrane rupture (C).

SYNCHRONIZED RF & HIFEM: BUTTOCK MRI STUDY

HIFEM WITH SYNCHRONIZED RADIOFREQUENCY ACHIEVES SUPERIOR GLUTEAL MUSCLE CONTOURING THAN HIFEM PROCEDURE ALONE

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JD McCoy, NMD⁴; Suneel Chilukuri, MD, FAAD, FACMS⁵

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Accepted at American Society for Laser Medicine and Surgery 2022, San Diego, CA

HIGHLIGHTS

- 67 subjects (21-67 years, 16-34 kg/m², skin type I-VI) were divided into HIFEM+RF group (n=34) and Standalone HIFEM group (n=33), both receiving four 30-minute therapies
- MRI evaluation showed a **35.6% higher** growth of gluteal muscles measured in HIFEM+RF group than Standalone HIFEM group
- Group HIFEM+RF showed an average **+24.7% increase**, while standalone HIFEM group showed an average 15.9% increase in muscle thickness at 3 months follow-up visit
- There was no significant reduction in subcutaneous fat thickness in the gluteal area (p-value>0.05)

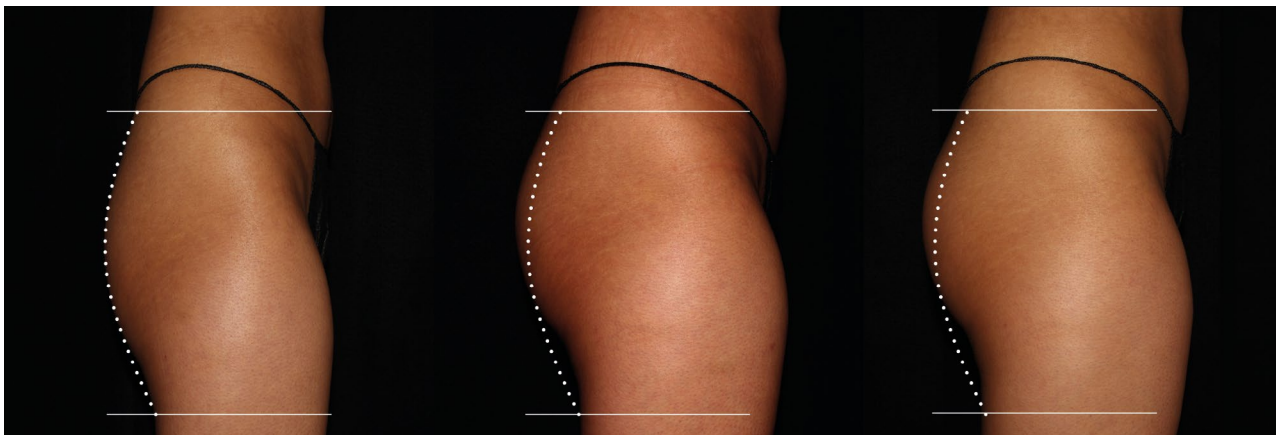


Figure 1: A 21 year old woman treated with combination RF+HIFEM, digital photographs were taken at baseline (left), after the 4th treatment (middle), at 3-month follow-up (right, a 22.8% increase in muscle mass), the dotted line shows the shape of the buttocks at baseline.

SYNCHRONIZED RF & HIFEM: INTERIM RESULTS OF INNER THIGHS MRI STUDY

EFFICACY AND SAFETY OF SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY FOR NON-INVASIVE LIPOLYSIS IN INNER THIGHS: PRELIMINARY DATA

Diane Duncan MD, F.A.C.S¹

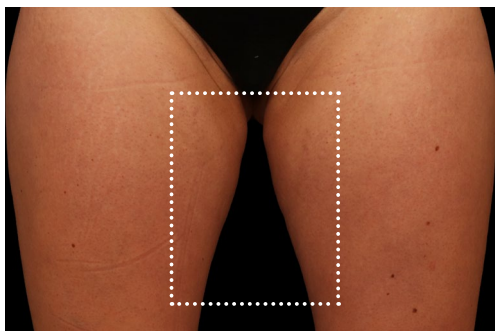
1. Plastic Surgery Associates, Fort Collins CO, USA

