

DETAILED CLINICAL STUDIES



EMSCULPT neo®

The **One** in Body Shaping



MORE FOR LESS

EMSCULPT®
neo

SUMMARY OF EMSCULPT NEO STUDIES

21

Peer reviewed
publications for
simultaneous application
of Synchronized
RF & HIFEM+^{I-XXI}

70+

Investigators for HIFEM
technology*

28

Investigators for Emsculpt
NEO^{I-XXI}

-30%

Fat reduction
at 3 months^{I-III}

+25%

Muscle growth
at 3 months^{I,II}

-19%

Abdominal separation
at 3 months^I

*Data on File



MORE FOR LESS

EMSCULPT^{Neo}

REFERENCES

- I)** Jacob C, Kent D, Ibrahim O. Efficacy and Safety of Simultaneous Application of HIFEM and Synchronized Radiofrequency for Abdominal Fat Reduction and Muscle Toning: A Multicenter Magnetic Resonance Imaging Evaluation Study. *Dermatol Surg.* 2021;47(7):969-973.
- II)** Samuels JB, Katz B, Weiss RA. Radiofrequency Heating and High-Intensity Focused Electromagnetic Treatment Delivered Simultaneously: The First Sham-Controlled Randomized Trial. *Plastic & Reconstructive Surgery.* 2022;149(5):893e-900e.
- III)** Palm M, Halaas Y, Kinney B, Goldfarb R. Spot Reduction of Localized Fat Deposits on the Lateral Thighs by Simultaneous Emission of Synchronized Radiofrequency and HIFEM energy: Magnetic Resonance Multicentre Study. Published in the *Dermatologic Surgery* 49(1):p 48, 2023
- IV)** Weiss RA, Bernardy J, Tichy F. Simultaneous Application of High-Intensity Focused Electromagnetic and Synchronized Radiofrequency for Fat Disruption: Histological and Electron Microscopy Porcine Model Study. *Dermatol Surg.* 2021;47(8):1059-1064.
- V)** Goldberg DJ. Deletion of adipocytes induced by a novel device simultaneously delivering synchronized radiofrequency and hifem: Human histological study. *J Cosmet Dermatol.* 2021;20(4):1104-1109.
- VI)** Halaas Y, Duncan D, Bernardy J et al. Activation of Skeletal Muscle Satellite Cells by a Device Simultaneously Applying High-Intensity Focused Electromagnetic Technology and Novel RF Technology: Fluorescent Microscopy Facilitated Detection of NCAM/CD56. *Aesthet Surg J.* 2021;41(7):NP939-NP947.
- VII)** DiBernardo B, Goldberg D, Katz B, McCoy JD, Chilukuri S. Augmentation of Gluteal Muscles by HIFEM Procedure is Considerably Enhanced by Simultaneous Radiofrequency Heating. *Aesthetic Surgery Journal Open Forum.* 2023;5:ojac087.
- VIII)** Duncan D. Safety and Efficacy of Simultaneous Application of HIFEM and Synchronized Radiofrequency for Non-invasive Fat Reduction and Muscle Toning in Inner Thighs: Magnetic Resonance Imaging Evaluation. *J Clin Aesthet Dermatol.* 2022;15(8):28–32.
- IX)** Katz B. Concomitant Use of Radiofrequency and High Intensity Focused Electromagnetic Field Energies for Full-body Remodeling: MRI-evidence Based Prefatory Trial. *J Cosmet Dermatol.* 2021;00:1–7.
- X)** Jacob C, Weiss R. Upper Arm Toning and Strengthening With Simultaneous Application of HIFEM and Synchronized RF. *J Clin Aesthet Dermatol.* 2023;16(2):50–54.
- XI)** Weiss R. Safety of Simultaneous Application of HIFEM and Synchronized RF for Fat Reduction in Multiple Zones on the Same Day Verified by Plasma Analysis of Liver and Lipid Profiles. Accepted for publication in the *Dermatologic Surgery*.
- XII)** Kent D, Jacob C, Kinney B. Visceral Fat Reduction with Simultaneous Application of HIFEM and Radiofrequency Energies Retrospectively Assessed from MRI Scans. Accepted for publication in the *Journal of Cosmetic Dermatology*.
- XIII)** Goldberg D, Lal K, Pospiech M. Adipocyte Apoptosis Induced by Treatment With Synchronized Radiofrequency and High-intensity Focused Electromagnetic Procedure: Human Histologic Analysis. Presented at: 41st Annual Conference of the American Society for Laser Medicine and Surgery. April 27-30, 2022; San Diego, CA.
- XIV)** Duncan D. A Novel Technology Combining RF and Magnetic Fields: Technical Elaboration on Novel RF Electrode Design. *Am J Biomed Sci Res.* 2020;11(2):147
- XV)** Duncan DI, Busso M. Effectiveness of combined use of Targeted Pressure Energy, Radiofrequency, and High Intensity Focused Electromagnetic fields to improve skin quality and appearance of fat and muscle tissue in different body parts. *J of Cosmetic Dermatology.* Published online July 29, 2022:jocd.15280.



