

# SYNCHRONIZED RF & HIFEM: HISTOLOGICAL EVALUATION OF THE EFFECT ON FAT IN HUMANS

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

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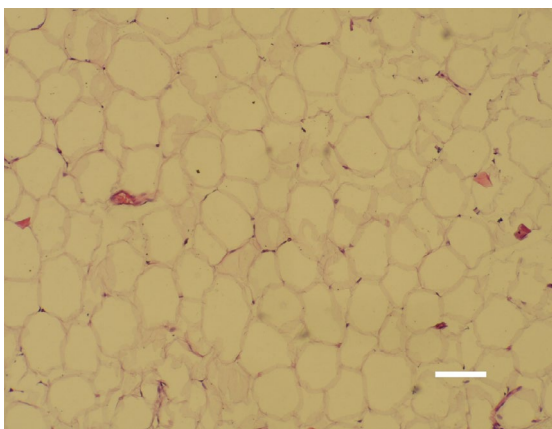
Source: U.S. Food and Drug Administration. 510(k) Premarket Notification: K192224. Published online December 5, 2019.

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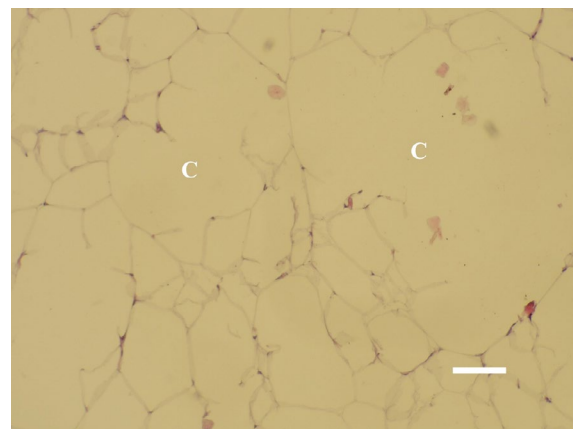
### HIGHLIGHTS

- Intensive fat cell disruption peaking at 20 days post-treatment.
  - Non-invasive lipolysis seen in the first 10 days post-treatment.
  - Investigated device was found to be effective for **elimination of fat cells**.
  - **No damage** to skin, sweat glands and sebaceous glands was observed, ensuring procedural safety.
  - **Deformed nucleus** and **pyknotic nucleus** indicating **cell death**.
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BASELINE



20 DAYS AFTER



Normal subcutaneous tissue morphology with typical uniform size of adipocytes at the left; bar = 40 micrometers. Intensive fat cell disruption (C) and alternation of adipocytes shape 20 days post-treatment at the right; bar = 30 micrometers.

# 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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3. Department of Anatomy and Histology, University of Veterinary and Pharmaceutical Sciences Brno, CZ

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

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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)

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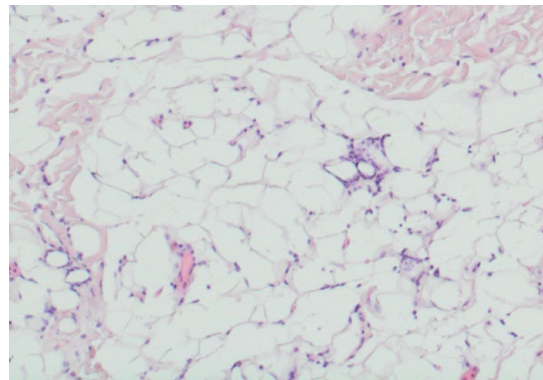
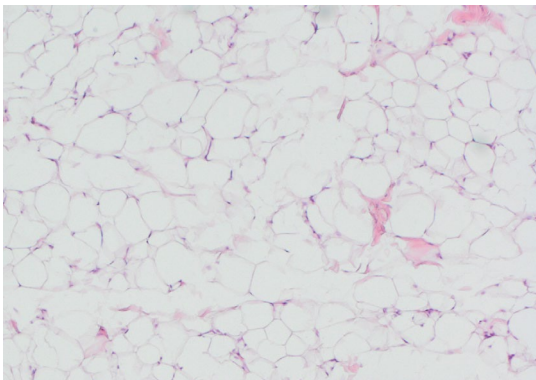
## STUDY DESIGN

- 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.