Interim data from ongoing clinical study, ClinicalTrials.gov Identifier: NCT04596228

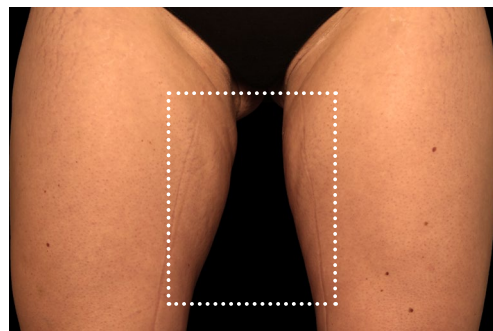
HIGHLIGHTS

- **16 subjects** (24-69 y/o; BMI 21.3-35.0 kg/m²) received four 30-minute treatments.
- MRI showed an average **fat thickness reduction by 0.84 cm** at 1 month (N=15) and **1.02 cm** at 3 months (N=6), respectively.
- Thigh **circumference decreased** on average by **1.0 cm** at 1 month.
- **94%** of patients reported **satisfaction** with the treatment results.

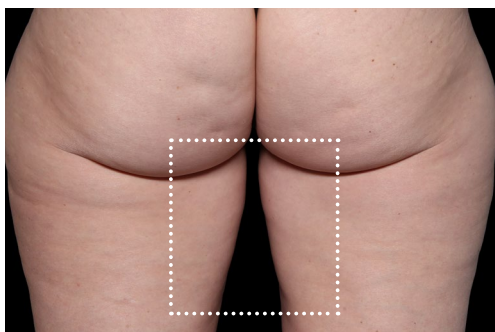
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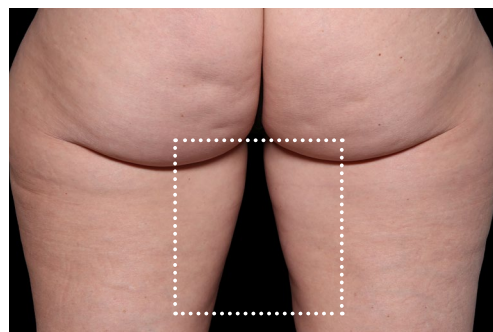
1 MONTH FOLLOW-UP



BASELINE



AFTER THE LAST TREATMENT



Courtesy of: Diane Duncan, M.D.

SYNCHRONIZED RF & HIFEM: OUTER THIGHS MRI STUDY

SPOT REDUCTION OF LOCALIZED FAT DEPOSITS ON THE LATERAL THIGHS BY SIMULTANEOUS EMISSION OF SYNCHRONIZED RADIOFREQUENCY AND HIFEM ENERGY: MAGNETIC RESONANCE MULTICENTRE STUDY

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Accepted at the Annual Meeting of the Vegas Cosmetic Surgery 2022

HIGHLIGHTS

- 93 subjects (21-70 years, 19.0-34.5 kg/m², skin type I-VI) underwent four 30-minute treatments on lateral thighs, changes evaluated **via MRI**
- MRI showed a **29.9%** (-1.8 cm) **reduction** in fat thickness in the lateral thighs at 3 months
- The average thigh circumference reduction was **-3.5 cm**
- 82% of patients were satisfied with the results
- 84% of patients felt more toned post-treatment



Figure 1: A visible reduction of the saddlebag area of a 49-years old woman, photographs were taken at baseline (left) and 1-month follow-up (right). The dotted line visualizes the change in lateral thigh contour.



Figure 2: The MRI scans of a 40-year-old female patient showing reduction in subcutaneous fat thickness post treatment (-19.6 mm, right) compared to baseline (left).



Figure 3: A 40-years old woman with a BMI of 24.6 kg/m², photos taken at baseline (left), 3-month follow-up (middle; -21.2 mm), and 6-month follow-up (right; -20.9 mm).