MORE FOR LESS

EMSCULPT^{Neo}

REFERENCES

XVI) Duncan D, Kent D, Appelbaum E. The Improvement in Quality of Life and Core Muscle Strength in Elderly Patients by Simultaneous Application of HIFEM with Synchronized Radiofrequency: Preliminary Data. Presented at IMCAS world congress, Paris, 2023.

XVII) McCoy JD, Pezzella A, Samuels J. The Improvement of Quality of Life in Female Patients after Childbirth by HIFEM with Synchronized Radiofrequency for the Strengthening of Core Muscles: Interim Data. Presented at IMCAS world congress, Paris, 2023.

XVIII) Duncan D, Consecutive application of Standalone HIFEM procedure with Simultaneous application of HIFEM and Synchronized Radiofrequency for Sarcopenia Treatment. Presented at: the 5th Annual Global Aesthetics Conference. November 3-6, 2022, Miami, FL

XIX) Jacob C, Cohen J, DiBernardo B et al. The Simultaneous Application of HIFEM Procedure with Synchronized Radiofrequency on Lateral Abdomen for Fat Reduction and Muscle Strengthening - Interim Data. Presented at American Society of Dermatologic Surgery Annual Meeting 2022. October 6-10, 2022; Denver, CO.

*Results and patient experience may vary. Above mentioned averages are based on the patients results who participated in referenced clinical trials. These averages may differ in commercial patients.

XX) Duncan D, Chilukuri S, Kent D, Hoffmann K, Tingsong L. Non-invasive Alternatives for Liposuction. In: Enhanced Liposuction - New Perspectives and Techniques [Working Title]. IntechOpen, London. 2022

XXI) Goldberg DJ, Enright KM, Goldfarb R, Katz B, Gold M. The role and clinical benefits of high-intensity focused electromagnetic devices for noninvasive lipolysis and beyond: A narrative review and position paper. J Cosmet Dermatol. 2021;00:1–6. <https://doi.org/10.1111/jocd.14203>



MORE FOR LESS

EMSCULPT[®] Neo

I) EFFICACY AND SAFETY OF SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY FOR ABDOMINAL FAT REDUCTION AND MUSCLE TONING: A MULTICENTER MRI EVALUATION STUDY

Carolyn Jacob MD¹, David Kent MD², Omer Ibrahim MD¹

¹Chicago Cosmetic Surgery and Dermatology, Chicago, IL

²Skin Care Physicians of Georgia, Macon, GA

Published in Dermatologic Surgery Journal, 2021

<https://doi.org/10.1097/DSS.0000000000003086>



MORE FOR LESS

EMSCULPT[®]
neo

STUDY DESIGN

- **41 subjects** (17 males, 24 females)
- **Subjects of all skin types (I-VI) were included in the study.**
- Age **22-62 years** (39.1 ± 11.4) and BMI 21.2-34.3 kg/m² (26.5 ± 3.7 kg/m²)
- Simultaneous application of HIFEM and radiofrequency energies
- **3 treatments on abdomen** (one per week, 30 minutes each)
- Evaluation at **baseline, 1 month, 3 months and 6 months** post-treatment