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## CONCLUSION

- The procedure elevates the **temperature** in subcutaneous fat to levels **necessary** for **apoptosis induction**.
- **Efficacy** of the procedure for **disruption of adipocytes** 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: ULTRASOUND EVALUATION OF FAT TISSUE

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

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

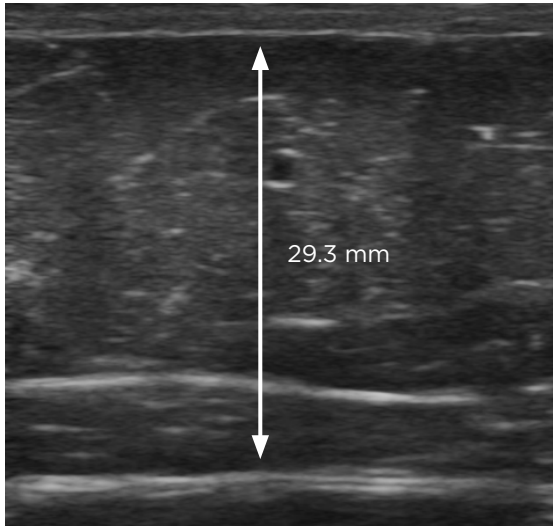
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### HIGHLIGHTS

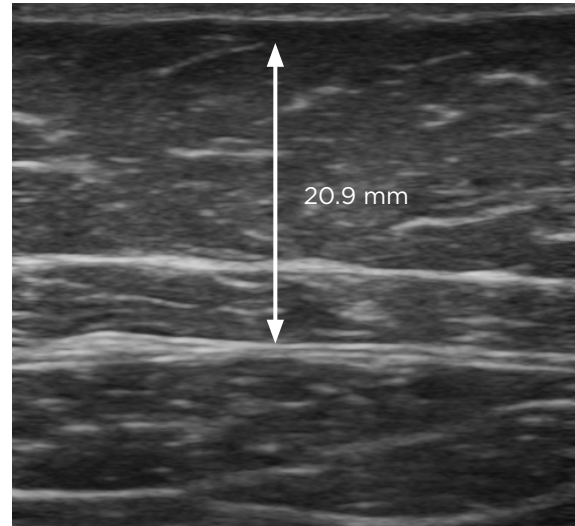
- **Reduction in subcutaneous fat thickness at 3 months was 29.8%.**
- A total of **88.1%** of patients **were satisfied** with treatment outcomes.
- **92.9%** of patients found the treatments **comfortable**.
- **Waist circumference was reduced on average by 3.2 cm.**

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BASELINE



3 MONTHS AFTER



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

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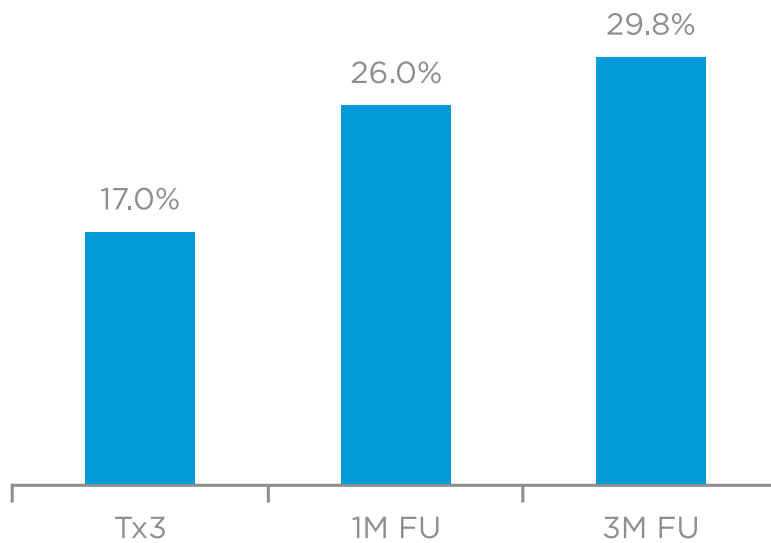
## STUDY DESIGN

