

# MRI AND CT EVALUATION STUDY: 1-YEAR FOLLOW-UP

## LONG-TERM FOLLOW-UP ON PATIENTS WITH HIFEM-INDUCED ABDOMINAL TISSUE CHANGES: MRI AND CT ASSISTED QUANTIFICATION OF MUSCLE GROWTH AND FAT REDUCTION.

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### HIGHLIGHTS

- **21 subjects** were recalled **1 year** after **4-8 abdominal treatments** for long-term evaluation.
  - The patients showed an **average fat reduction of 14.63%** 1 year post-treatment.
  - In comparison to baseline, the muscle thickness was **increased by 19.05%**, and abdominal separation was **reduced by 10.46%** 1 year post-treatment.
  - Treatment results were **preserved on average 1 year** after the last session.
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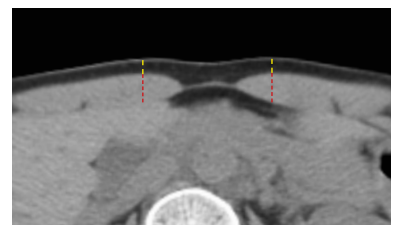
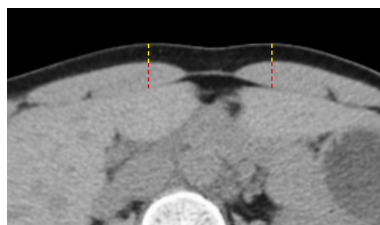
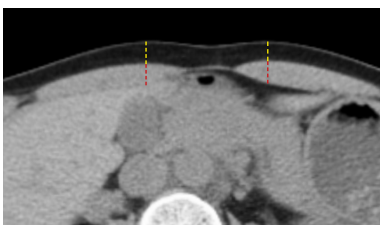
BASELINE



6-WEEK FU



1-YEAR FU

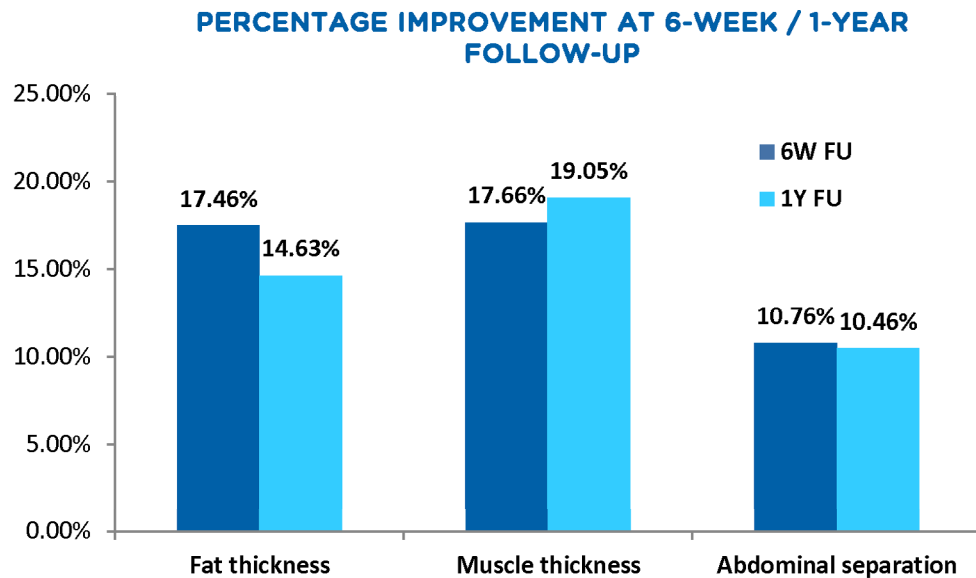


## DESIGN AND METHODOLOGY

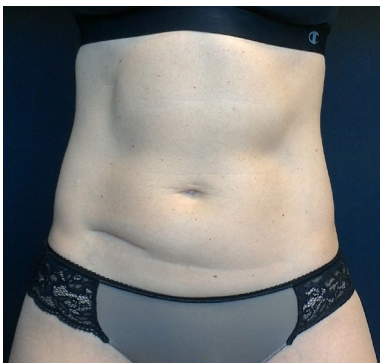
- The initial **evaluation** was performed at the **baseline** and **6-week** follow-up.
- The average time of the follow-up visit was **333±88.5** days after the last treatment.
- No additional treatments were delivered.

