

# HISTOLOGICAL IN VIVO STUDY: THE MECHANISM OF ACTION

INDUCTION OF FAT APOPTOSIS BY A NON-THERMAL DEVICE:  
SAFETY AND MECHANISM OF ACTION OF NON-INVASIVE HIFEM®  
TECHNOLOGY EVALUATED IN A HISTOLOGICAL PORCINE MODEL.

Robert Weiss M.D.<sup>1</sup>, MVDr. Jan Bernardy<sup>2</sup>

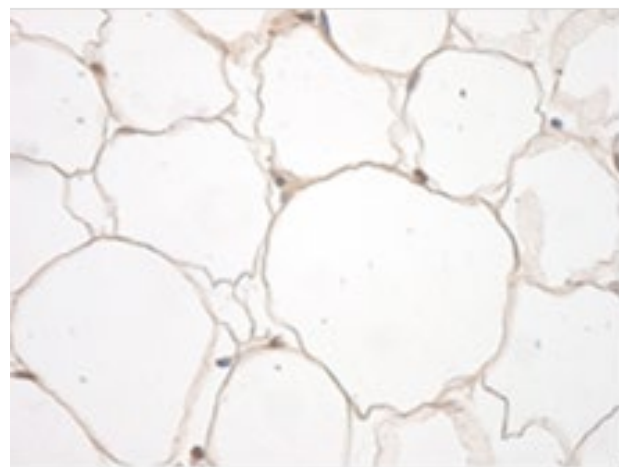
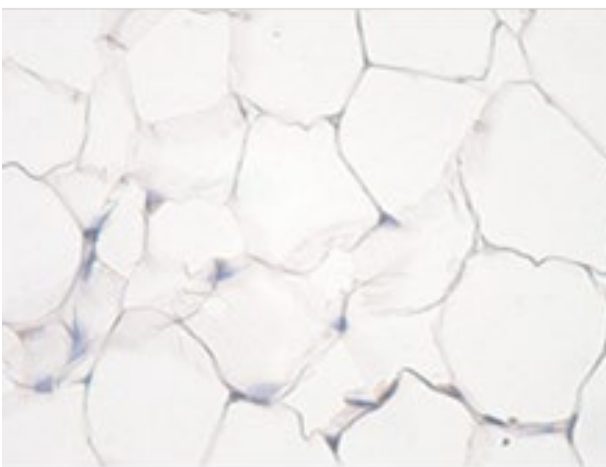
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Presented at the Annual Meeting of the American Society for Laser Medicine and Surgery, 2018 Dallas, TX.

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## HIGHLIGHTS

- **92 % increase in average apoptotic levels** in fat cells from 18.75 % at baseline to 35.95 % 8 hours post 1 treatment (levels in the control subject remained stable).
- The results show link between **fat cells apoptosis** and elevated levels of free fatty acids released during **supramaximal muscle contractions** induced by the treatment.
- Blood analysis confirmed a rapid metabolic reaction after the treatment as supporting evidence of changes in the subcutaneous fat tissue. **No safety risks were identified.**



Microscopic analysis of the fat tissue confirmed that the amount of apoptotic cells increased significantly after the treatments (right) compared to the baseline (left).

## STUDY DESIGN

- Evaluation of changes in the levels of **programmed cell death of adipocytes** in a porcine model in vivo **following a single EMSCULPT® treatment**.
- Two Yorkshire pigs were treated for 30 minutes. One pig was recruited as a control subject.



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



The fat thickness was checked before the experiment using the linear probe of a diagnostic ultrasound device (Mindray M5Vet).



The abdomen was treated for 30 minutes using the EMSCULPT applicator secured by a fixation belt.

- **Punch biopsy** specimens of fat tissue together with **blood samples** were taken before the treatment, after 1 hour and 8 hours post-treatment.
- **TUNEL assay** was applied on **histological samples** and the blood samples were tested for biochemical and hematological parameters.



An image of a biopsy sample being taken 8 hours post-treatment.

## RESULTS

- The apoptotic index was calculated from **120 histological samples**. Data were statistically analyzed using rANOVA.