MORE FOR LESS

EMSCULPT®

EVALUATION METHODOLOGY

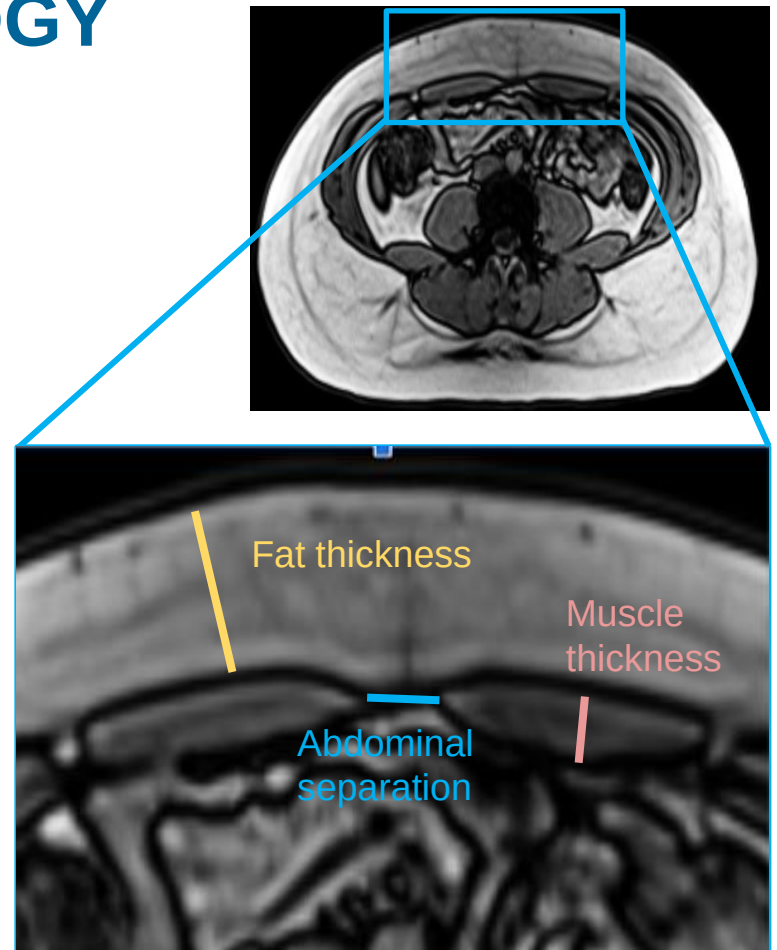
Primary evaluation: MRI imaging

Infraumbilical and supraumbilical slices:

- Fat thickness
- Muscle thickness
- Abdominal separation

Secondary evaluations:

- Waist circumference
- Subject satisfaction
- Therapy comfort



Thickness of subcutaneous fat and muscle, and the abdominal separation was measured



MORE FOR LESS

EMSCULPT®

RESULTS: MRI - FAT TISSUE

1 MONTH POST TREATMENT (N=40)

- Average fat reduction across the abdomen was **24.4% (P<0.05)**

3 MONTHS POST TREATMENT (N=29)

- Average fat reduction across the abdomen was **30.8% (P<0.05)**
- **-29.7%** reduction infraumbilically, **-31.9%** reduction supraumbilically
- **23 out of 29** subjects had **reduction higher than 25%**
- **2 non-responders**

6 MONTHS POST TREATMENT (N=20)

- Average fat reduction across the abdomen was **28.3% (P<0.05)**
- The improvement was **preserved with insignificant decline**



RESULTS: MRI - MUSCLE TISSUE

1 MONTH POST TREATMENT (N=40)

- Abdominal **separation reduced by 16.7%**
- Average increase in **muscle thickness 23.5%**

3 MONTHS POST TREATMENT (N=29)

- **Abdominal separation reduced by 18.8%**
- Average increase in **muscle thickness 26.1%**
- **Changes seen in all patients**

6 MONTHS POST TREATMENT (N=20)

- Abdominal **separation reduced by 19.8%**
- Average increase in **muscle thickness 25.3%**

All results were
significant ($P < 0.05$)
relative to baseline



MORE FOR LESS

EMSCULPT^{neo}

OTHER RESULTS

- **Waist circumference: -3.3 cm (1 month), -5.9 cm (3 months) and -6.7 cm (6 months)**
- **Treatments were perceived as comfortable** (score 2.3 ± 1.8 on a 10 point VAS)
- **91% of patients reported satisfaction with treatment results.**
- **94% of the patients** stated that their **abdominal appearance has been improved**
- **91% of the patients** reported **improvement in both muscle and fat**
- **Weight change was not statistically significant**