## RESULTS

- **HIFEM** is effective for inducing long-lasting changes.
- **Results** were **independent** of the number of treatments and the time of the follow-up.
- **No adverse events** were observed during the 1-year follow-up.



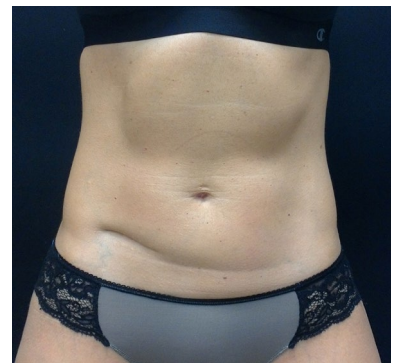
BASELINE



6-WEEK FU



1-YEAR FU



Digital images of patient ID14 at the baseline (left), after 6 weeks (in the middle) and 1 year (right) after the last treatment. The fat reduction measured at 6 weeks was preserved during 1Y FU.

# LITERATURE REVIEW: HIFEM® AND THERMAL PROCEDURES

## THERMAL VS. NON-THERMAL TECHNOLOGIES IN NON-INVASIVE BODY CONTOURING.

Dr. Rita Rakus MBBS FBCAM<sup>1</sup>

1. Dr. Rita Rakus Clinic, London, UK

Presented at the World Congress of the International Master Course on Aging Science, 2019 Paris, FR

### HIGHLIGHTS

- Results based on **42** identified studies using quantitative evaluation of outcomes.
- **HIFEM** is the **most effective** technology for **reduction in waist circumference**.
- **HIFEM** technology combines **fat reduction (18.6%)** and **muscle thickening (15.4%)**.
- **Thermal technologies show risks** of AE due to tissue hyper/hypothermia such as erythema, swelling, pain, burns, numbness, bruising, etc. **No adverse events** related to the **HIFEM** treatments were reported.

### RESULTS

MODALITY	FAT THICKNESS	MUSCLE THICKNESS	WAIST CIRCUMFERENCE
LLT	0.0%	0.0%	-3.03 cm
HIFU	0.0%	0.0%	-2.76 cm
RF	-29.0%	0.0%	-3.44 cm
CRYOLIPOLYSIS	-21.2%	0.0%	-3.88 cm
HIFEM	-18.6%	+15.4%	-4.09 cm

Efficiency comparison of different body contouring methods.

# MECHANISM OF ACTION: EFFECT OF HIFEM® ON FAT

## BIOCHEMICAL PERSPECTIVE OF FAT PHYSIOLOGY AFTER APPLICATION OF HIFEM FIELD TECHNOLOGY: ADDITIONAL INVESTIGATION OF FAT DISRUPTION EFFECTS IN A PORCINE STUDY.

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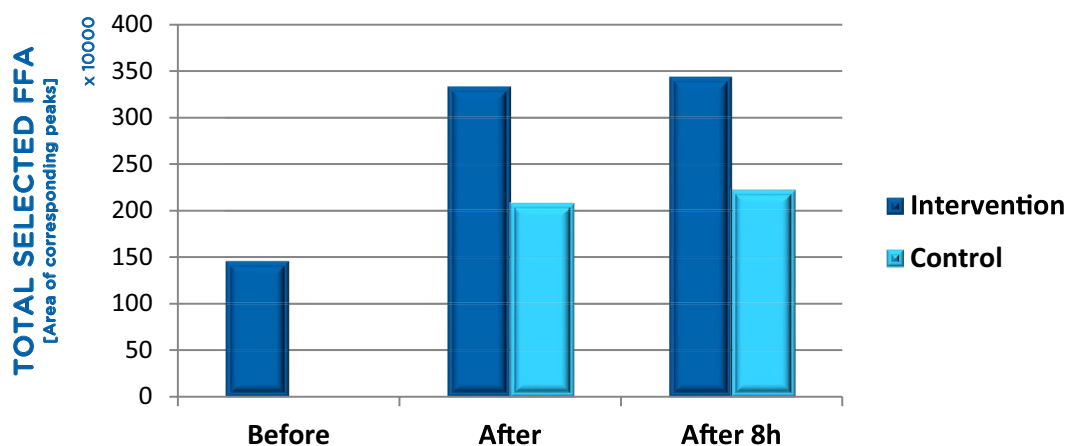
2. University of Life Sciences - Department of Veterinary Sciences, Prague, CZ