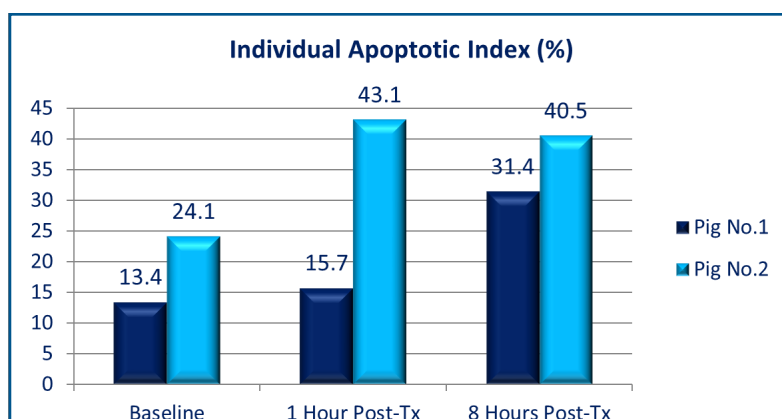


Figure 1: Average apoptotic index (%) evaluated in each pig individually.

# ULTRASONOGRAPHY

## STUDY: SUBCUTANEOUS FAT REDUCTION

### CHANGES IN SUBCUTANEOUS ABDOMINAL FAT THICKNESS FOLLOWING HIGH-INTENSITY FOCUSED ELECTRO-MAGNETIC (HIFEM®) FIELD TREATMENTS: A MULTI CENTER ULTRASOUND STUDY.

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Aaron Shiloh M.D.<sup>4</sup>, Dilyana Kenolova M.D.<sup>5</sup>

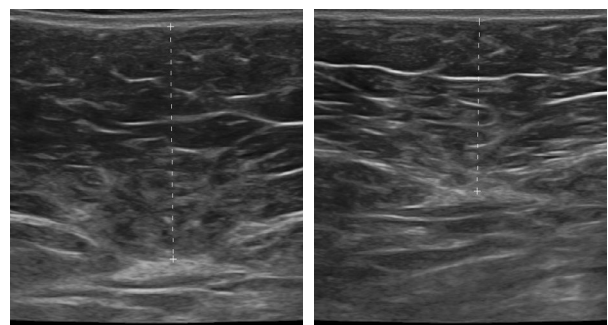
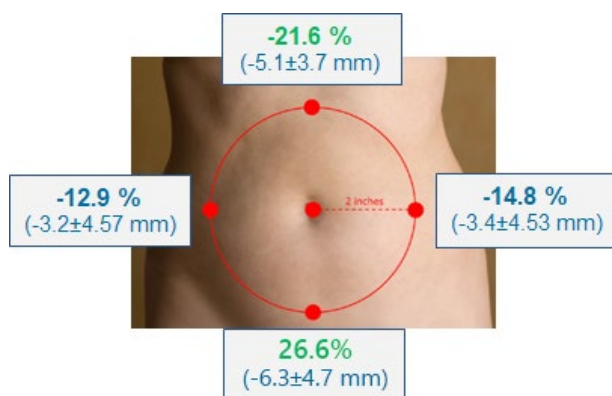
1. Juva Skin and Laser Center, Manhattan NY, USA; 2 Bard Cancer Diagnostics, Manhattan, NY, USA; 3. Center for SmartLipo & Plastic Surgery, Langhorne PA, USA; 4. Shiloh Vein and Aesthetic Institute, Philadelphia PA, USA; 5. Dermasense Dermatology Clinic, Burgas, Bulgaria.

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

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## HIGHLIGHTS

- **33 patients** received four 30-minute treatments and were evaluated 1 month post application.
  - **Ultrasonography** calculated fat thickness in multiple measurement points **covering the whole abdomen**.
  - On average **19.0 % (4.4 mm)** reduction of fat was observed. The most significant **reduction in fat (26.6 %)** was observed **subumbilicaly**.
  - **High consistency** with **0 non-responders**; 21 out of 33 patients had greater than 15 % fat reduction.
  - **91 % satisfaction** with treatment results.
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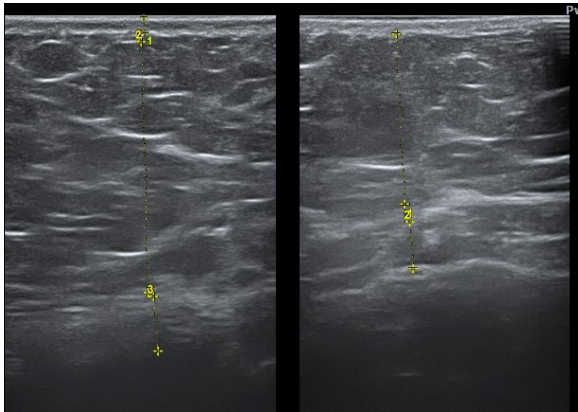
Ultrasound measurements revealed that fat was reduced significantly ( $p < 0.05$ ) in all abdominal areas, with the highest change seen in epi- and sub-umbilical regions.