SYNCHRONIZED RF & HIFEM: HUMAN FAT HISTOLOGY & TEMPERATURE MEASUREMENT

DELETION OF ADIPOCYTES INDUCED BY A NOVEL DEVICE SIMULTANEOUSLY DELIVERING SYNCHRONIZED RADIOFREQUENCY AND HIFEM: HUMAN HISTOLOGICAL STUDY

David J. Goldberg MD, JD¹

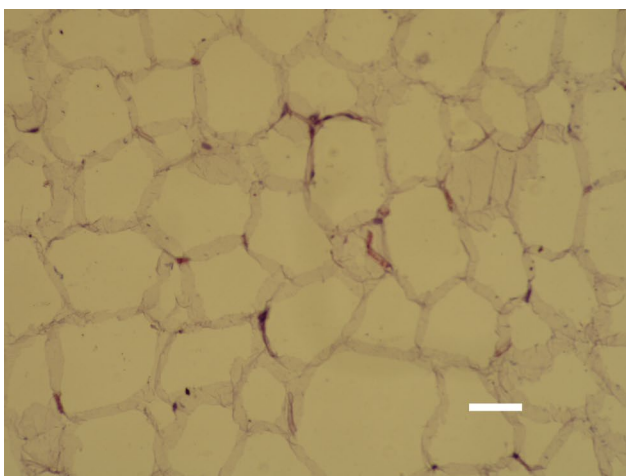
1. Icahn School of Medicine, New York, NY, USA

Published in the Journal of Cosmetic Dermatology, February 2021, DOI: 10.1111/jocd.13970

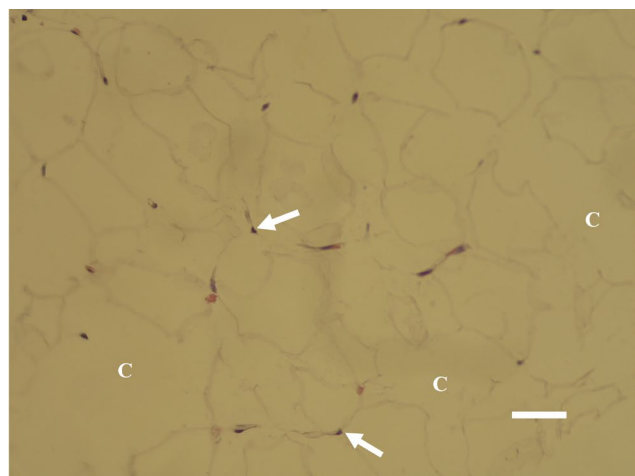
HIGHLIGHTS

- **Elimination** of adipocytes and **significant reduction in size** of fat cells resulted in **overall reduction** of fat tissue.
- **Effective temperature** needed for apoptotic processes was reached in **4 minutes**.
- Adipocyte size was reduced by **33.5%** ($P < 0.05$) at **1 week post-treatment**.
- Sham subject **did not show** any changes in fat tissue.

CONTROL



1 WEEK AFTER



Elimination of fat cells (C), noticeable shape alternations, and pyknotic nuclei (depicted by an arrow) found in the treated adipose tissue at 1 week (right, bar = 30 μm). No changes were found in control/sham subject (left, bar = 30 μm).

SYNCHRONIZED RF & HIFEM: UPPER ARMS MRI STUDY

SIMULTANEOUS HIFEM AND SYNCHRONIZED RF PROCEDURE CAN BE EFFECTIVELY USED FOR UPPER ARM TONING AND STRENGTHENING

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Accepted at American Society for Laser Medicine and Surgery 2022, San Diego, CA

HIGHLIGHTS

- 34 subjects (23-72 years old, BMI 18.5-33.9 kg/m²) received four 30-minute treatments
- **Fat thickness** was reduced significantly by **25.5%** (0.5±0.1cm) at 3-month follow-up visit.
- The average increase in **triceps muscle thickness** at 3 months was **23.9%** (0.9±0.2cm)
- 87% of patients reported satisfaction with treatment results