Presented at the Annual Meeting of the American Society for Laser Medicine and Surgery, 2019 Denver, CO

### HIGHLIGHTS

- The levels of FFA (free fatty acids) in the treated area increased by 127.1% immediately post-treatment and by 134.1% 8h post-treatment. High levels of FFA indicate **strong metabolic response** in the fat tissue.
- The levels of four out of five analyzed DNA **pro-apoptotic markers increased significantly** after application, providing evidence of **enhanced apoptosis in the subcutaneous adipose tissue**.
- The average fat pH decreased from  $7.30 \pm 0.12$  to  $6.60 \pm 0.07$  immediately post-treatment and to  $7.19 \pm 0.12$  8h post-treatment.

AVERAGE LEVELS OF FFA



Metabolic reaction leading to the breakdown of fat into FFA and glycerol was superior in the treated area, where it could possibly lead to saturation and initiation of apoptosis.

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## STUDY DESIGN

- The aim was to investigate the mechanism of apoptosis induced through saturation of FFA in the fat cells.
- Two Large White pigs received a **single 30-minute** long treatment of thigh.
- **Punch biopsies** were collected **before, immediately after and 8 hours after treatment**. Control samples were obtained from the abdomen at the baseline and 8 hours post-treatment.



Measurements of pH were performed immediately after the punch biopsy directly in the fat tissue.



Collection of control punch biopsies of the fat tissue from the abdomen. The biopate was pulled out by tweezers.

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## CONCLUSIONS

- **Levels of pro-apoptotic markers** in histological samples were **increased post-treatment**, indicating enhanced **apoptosis** in the tissue.
- **FFA concentrations increased and pH decreased significantly post-treatment**, suggesting that HIFEM induces a strong metabolic response in the fat tissue which leads to **the breakdown of fat**. High levels of FFA may saturate the fat cell and trigger fat cell apoptosis.
- Results of this study **correlate with previous research** reporting elevated apoptotic levels post HIFEM treatments as well as with fat reduction observed in human studies.
- **The results support the proposed MOA** stating that HIFEM contractions evoke a strong metabolic reaction and trigger cascade effect leading to FFA saturation, the stress of endoplasmic reticulum and fat cell apoptosis.



# IN VIVO MUSCLE HISTOLOGY STUDY

## NON-INVASIVE INDUCTION OF MUSCLE FIBER HYPERTROPHY AND HYPERPLASIA: EFFECTS OF HIGH-INTENSITY FOCUSED ELECTROMAGNETIC (HIFEM) FIELD EVALUATED IN AN IN-VIVO PORCINE MODEL.

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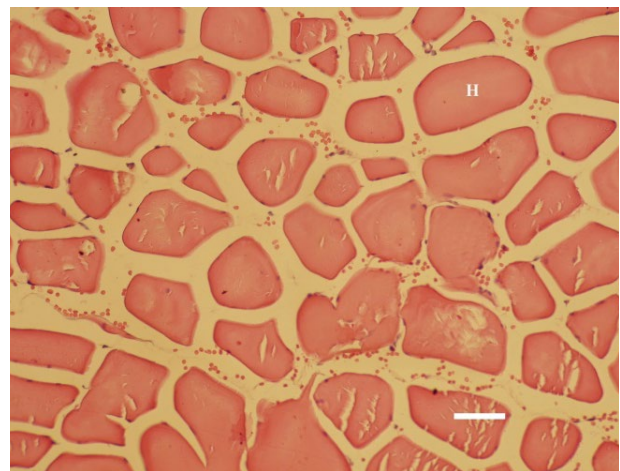
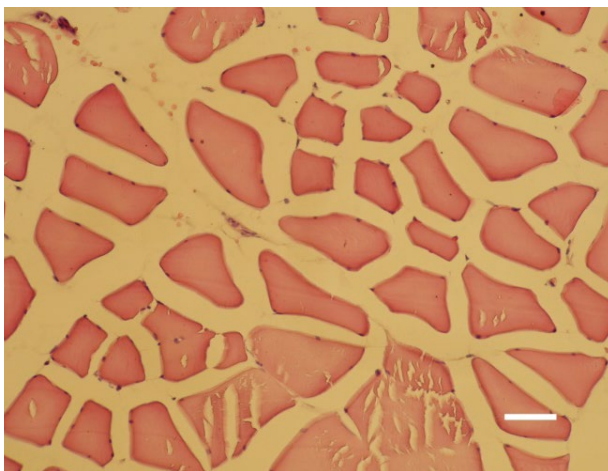
2. General and Clinical Pathology, Faculty of Veterinary Medicine, Trakia University, Stara Zagora, Bulgaria