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

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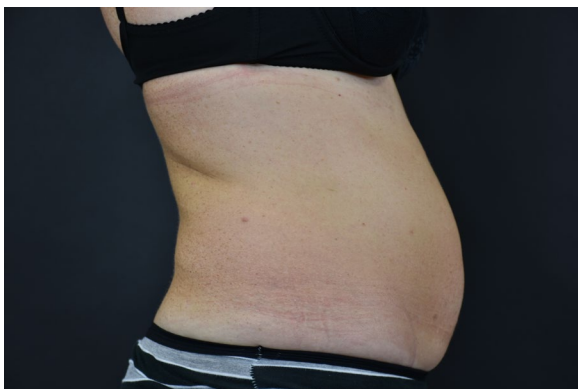
## RESULTS

- Results showed continuous improvement over time.

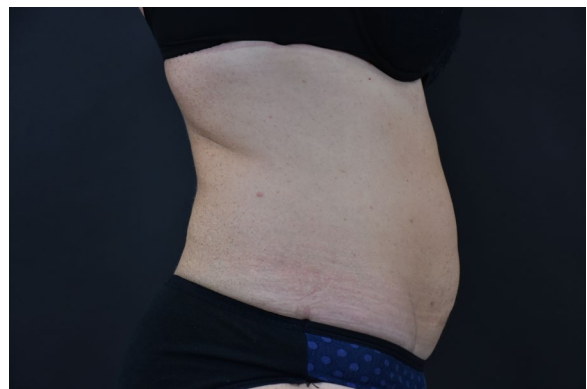


The chart showing continuous improvement in the fat reduction over time.

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.

# 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.

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### 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.

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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 ( $\varnothing$  6mm) were taken from the treated area, sectioned to 5-10  $\mu$ m thick slices and stained by H&E.

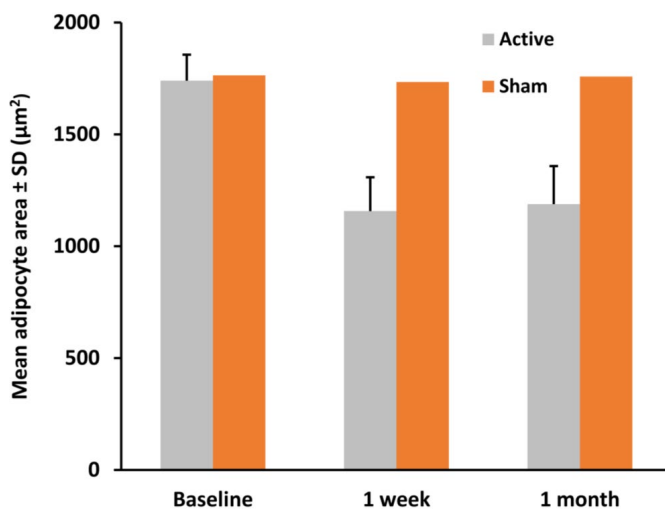


Optical probes were inserted into the subcutaneous layer under ultrasound guidance for in-vivo monitoring of temperature during the 30-minute.

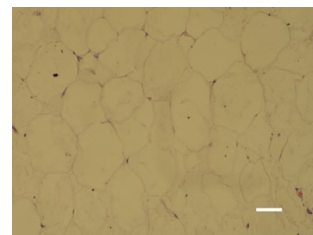


## RESULTS

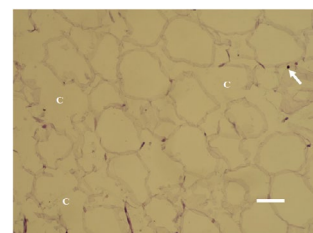
- Adipocyte size was reduced by up to **33.5%** at **1 week post-treatment**.
- **Baseline and control (sham) samples did not show any changes in fat tissue.**



Adipocyte size measurement



Baseline histology, bar = 40  $\mu$ m



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

# SYNCHRONIZED RF & HIFEM: ACTIVATION OF MYOSATELLITE CELLS

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

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MVDr. Petra Ondrackova Ph.D.<sup>3</sup>, Ivan Dinev DVM, Ph.D., DSc<sup>4</sup>