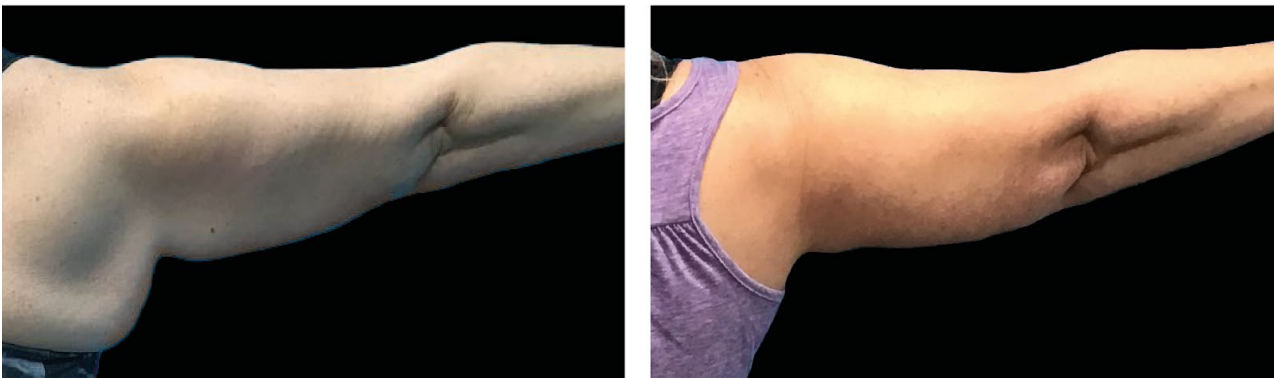


Figure 1: At baseline, the subject showed greater amount of upper arm adiposity, which hung rather loosely. 3-month photographs show upper arm tightening accompanied by marked decrease in arm fat.