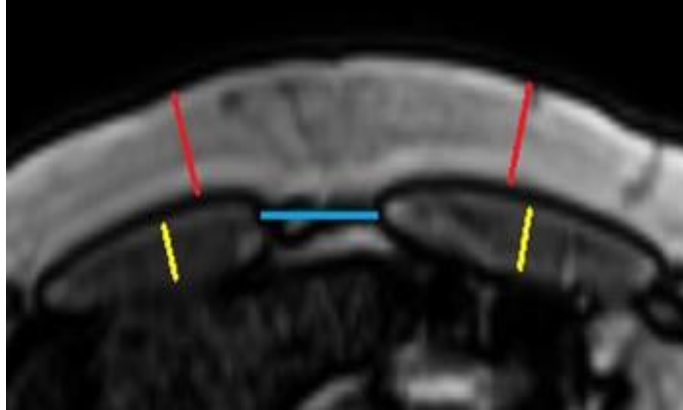


MORE FOR LESS

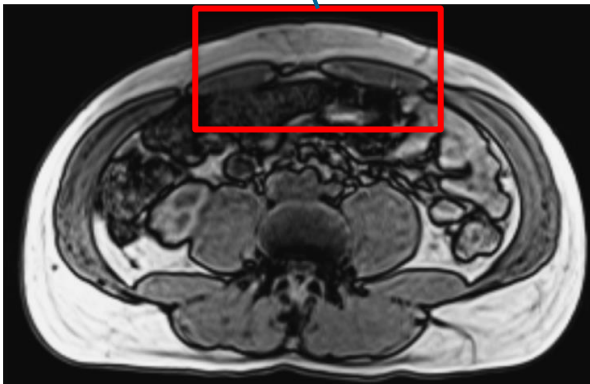
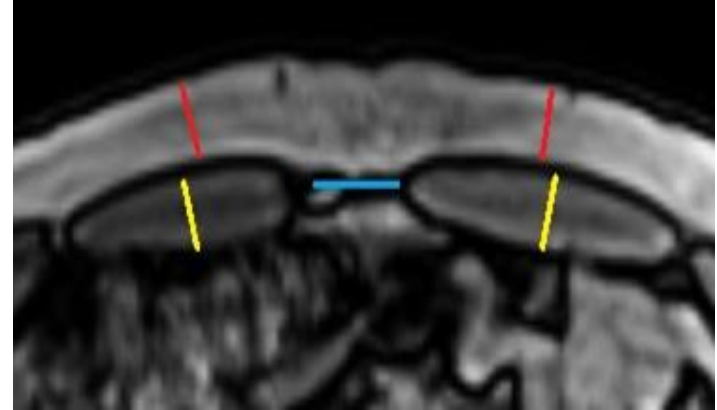
EMSCULPT^{neo}

EXAMPLE OF PATIENT RESULTS

BEFORE



3 MONTHS AFTER



Epi-umbilical slice, 34-year-old male, average BMI of 23.2 kg/m², **fat reduction: 32.8%**, **muscle increase: 26.8%**, abdominal **separation reduction: 14.1%**



MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS

- Visible improvement in the appearance of abdominal area
- **-32.8% of fat thickness, +26.8% of muscle thickness at 3 months**
- Waist circumference reduced by 7 cm



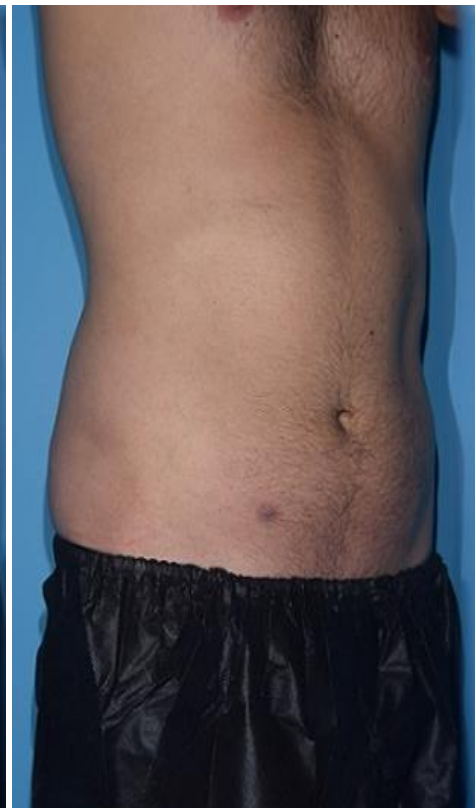
BEFORE



3 MONTHS AFTER



BEFORE



3 MONTHS AFTER



MORE FOR LESS

EMSCULPT^{neo}

CONCLUSION

- Combined application of HIFEM and RF resulted in **significant fat reduction (30.8%) and muscle thickening (26.1%)**
- **Abdominal separation was reduced by 19.8%**
- **Waist circumference was reduced by 6.7 cm**
- The treatments were effective and no serious adverse events were reported.