## RESULTS

### Patient 3: 24 years old female

BASELINE

1 MONTH FU



BASELINE

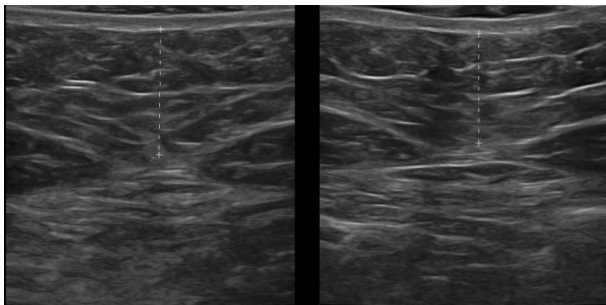
1 MONTH FU



### Patient 15: 47 years old female

BASELINE

1 MONTH FU



BASELINE

1 MONTH FU



### Patient 6: 44 years old female

#### 2D Photography

BASELINE

1 MONTH FU



#### 3D Photography

BASELINE

1 MONTH FU



# MAGNETIC RESONANCE IMAGING (MRI) STUDY: SIMULTANEOUS FAT AND MUSCLE EFFECT

HIGH INTENSITY FOCUSED ELECTRO-MAGNETIC THERAPY (HIFEM®) EVALUATED BY MAGNETIC RESONANCE IMAGING (MRI): SAFETY AND EFFICACY STUDY OF A DUAL TISSUE EFFECT BASED NON-INVASIVE ABDOMINAL BODY SHAPING.

Brian M. Kinney M.D. FACS<sup>1</sup>, Paula Lozanova M.D.<sup>2</sup>

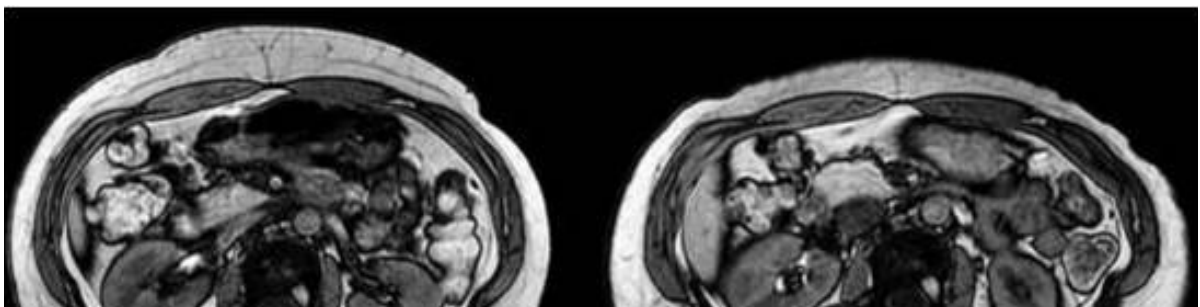
1. Plastic Surgery Excellence, Beverly Hills CA, USA; 2 Paula Fines Center, Sofia BG, Europe

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

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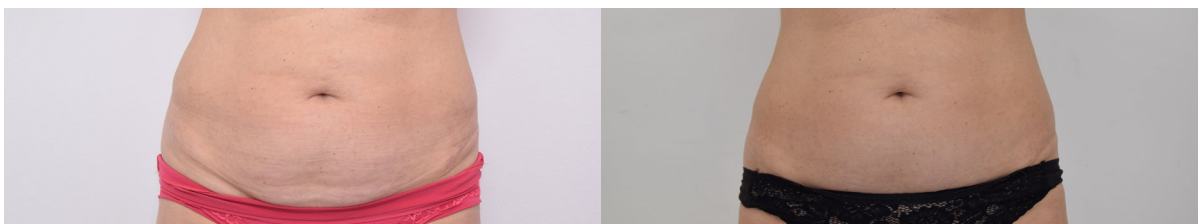
## HIGHLIGHTS