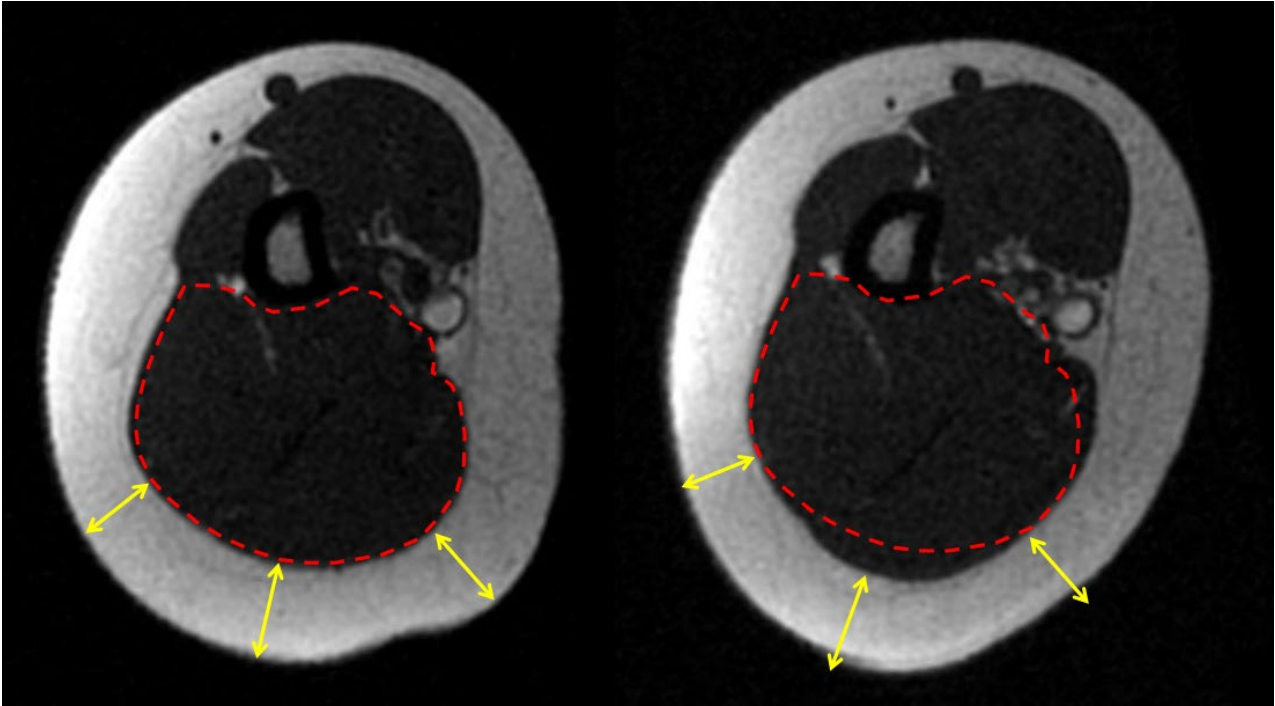


Figure 2: MRI scan showing difference in triceps muscle (red outlined area) and subcutaneous fat layer (yellow arrows) before (left) and 3 months after (right) treatment. The muscle increased in volume noticeably whereas the fat layer thickness reduced.



Figure 3: Female at baseline (left) and 3 months after treatment (right). Compared to baseline, this subject shows better triceps muscle definition and improved upper arm tone.

SYNCHRONIZED RF & HIFEM: INNER THIGHS MRI STUDY

SAFETY AND EFFICACY OF SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY FOR NON-INVASIVE FAT REDUCTION AND MUSCLE TONING IN INNER THIGHS: MAGNETIC RESONANCE IMAGING EVALUATION

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Accepted at American Society for Laser Medicine and Surgery 2022, San Diego, CA

HIGHLIGHTS

- 16 subjects (24-69 years old; BMI 21.3-35.0 kg/m²) received four treatments
- **Fat thickness was reduced** significantly by **27.4%** (1.01±0.17cm) at 3 months follow-up visit
- The average increase in **muscle thickness** was **23.2%** at 3-month follow-up visit
- **94%** of patients reported satisfaction with the treatment results

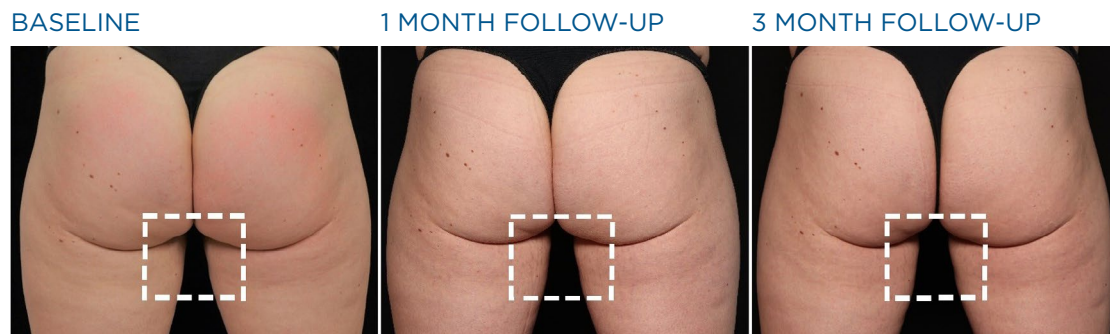


Figure 1: Inner thigh fat loss resulted in a wider gap between the thighs (back view).

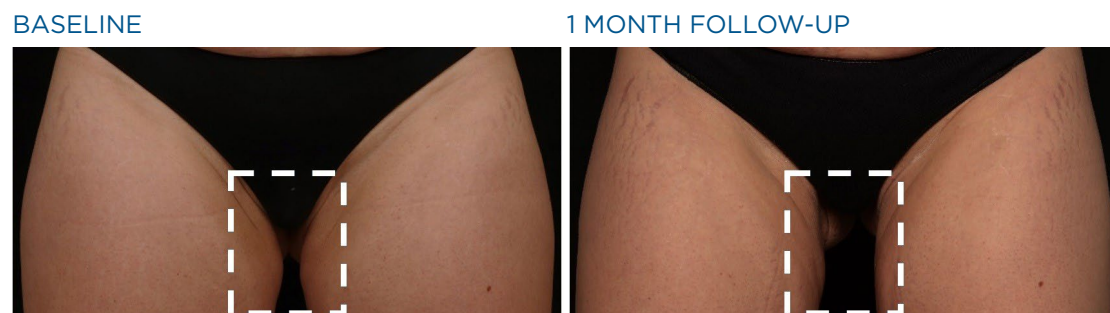


Figure 2: Inner thigh fat reduction at 1-month post-treatment (front view) showing noticeable improvement in both limbs.

