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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HIGHLIGHTS

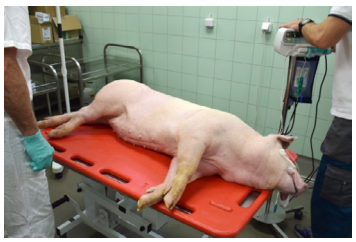
- **92 % increase in average apoptotic levels** in fat cells from 18.75 % at baseline to 35.95 % 8 hours post 1 treatment (levels in the control subject remained stable).
- The results show link between **fat cells apoptosis** and elevated levels of free fatty acids released during **supramaximal muscle 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).

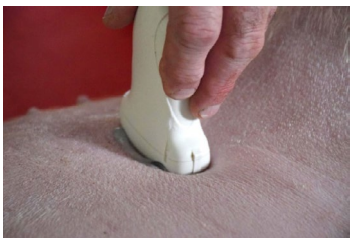
STUDY DESIGN

- Evaluation of changes in the levels of **programmed cell death of adipocytes** in a porcine model in vivo **following a single** EMSCULPT® **treatment**.

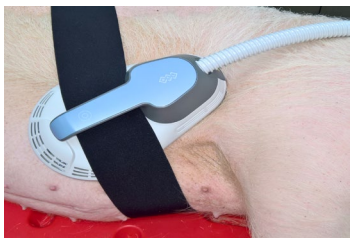
- Two Yorkshire pigs were treated for 30 minutes. One pig was recruited as a control subject.



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



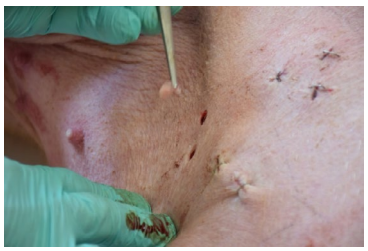
The fat thickness was checked before the experiment using the linear probe of a diagnostic ultrasound device (Mindray M5Vet).



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.

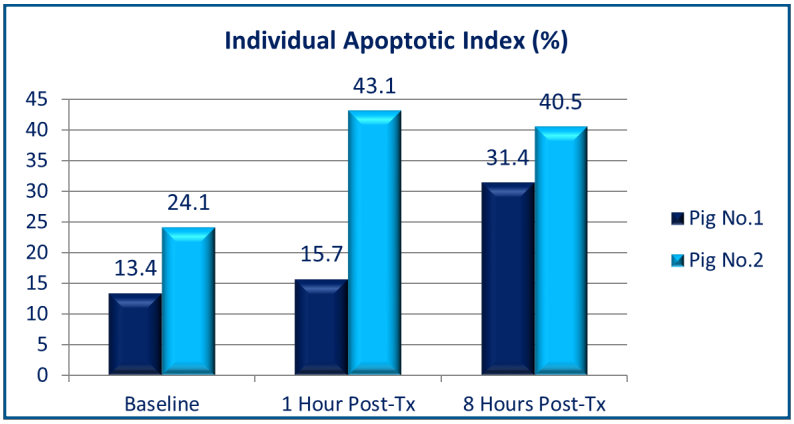


Figure 1: Average apoptotic index (%) evaluated in each pig individually.