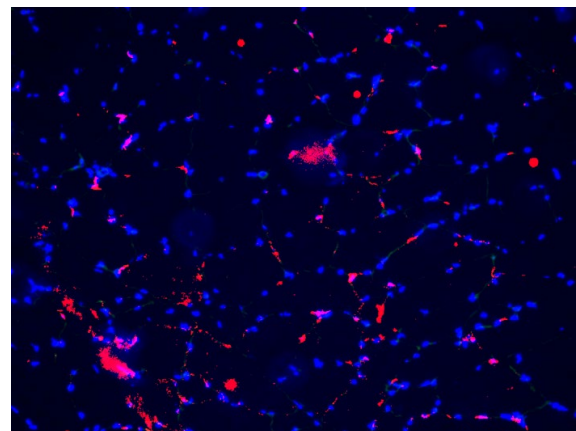
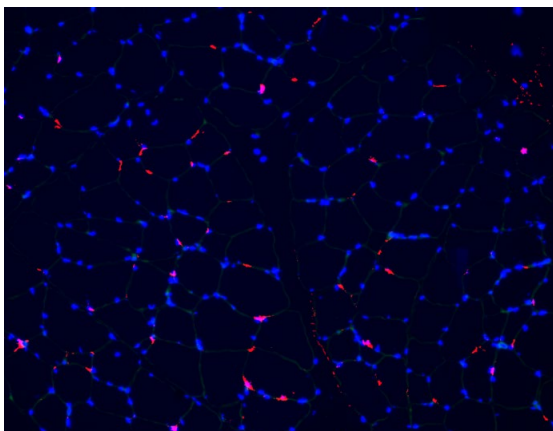
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Accepted for Oral Presentation at the Annual Meeting of the American Society for Laser Medicine and Surgery, 2020 Phoenix, AZ.

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### HIGHLIGHTS

- The levels of **satellite cells** increased by **30.2%** at 2 weeks post-treatment indicating muscle fiber growth and formation of new muscle fibers.
- Histological images showed **hypertrophic fibers** and signs of **newly formed myofibers**.
- The **muscle temperature** was between **40 - 41°C** during the whole treatment.
- The observed **results** are equivalent to **12-16 week** 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.



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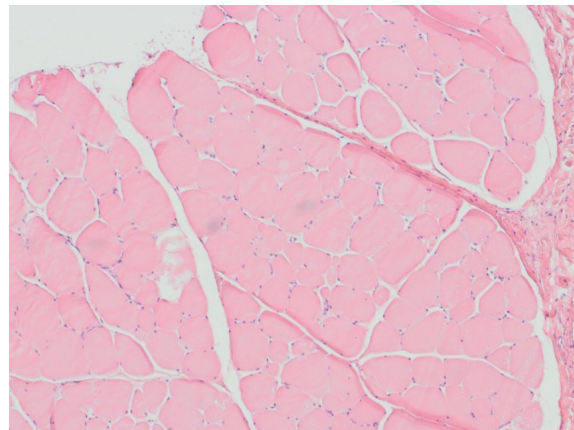
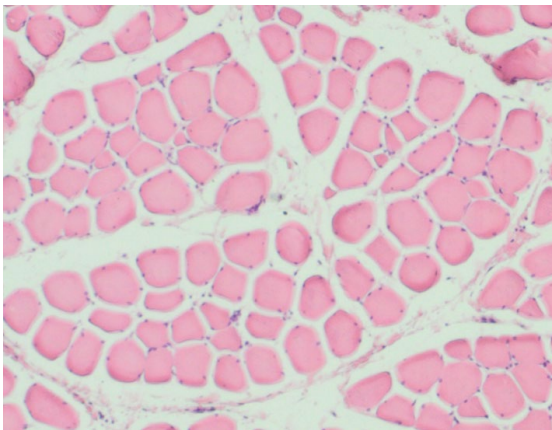
## STUDY DESIGN

- 5 Large White pigs (approximately 6 months old).
- All animals received three 30-minute treatments applied to abdomen (1 tx per week).
- Biopsies were collected at baseline, 4 days, 2 weeks and 1 month post-treatment. The **opposite site** of the abdomen was used as a **control area**.
- A total of **275 histological** slices were processed.
- Evaluation included monitoring of satellite cells levels (immunofluorescence), structural changes (histology) and muscle temperature (in-vivo thermal probe measurement).

