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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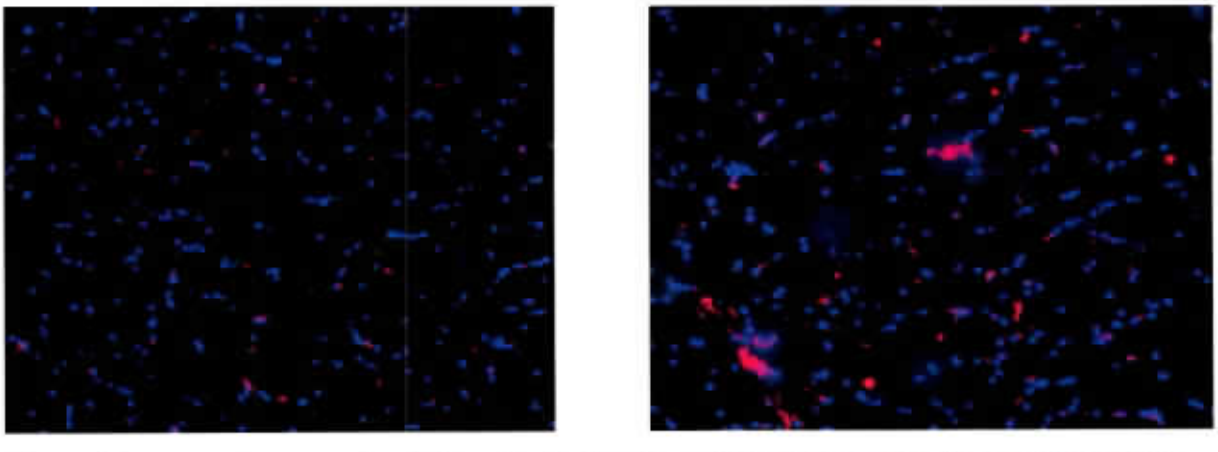
HIGHLIGHTS

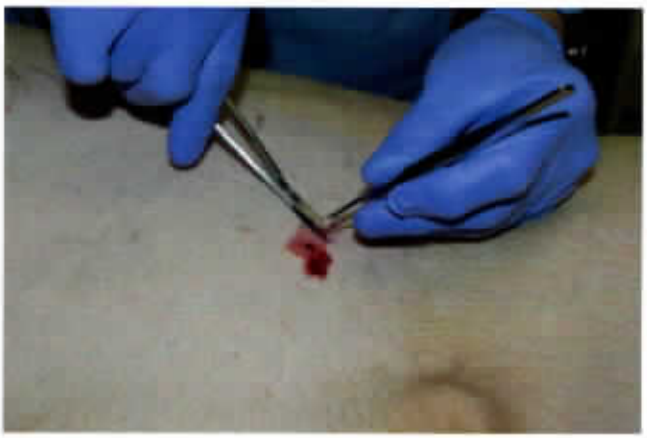
- The study was primarily focused on **Satellite cells** (muscle stem cells) that differentiate to **form new muscle fibers** or new myonuclei **supporting growth** of existing fibers.
- The levels of **satellite cells** increased by **30.2%** at 2 weeks FU.
- Histology images showed **hypertrophic fibers** 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

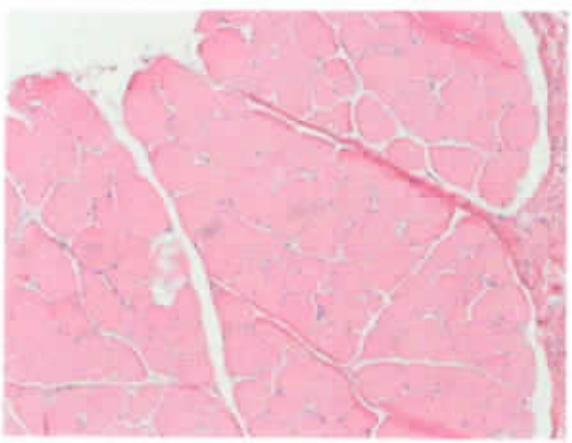
- 5 Large White pigs (approximately 6 months old).
- All animals received **three 30-minute** treatments applied to **half** of the abdomen (1 tx per week).
- The **opposite site** of the abdomen was used as a **control area**.
- A total of **275 histological** slices were processed.