MORE FOR LESS

EMSCULPT^{neo}

II) RADIOFREQUENCY HEATING AND HIFEM DELIVERED SIMULTANEOUSLY - THE FIRST SHAM-CONTROLLED RANDOMIZED TRIAL

Julene B. Samuels M.D., FACS¹, Bruce Katz M.D.², Robert A. Weiss M.D., FAAD³

¹Julene B. Samuels, MD, FACS, Louisville, KY

²Juva Skin and Laser Center, New York, NY

³Maryland Dermatology Laser Skin, & Vein Institute, Hunt Valley, MD

Published in Plastic & Reconstructive Surgery Journal, 2022
<https://doi.org/10.1097/PRS.00000000000009030>



MORE FOR LESS

EMSCULPT[®]
neo

STUDY DESIGN

- **72 subjects** randomly divided into **active (A)** and **sham (S)** group
- **All skin type (I - VI) subjects were included.**

Active group (N=48)

- **Age:** 21-73 years
 - **BMI:** 19.5-34.3 kg/m²
 - 3 treatments on abdomen
 - Once a week
 - **Maximum tolerable intensities (100%)**
-

Sham group (N=24)

- **Age:** 24-66 years
 - **BMI:** 18.8-32.5 kg/m²
 - 3 treatments on abdomen
 - Once a week
 - **Intensities being set to 5%**
-

- Evaluation at the **baseline, 1, 3 and 6 months (optional visit)** post-treatment
- Patients were instructed to maintain their dietary intake and normal activities



EVALUATION METHODOLOGY

Primary evaluation:

Ultrasound Images 2 inches right and left of the umbilicus

- Changes in subcutaneous fat thickness
- Changes in rectus abdominis muscle thickness

Secondary evaluation:

- Digital photographs
- Satisfaction Questionnaire
- Therapy Comfort Questionnaire



MORE FOR LESS

EMSCULPT^{neo}

RESULTS: ULTRASOUND IMAGING (FAT)