Presented at the Annual Meeting of the American Society for Laser Medicine and Surgery, 2018 Dallas, TX

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### HIGHLIGHTS

- In treated animals, the **muscle mass** in examined slices increased by 23.44% ( $18934.0 \pm 5089.5 \mu\text{m}^2$ ) on average.
  - The average **area per single muscle fiber** increased by **16.4%** ( $469.48 \pm 371.95 \mu\text{m}$ ).
  - The average **number of muscle fibers** increased by 7%, and although not statistically significant, it **indicates** muscle fiber **hyperplasia**.
  - Control animal did not show any significant changes in any of the measured parameters.
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Histological evaluation showed strong muscle fiber hypertrophy and indicated fiber hyperplasia.

## STUDY DESIGN

- Three Yorkshire pigs received four 30-minute long treatments. Fourth pig served as a control.



Animal care complied with the convention for the protection of vertebrate animals used for experimental and other scientific purposes.



The thigh was treated for 30 minutes using the HIFEM applicator secured by a fixation belt.

- Biopsy specimens of muscle tissue were taken **before the treatments** and during **2-week follow-up**. Collected tissue slices were evaluated for any structural changes by a certified histopathologist.



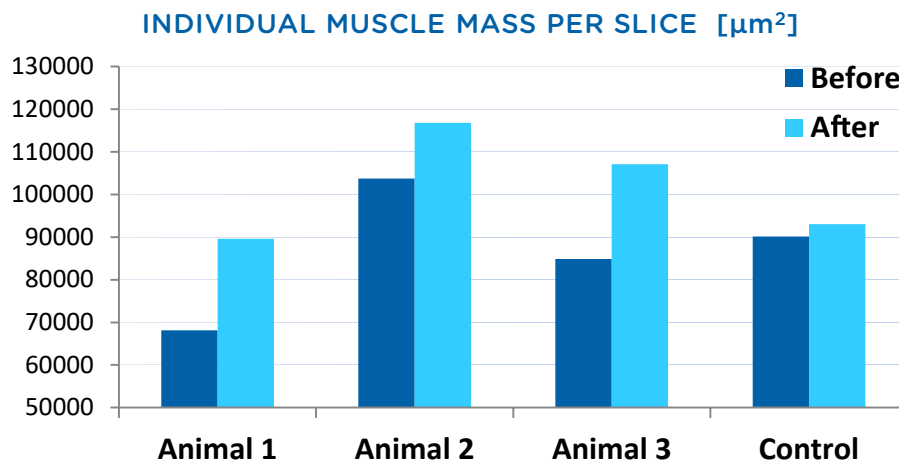
Punch biopsies of the muscle tissue were taken from the treated area and pulled out using tweezers.



The samples were fixed in 10% neutral buffered formalin and colored using hematoxylin. The samples were sliced and microscopically evaluated.

## RESULTS

- The results confirmed **muscle hypertrophy** on the histological level, which correlates with previous CT and MRI studies.



The individual average muscle mass in a single slice for each animal.

# QUANTIFICATION OF HIFEM<sup>®</sup> EFFECTS ON BUTTOCKS

## MRI EVALUATION OF CHANGES IN GLUTEAL MUSCLES FOLLOWING TREATMENTS WITH THE HIGH-INTENSITY FOCUSED ELECTROMAGNETIC (HIFEM) TECHNOLOGY.

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1. Art of Skin MD, Solana Beach CA, USA 2. Paula Fines Center, Sofia, Bulgaria

Presented at the Annual Meeting of the American Society for Laser Medicine and Surgery, 2019 Denver, CO

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### HIGHLIGHTS

- Patient group of **25 subjects** who received four **30-minute HIFEM treatments** underwent MRI screening at the baseline and 1-month follow-up.
- MRI analysis of **gluteal muscles** (musculus gluteus maximus, medius and minimus) revealed an average **volumetric increase in muscle mass** after four HIFEM treatments.
- **The most substantial increment** was observed in the **gluteus maximus** (10.59+3.37%\*), the muscle enhancement showed **to be uniform across all three evaluated muscles**.
- **The most profound hypertrophic effect** was observed in the **upper buttock region**, where it translated into a **visible buttock lifting**.