1 biopsy specimen (Φ6mm) 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 **was effective and did 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).

MECHANISM OF ACTION: EFFECT OF HIFEM® ON FAT

MECHANISM OF NONTHERMAL INDUCTION OF APOPTOSIS BY HIGH-INTENSITY FOCUSED ELECTROMAGNETIC PROCEDURE: BIOCHEMICAL INVESTIGATION IN A PORCINE MODEL

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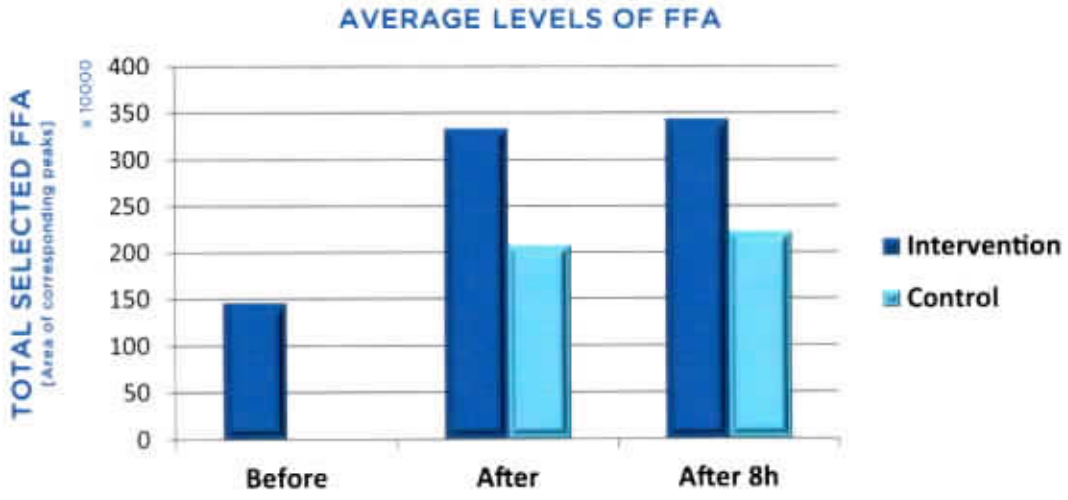
HIGHLIGHTS

- **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±0.12 to 6.60±0.07** immediately post-treatment and to **7.11 ± 0.11** 8h post-treatment.



Results of total FFA amount in specimens (mean ± SD) at baseline, immediately after treatment (after Tx), and 8 h after treatment (after 8 h). Values correspond to the overall area under the peaks obtained by mass spectrometry

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 bioptate was pulled out by tweezers.

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.

SYNCHRONIZED RF & HIFEM: MULTI-CENTER OUTER THIGH MRI STUDY

MRI MULTICENTRE STUDY ON HIGH-INTENSITY FOCUSED ELECTROMAGNETIC PROCEDURE SIMULTANEOUSLY COMBINED WITH SYNCHRONIZED RADIOFREQUENCY FOR TREATMENT OF LATERAL THIGHS: PRELIMINARY 3-MONTH FOLLOW-UP DATA

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HIGHLIGHTS

- **93 subjects** (21-70 y/o, 19.0-34.5 kg/m²) were recruited in the study.
- MRI assessment revealed an **average reduction of fat** thickness by **-30.9±4.2%** (-18.6±4.6 mm) in saddlebag region at **3-month** follow-up visit.
- Therapies were perceived as **comfortable** (VAS score of 2.0 points).
- Noticeable **reduction of saddlebags** was seen on digital photographs.

BASELINE

AFTER THE LAST TREATMENT

COURTESY OF: MELANIE PALM, M.D.

BASELINE

1-MONTH FOLLOW-UP

COURTESY OF: BRIAN KINNEY, M.D.