- **22 patients** were evaluated **2 months after four 30-min treatments**.
  - Abdominal **fat thickness was reduced on average by 18.6 %** or **4.3 mm**.
  - Abdominal **muscle mass increased on average by 15.4 %**, coupled with a **10.4 % average reduction in diastasis recti**.
  - Waist circumference decreased on average by **1.4 inch**.
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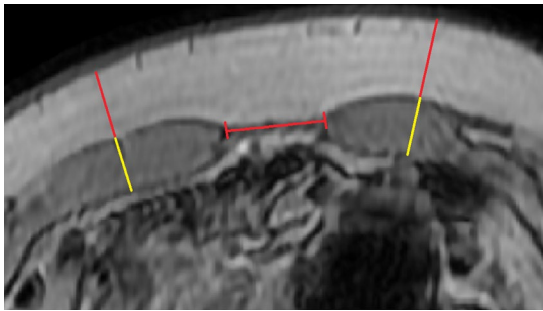
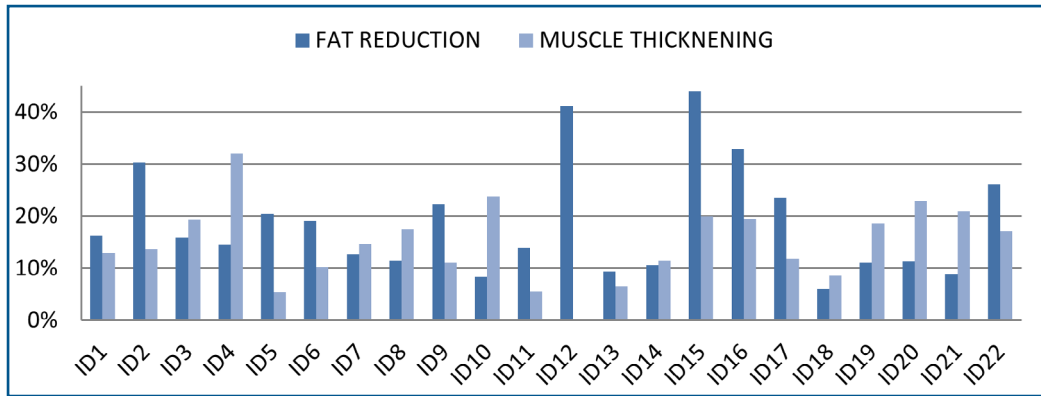
BASELINE

2 MONTH FU

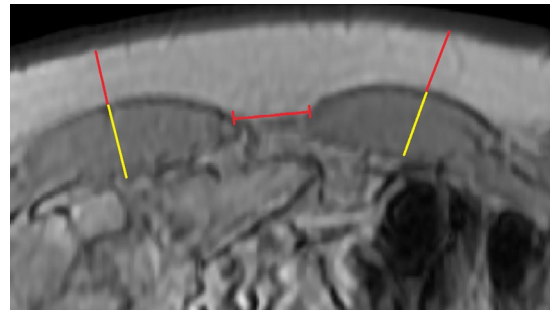


## RESULTS

- No adverse event. Several patients reported mild muscle fatigue which resolved within 12-48 hours.
- Simultaneous reduction in subcutaneous fat and strengthening of abdominal muscles in treated patients evaluated by MRI.



BASELINE



2 MONTH FU



Tissue changes 2-months post-treatment (right) versus baseline (left) captured by magnified MRI cuts. The patient showed 30.2% reduction in subcutaneous fat thickness (upper red lines) and 14% thickening of rectus abdominis (yellow lines) compared to baseline. This tissue re-composition was coupled with a 24.9% reduction in the lateral sinister/dexter distance (middle red line segment). Subject ID2, aged 30, weight change -2.2 lbs (-1.2%).