SYNCHRONIZED RF & HIFEM: HUMAN BLOOD DRAW SAFETY STUDY

SAFETY OF SIMULTANEOUS APPLICATION OF RADIOFREQUENCY SYNCHRONIZED WITH HIFEM PROCEDURE FOR FAT REDUCTION IN MULTIPLE BODY PARTS TREATED ON THE SAME DAY VERIFIED BY PLASMA ANALYSIS OF LIVER AND LIPID PROFILES

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Accepted at American Society for Laser Medicine and Surgery 2022, San Diego, CA

HIGHLIGHTS

- Ten patients (24-59 years) underwent multiple lipolysis treatments with synchronized RF and HIFEM treatments **on the same day** for four weeks.
- 40 blood samples were drawn and evaluated
- The lipid panel and liver function test showed **no significant changes** post treatments.
- No adverse events occurred, patients found the treatment comfortable with high satisfaction with the results (**4.7 ± 0.5 points** on a 5-point Likert scale)

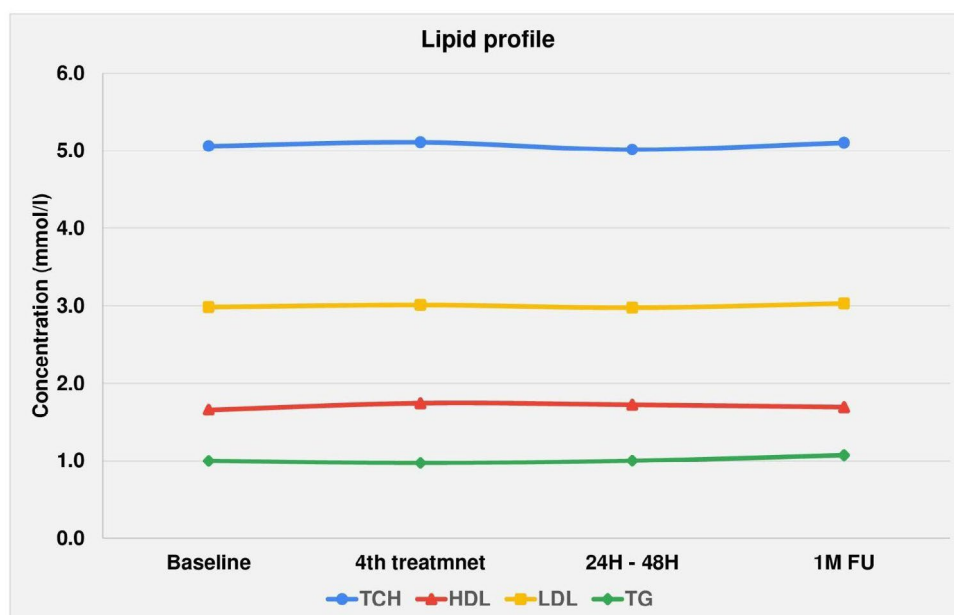


Figure 1: lipid profile shows no relevant fluctuation in any of the measured analytes (TCH = total cholesterol, HDL= high-density lipoprotein, LDL= low-density lipoprotein, TG = triglycerides).