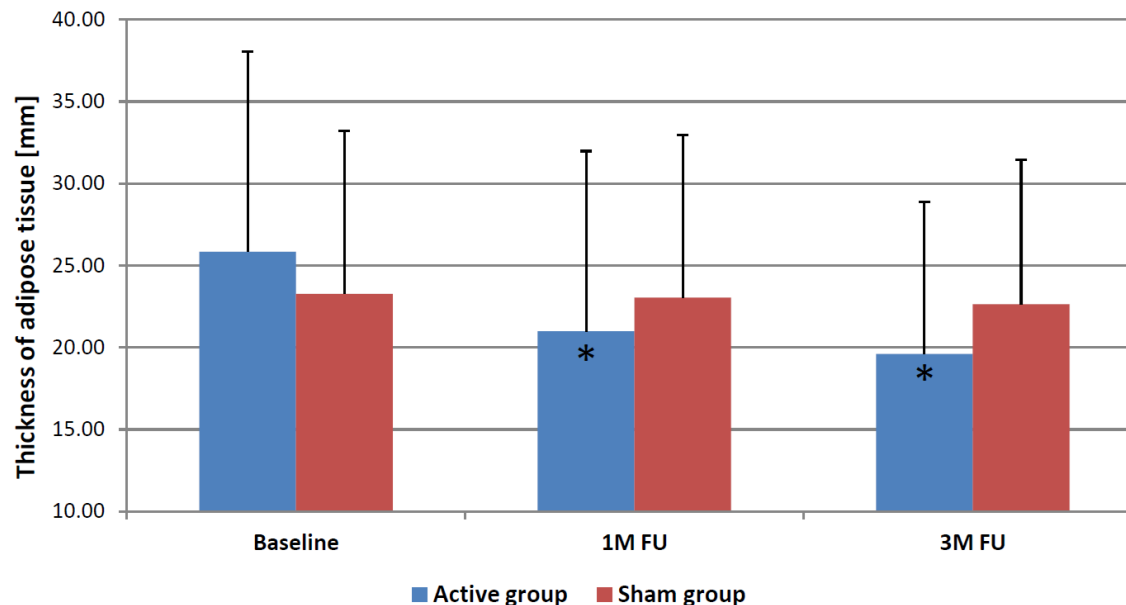
Active group

Fat reduction by 20.5% (1 month, N=48), 28.3% (3 months, N=40), and 25.8% (6 months, N=21)

Changes were statistically significant against baseline ($p < 0.05$)

Sham group

Insignificant changes of negligible magnitude (Maximum change of 1.1%)



MORE FOR LESS

EMSCULPT®

RESULTS: ULTRASOUND IMAGING (MUSCLE)

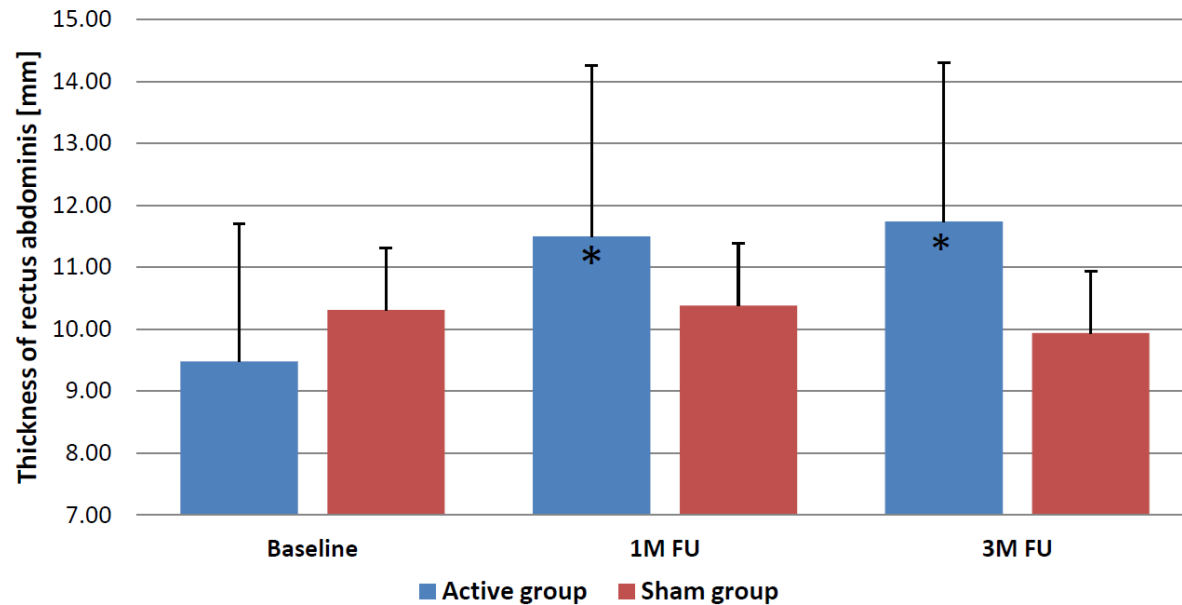
Active group

Muscle thickening by 21.5% (1 month, N=48), 24.2% (3 months, N=40) and 24.4% (6 months, N=21)

Changes were statistically significant against baseline ($p < 0.05$)

Sham group

Insignificant changes of negligible magnitude (maximum change of 0.9%)