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## CONCLUSION

- **Dual field therapy** significantly **increases** the levels of labeled **satellite cells**.
- The satellite cells appear to **form new muscle fibers** and incorporate into the existing muscle fibers to **create new myonuclei**.
- **Procedure** based on stimulating and heating muscle tissue **is 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: 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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Presented at the Annual Meeting of the American Society for Dermatologic Surgery, 2020 Virtual Meeting.

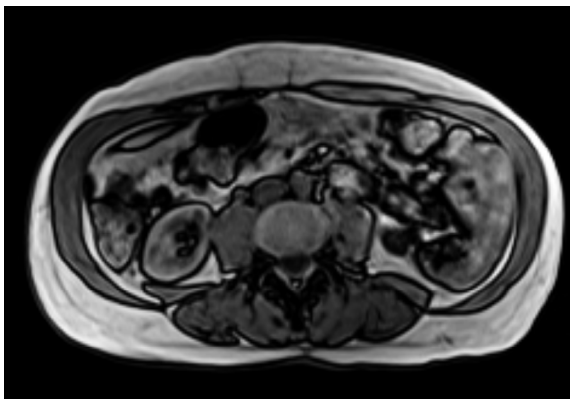
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### HIGHLIGHTS

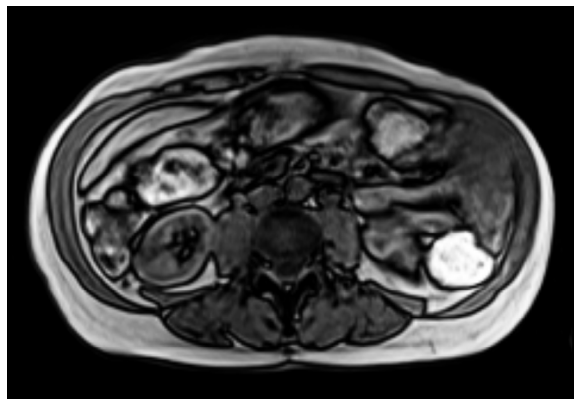
- Study included 41 subjects (average age 39.1).
- MRI assessment showed **30.8% reduction in subcutaneous fat** and **26.1% increase in muscle thickness at 3 months**.
- **Abdominal separation decreased by 18.8% at 3 months**.
- **Waist circumference was reduced by 5.9 cm at 3 months**.

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BASELINE



3 MONTHS AFTER



MRI scans of a 62-year old female showing 30% muscle thickening, 16.5% reduction in abdominal separation, 40.8% fat reduction and 6 cm reduction in waist circumference.

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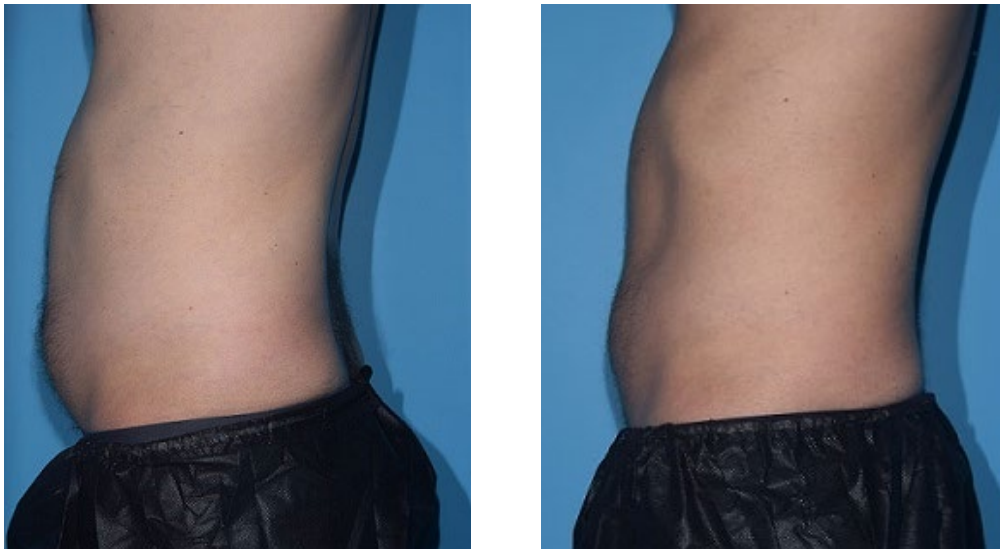
## STUDY DESIGN