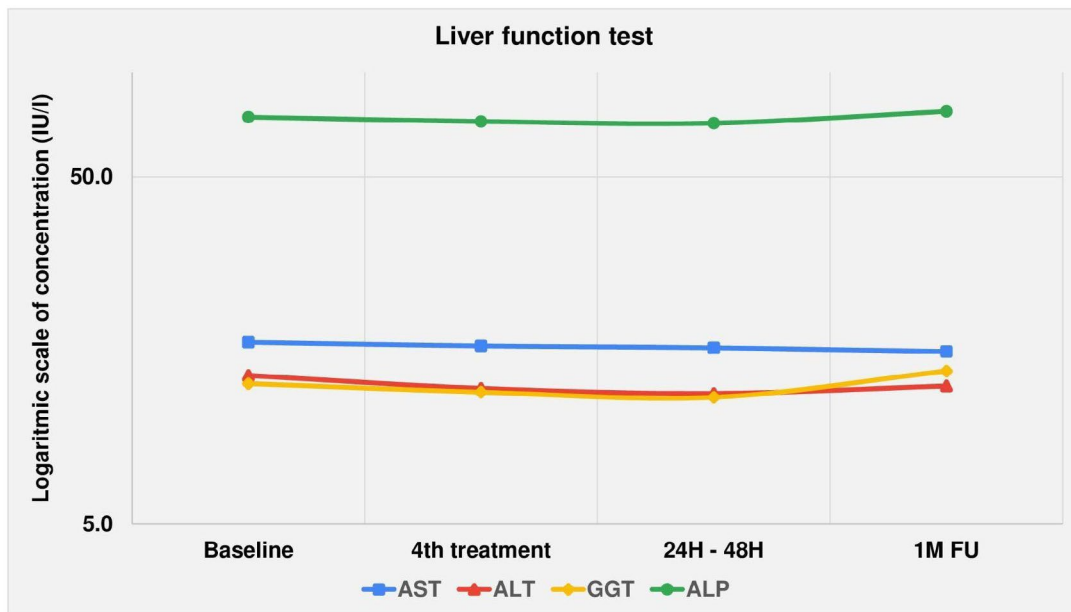


Figure 2: Liver function test shows no relevant fluctuation in any of the measured analytes (ALT= alanine aminotransferase, AST = aspartate aminotransferase, ALP = alkaline phosphatase, GGT = gamma-glutamyl transferase).

Lipid panel (TCH, HDL, LDL, TG): measure the amount of lipid in the bloodstream, elevated levels of lipids in the blood increase the chance of having a heart attack or stroke

Liver function test (ALT, AST, ALP, GGT): increased levels of these analytes in the bloodstream indicate liver damage

SYNCHRONIZED RF & HIFEM: ULTRASOUND EVALUATION OF FAT TISSUE

ULTRASOUND EVALUATION OF THE SIMULTANEOUS RF AND HIFEM TREATMENTS ON HUMAN FAT TISSUE

Radina Denkova MD¹

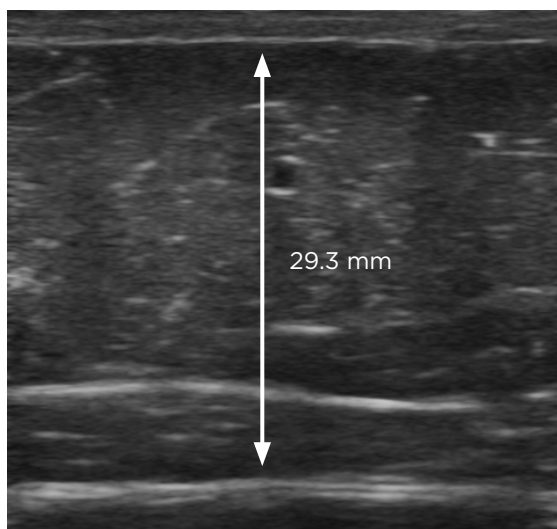
1. Aesthetic Clinic Beauty, Sofia, BG

Source: U.S. Food and Drug Administration. 510(k) Premarket Notification: K192224. Published online December 5, 2019.

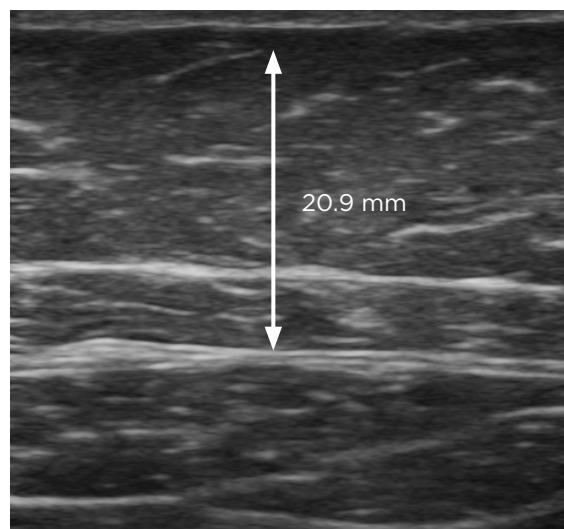
HIGHLIGHTS

- **Reduction in subcutaneous fat thickness at 3 months was 29.8%.**
- A total of **88.1%** of patients **were satisfied** with treatment outcomes.
- **92.9%** of patients found the treatments **comfortable**.
- **Waist circumference was reduced on average by 3.2 cm.**