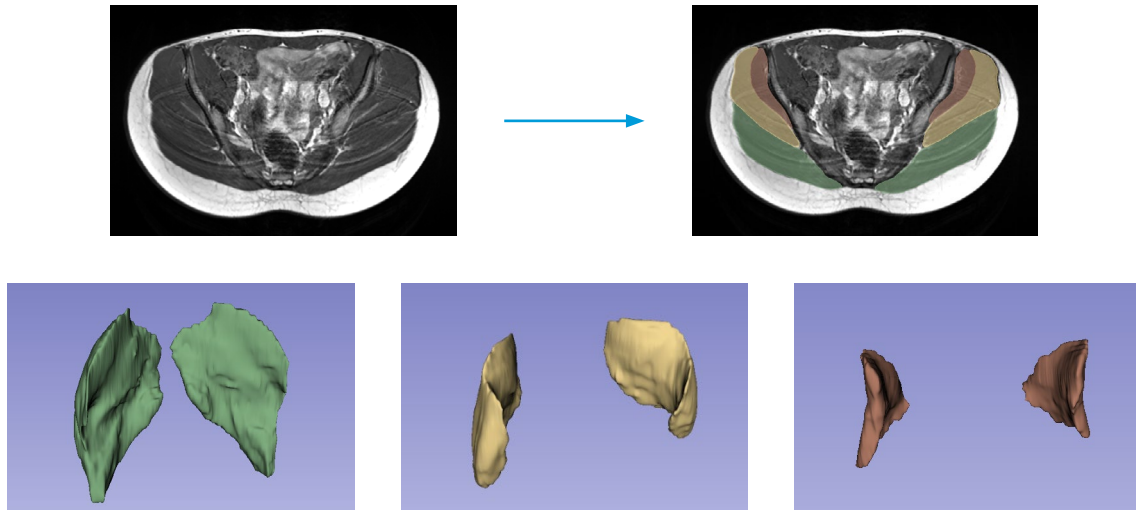
Standardized photography of a patient at baseline (left) and 1-month follow-up (right), left view.  
The dotted line indicates visible enhancement of muscle tissue and buttock lifting.



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## STUDY DESIGN

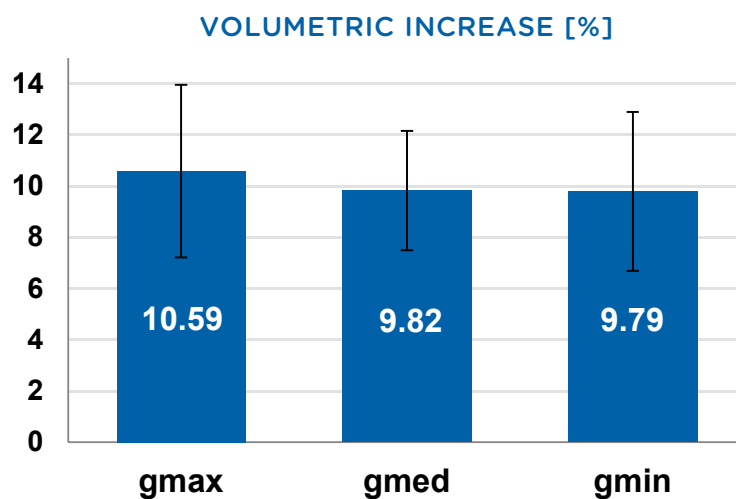
- **MRI scans of the pelvic region** along with standardized photographs were collected.
- MRI scans were **manually segmented** to reconstruct **3D volumes** of m. gluteus maximus (gmax), m. gluteus medius (gmed) and m. gluteus minimus (gmin). Volumetric changes were calculated and statistically analyzed using a paired t-test.



Example of gluteal muscle segmentation and 3D reconstruction. The gluteus maximus (green), medius (yellow) and minimus (red) were identified and manually segmented slice by slice.

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## RESULTS



Average muscle enhancement of individual muscles increase at the 1-month follow-up. All of the results were statistically significant.\*

\*Based on the evaluation of 18 out of 25 patients.

# ULTRASOUND IMAGING STUDY: 6-MONTH FOLLOW-UP

## CHANGES IN SUBCUTANEOUS ABDOMINAL FAT THICKNESS FOLLOWING HIGH-INTENSITY FOCUSED ELECTRO-MAGNETIC (HIFEM) FIELD TREATMENTS SIX MONTHS POST-TREATMENT: A MULTICENTER ULTRASOUND STUDY.