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

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## 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 safe and comfortable.**
- **All of the patients were satisfied with the 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

**Bruce Katz MD<sup>1</sup>, Robert Weiss MD<sup>2</sup>, Julene B. Samuels MD<sup>3</sup> F.A.C.S**

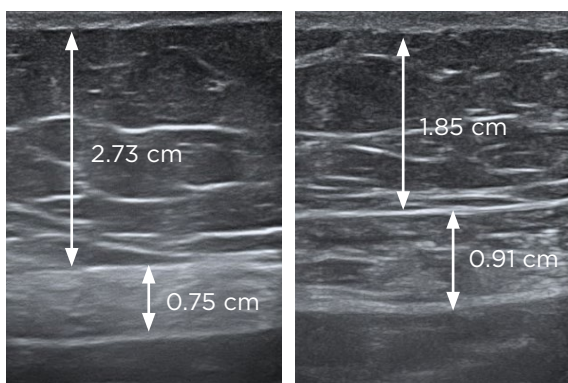
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3. Julene B Samuels MD. F.A.C.S, Louisville, KY, USA

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

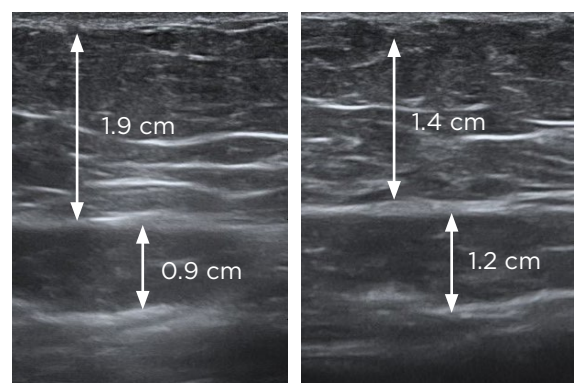
### HIGHLIGHTS

- A total of 72 subjects allocated into two groups (Active: N=48, **BMI of 25.8 kg/m<sup>2</sup>**); Sham: N=24, **BMI of 25.6 kg/m<sup>2</sup>**).
- 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.**
- At 3 months **38/40 patients** showed fat reduction **higher than 20%.**

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.

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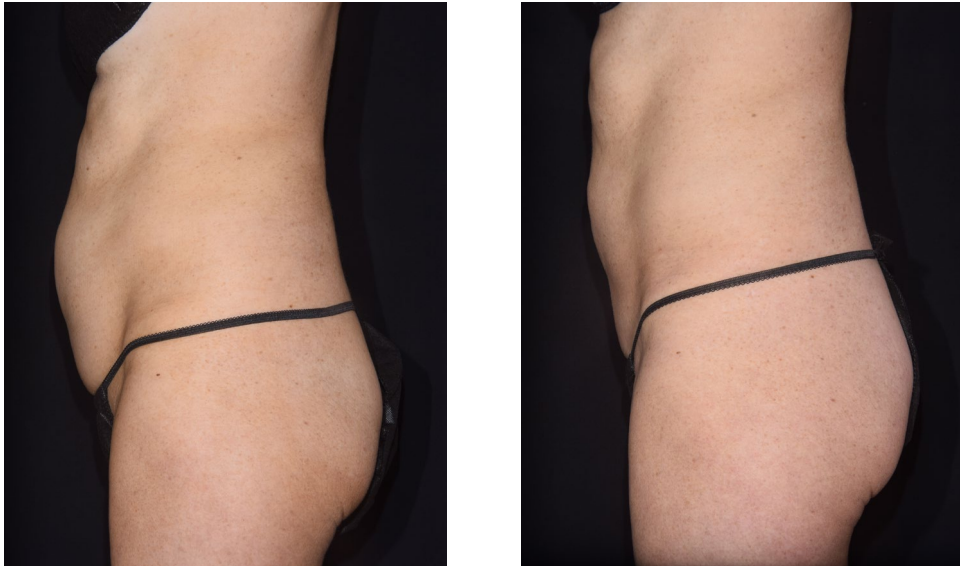
## STUDY DESIGN

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

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## 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.