# COMPUTED TOMOGRAPHY STUDY: SIMULTANEOUS FAT AND MUSCLE EFFECT

COMPUTED TOMOGRAPHY (CT) BASED EVIDENCE OF SIMULTANEOUS CHANGES IN HUMAN ADIPOSE AND MUSCLE TISSUES FOLLOWING A HIGH INTENSITY FOCUSED ELELCTRO-MAGNETIC FIELD (HIFEM®) APPLICATION: A NEW METHOD FOR NON-INVASIVE BODY SCULPTING.

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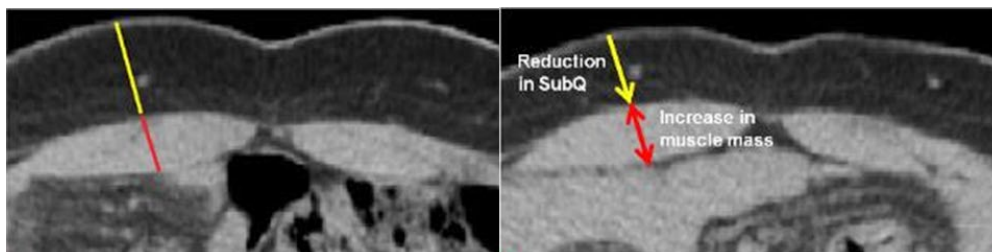
1. Dermatologic Surgery Specialists, Macon GA, USA; 2. Chicago Cosmetic Surgery and Dermatology, Chicago IL, USA

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## HIGHLIGHTS

- 16 patients received 5-8 treatments to evaluate effects of an extended protocol. Subject were evaluated 1 month post-treatments.
- Abdominal **fat thickness** was **reduced** on average by **19.2 %** or 3.4 mm.
- Simultaneously a **15.8 % increase in abdominal muscle thickness** was observed, coupled with a 10.8 % reduction in diastasis recti.
- **Waist circumference decreased on average by 1.2 inch** (after 4th Tx) and 1.6 inch (after the last Tx).
- Data suggest **4 treatments as the ideal protocol**.



BASELINE

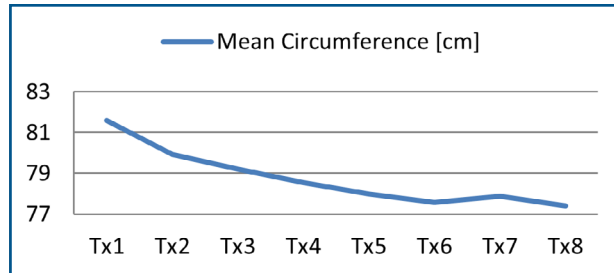
1 MONTH FU



## RESULTS

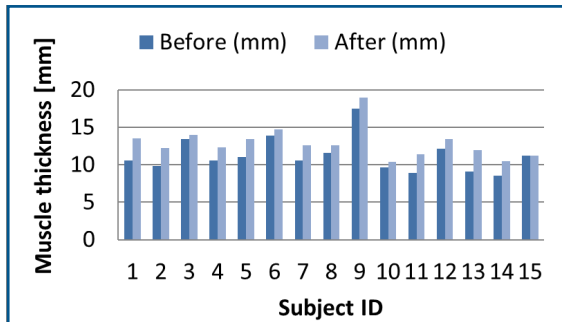
### UMBILICAL CIRCUMFERENCE

- The average circumference decreased by 3.04 cm and 4.17 cm after 4th and last (5th to 8th) treatment, respectively ( $p < 0.003$ )

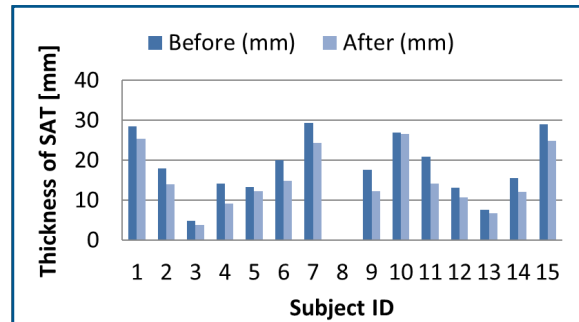


### CT MEASUREMENTS

CT calculated thickness of rectus abdominis at baseline and 1 month post treatments.