Bruce Katz M.D.<sup>1</sup>, Robert Bard M.D.<sup>2</sup>,  
Richard Goldfarb M.D.<sup>3</sup>, Aaron Shiloh M.D.<sup>4</sup>

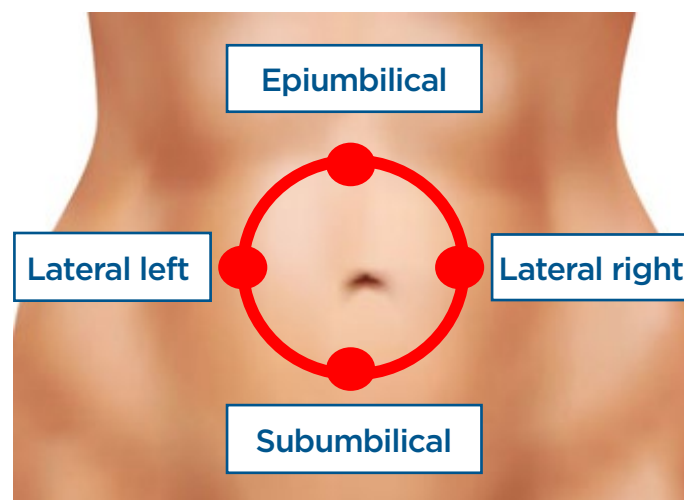
1. Juva Skin and Laser Center, Manhattan NY, USA, 2. Bard Cancer Diagnostics, Manhattan NY, USA  
3. Center for SmartLipo & Plastic Surgery, Langhorne PA, USA, 4. Shiloh Vein and Aesthetic Institute, Philadelphia PA, USA

Presented at the Annual Meeting of the American Society for Laser Medicine and Surgery, 2019 Denver, CO

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### HIGHLIGHTS

- **18 patients** were recalled 6 months after four 30-minute treatments for ultrasound assessment of abdominal fat thickness.
- **Ultrasound measurements** were performed at **four predefined locations**, and the outcomes were compared with baseline and 1-month results.
- Average reduction across abdomen was **7.73±5.68 mm at 6M FU.\***
- **High consistency:** Each subject showed a reduction, 11 out of 18 patients had a total reduction greater than 20%.



Visualization of predefined locations for ultrasound measurements. Four different points at a distance of 2 inches from the umbilicus were used.

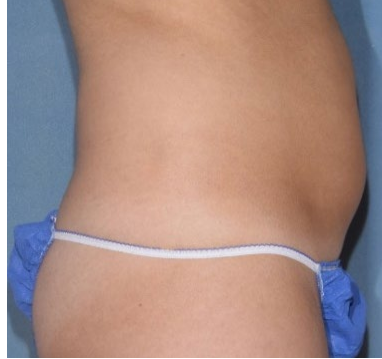
## RESULTS

### PATIENT 3: 23 years old female

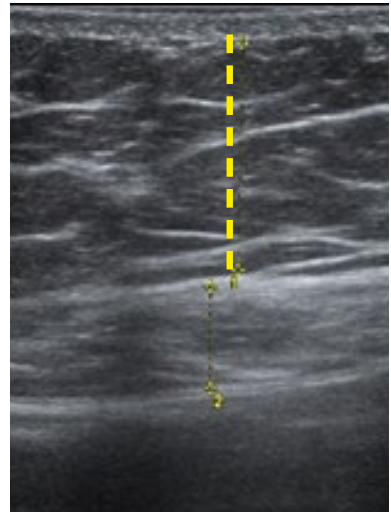
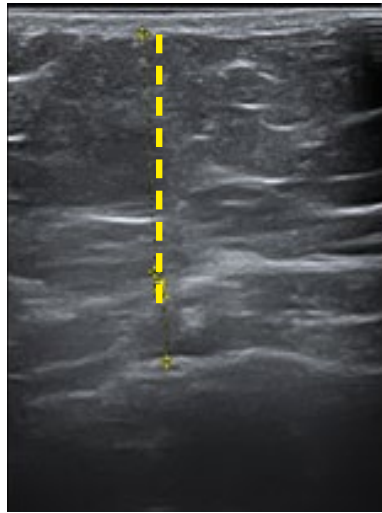
BASELINE



1-MONTH FU



6-MONTH FU



### PATIENT 4: 32 years old female

BASELINE



1-MONTH FU



6-MONTH FU

