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.

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

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).
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.

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.

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.
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 2D Photography](image1)

![Baseline 3D Photography](image2)

![1 Month FU 2D Photography](image3)

![1 Month FU 3D Photography](image4)

**Patient 6:** 44 years old female

![Baseline 2D Photography](image5)

![Baseline 3D Photography](image6)

![1 Month FU 2D Photography](image7)

![1 Month FU 3D Photography](image8)

**Patient 15:** 47 years old female

![Baseline 2D Photography](image9)

![Baseline 3D Photography](image10)

![1 Month FU 2D Photography](image11)

![1 Month FU 3D Photography](image12)
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.

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

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.
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.

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 ELECTRO-MAGNETIC FIELD (HIFEM®) APPLICATION: A NEW METHOD FOR NON-INVASIVE BODY SCULPTING.

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

HIGHLIGHTS

• 16 patients received 5-8 treatments to evaluate effects of an extended protocol. Subjects 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 diastatis 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

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%).
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.

HIGHLIGHTS

• **22 patients** (lower BMI profile - average 23.8kg/m2) 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**.
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.

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.

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.
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

<table>
<thead>
<tr>
<th>Satisfaction with results (0-10)</th>
<th>After treatment</th>
<th>1 month follow-up</th>
<th>3 month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average (n=22)</td>
<td>7.2±1.8</td>
<td>7.4±1.8</td>
<td>7.8±2.0</td>
</tr>
</tbody>
</table>

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.

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

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

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.

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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.