Subcutaneous fat thickness at baseline and 1-month post treatments. Patient ID8 fat measurements could not be objectively made due to close-to-zero baseline fat thickness.



BASELINE

1 MONTH FU



CT scans of patient ID9 at baseline (left) and 1-month post treatments (right). The scan shows reduction of subcutaneous fat (-30.3%) and thickening of rectus abdominis muscle (+8.4%).

# WAIST CIRCUMFERENCE REDUCTION TESTED IN A MULTICENTRIC STUDY

A NOVEL NON-INVASIVE TECHNOLOGY BASED ON SIMULTANEOUS INDUCTION OF CHANGES IN ADIPOSE AND MUSCLE TISSUES: SAFETY AND EFFICACY OF A HIGH INTENSITY FOCUSED ELECTRO-MAGNETIC FIELD DEVICE USED FOR ABDOMINAL BODY SHAPING

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

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## HIGHLIGHTS

- **22 patients** (lower BMI profile - average 23.8kg/m<sup>2</sup>) were treated in 4 sessions within 2 weeks.
  - Patient **waist size was reduced** on average **by 4.37 cm** at **3 month post-treatments**.
  - Patient photography captured a combination of **muscle toning and fat reduction**.
  - **96 % patients** were satisfied with treatment results.
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Higher-BMI patient



BASELINE

1 MONTH FU

Lower-BMI patient

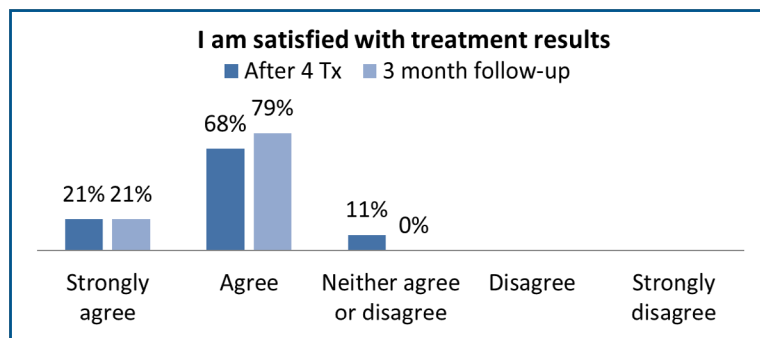


BASELINE

1 MONTH FU

## DETAILED RESULTS

- 19 patients completed the study; no adverse events.
- **16 out of 19 subjects (84%) showed >2.5 cm circumferential reduction** 3-months post-treatment (independent of weight changes).
- A significant portion of the **reduction (75%) was measured already after the last treatment**, further improving at 3-months.
- Two patients (11%) didn't have any waist size change, but their aesthetic appearance improved in digital photographs.
- The **overall recognition** rate of digital photographs (before and 3-months post) averaged **89.47%**. Images of 15 subjects were uniformly recognized by all 3 reviewers.
- At 3-months all patients expressed some level of satisfaction with treatment results, there were **no dissatisfied patients**.



BASELINE

1 MONTH FU

Digital images before (left) and 3-months after last procedure (right). Subject 04, age 36, BMI 20.4, waist circumference -4 cm (-5.3%), weight change +1.1 lbs (+0.7%).

# AN INITIAL STUDY INVESTIGATED THE EFFECTS ON BUTTOCKS

EFFICACY OF HIGH INTENSITY FOCUSED ELECTRO-MAGNETIC FIELD  
THERAPY WHEN USED FOR NON-INVASIVE BUTTOCKS AUGMENTATION  
AND LIFTING: A CLINICAL STUDY.

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

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## HIGHLIGHTS

- **22 women** received **4 bilateral treatments** on **their buttocks**.
- The treatments caused **significant changes** to **gluteus muscles** which translated into **overall aesthetic improvement**.
- Digital photographs showed **overall buttock lifting** and **reduction in muscle laxity**.
- **High levels of satisfaction** with treatment results (**7.3/10**).
- The **results triggered a following large-scale multicentric study** to bring further evidence.



BEFORE



AFTER

## DESIGN AND METHODOLOGY

- Evaluation at baseline, after last treatment, 1-month post, and 3-month post:
  - Weight measurement, standardized digital photography.
  - Patient comfort and satisfaction with results.