BASELINE



3 MONTHS AFTER



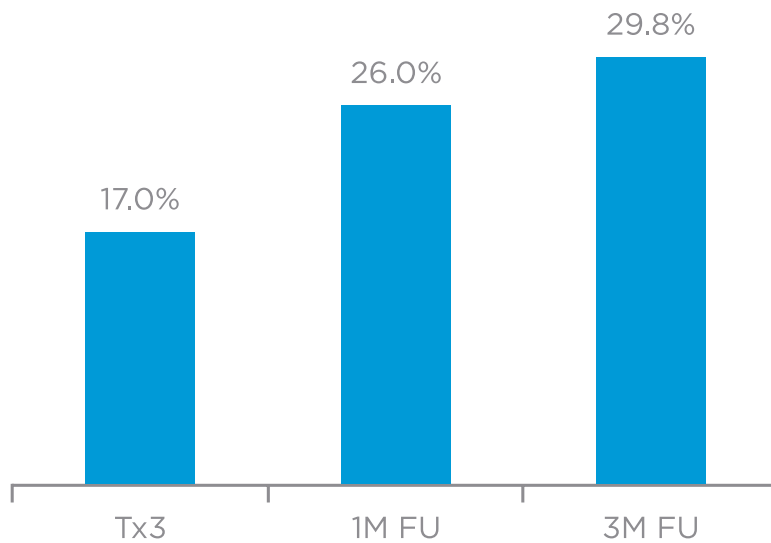
Ultrasound images of a 42-year old female, who also showed a 4-cm reduction in waist circumference.

STUDY DESIGN

- 42 subjects (29 females, 13 males).
- Three 30-minute treatments on abdomen.
- Evaluation by ultrasound imaging.

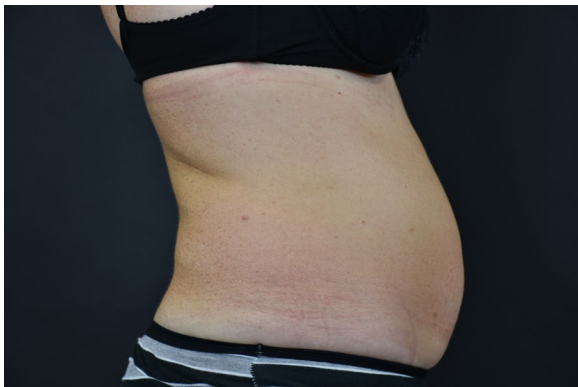
RESULTS

- Results showed continuous improvement over time.

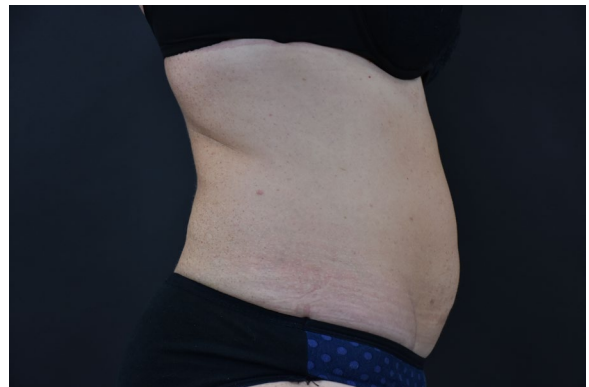


The chart showing continuous improvement in the fat reduction over time.

BASELINE



3 MONTHS AFTER



A 49-year old female at baseline and 3 months post-treatment showing 4.5 cm waist circumference reduction and 29.2% reduction in abdominal fat layer.