## RESULTS

Satisfaction with results (0-10)	After treatment	1 month follow-up	3 month follow-up
Average (n=22)	7.2±1.8	7.4±1.8	7.8±2.0

Chronologic evaluation of patient satisfaction with the treatment results using a VAS scale (10 = Complete satisfaction, 0 = Complete dissatisfaction). Average satisfaction was high and increased over time.

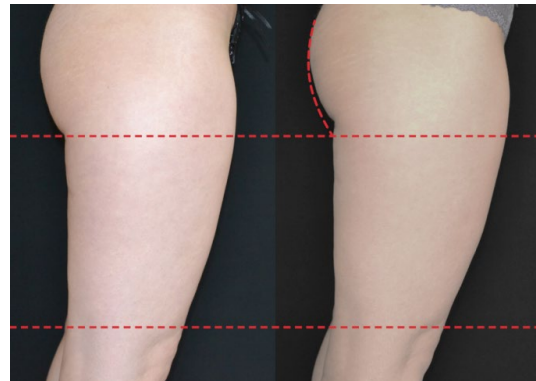
Treatment comfort (0-10)	1 <sup>st</sup> session	4 <sup>th</sup> session
Average (n=22)	7.0±2.3	8.3±1.9

VAS scale patient comfort during the treatment (10 = Complete comfort, 0 = complete discomfort).



BEFORE

AFTER



BEFORE

AFTER

Digital images of two patients showing overall lifting of their buttock coupled with elevation of the gluteal fold and a tighter and more sporty look after HIFEM® treatment (4x30min).

# A LARGE-SCALE MULTICENTRIC STUDY: NON-INVASIVE BUTT LIFTING EFFECTS

HIGH INTENSITY FOCUSED ELECTRO-MAGNETIC TECHNOLOGY (HIFEM)  
FOR NON-INVASIVE BUTTOCKS LIFTING AND TONING OF GLUTEAL  
MUSCLES: A MULTI-CENTER EFFICACY AND SAFETY STUDY.

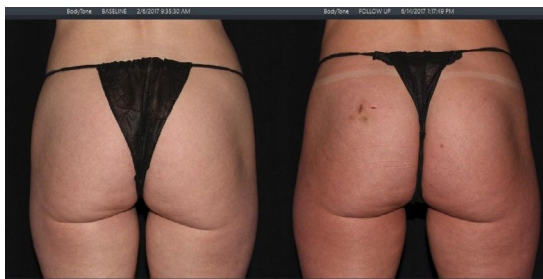
C. Jacob M.D.<sup>1</sup>, B. Kinney M.D.<sup>2</sup>, M. Busso M.D.<sup>3</sup>, S. Chilukuri M.D.<sup>4</sup>,  
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1. Chicago Cosmetic Surgery and Dermatology, Chicago IL; 2. Plastic Surgery Excellence, Beverly Hills CA; 3. Aesthetic Dermatology, Coconut Grove FL; 4. Refresh Dermatology, Huston TX; 5. Contour Medical, Gilbert AZ; 6. Ovation Med Spa, Houston TX; 7. Aesthe Clinic Beauty, Sofia BG.

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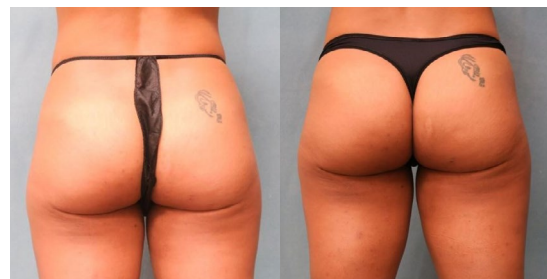
## HIGHLIGHTS

- A total of **75 patients** received **4 bilateral treatments** on their **buttocks**, and were evaluated 1 month post-treatments.
- **85 %** of patients reported **significant improvement in appearance of their buttocks**. **79 %** of patients reported improvement in their confidence.
- **80 %** of patients felt their buttock was **more lifted and toned** right after their last treatment. Patients reported improvement in **buttock laxity** and **tightness** post-treatment.
- Patient photography revealed **improvement in shape, tone and fullness of buttocks**.



BEFORE

AFTER



BEFORE

AFTER