MORE FOR LESS

EMSCULPT^{neo}

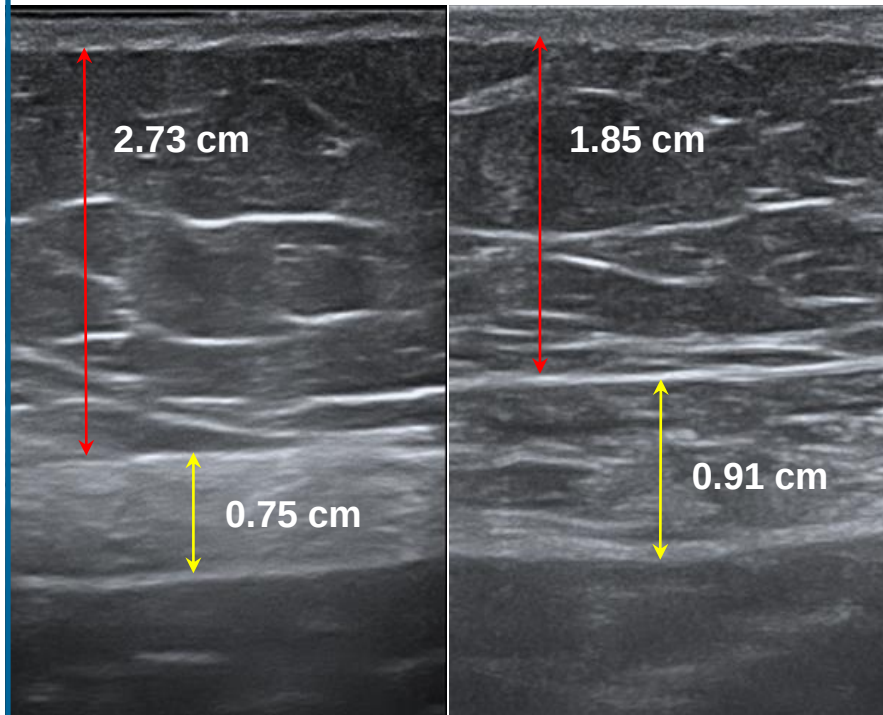
OTHER RESULTS

- Patients of both groups found the treatments comfortable
- **High satisfaction** with the treatment results reported by A group subjects (93.9%)
- **89.8% of A group subjects** observed improvement in both abdominal muscles and reduced fat
- Low level of improvement in muscle and fat reported by S group (31.6%)
- **All the outcomes were independent of skin type, gender, age or BMI**



EXAMPLE OF PATIENT RESULTS

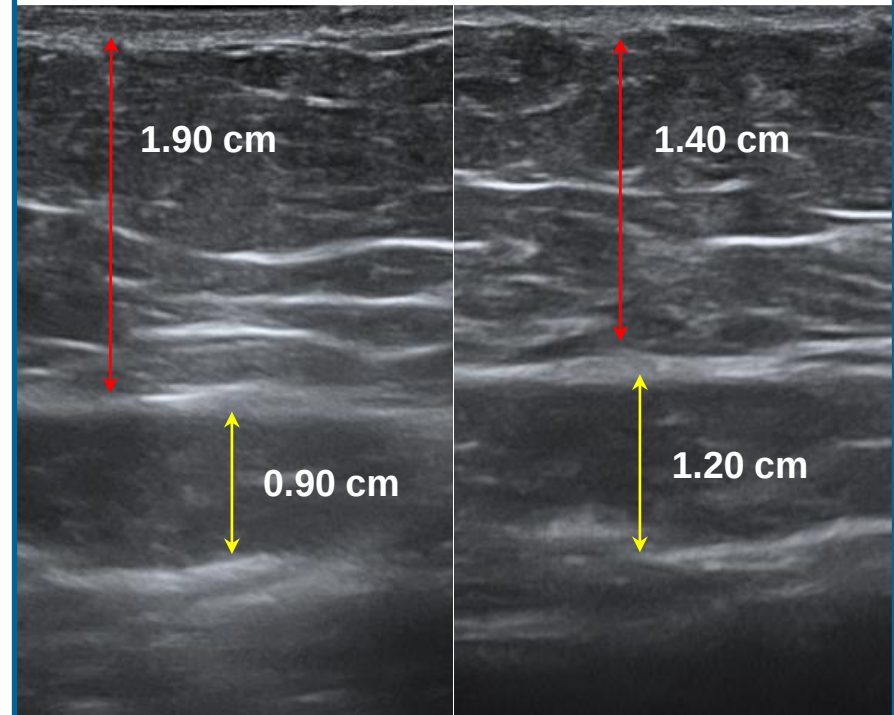
- 65-year-old female, BMI of 20.1 kg/m²
- Average **fat reduction of 32.1%**
- Average **muscle increase of 20.7%**



BEFORE

1 MONTH AFTER

- 51-year-old female, BMI of 33.4 kg/m²
- Average **fat reduction of 26.3%**
- Average **muscle increase of 33.3%**



BEFORE

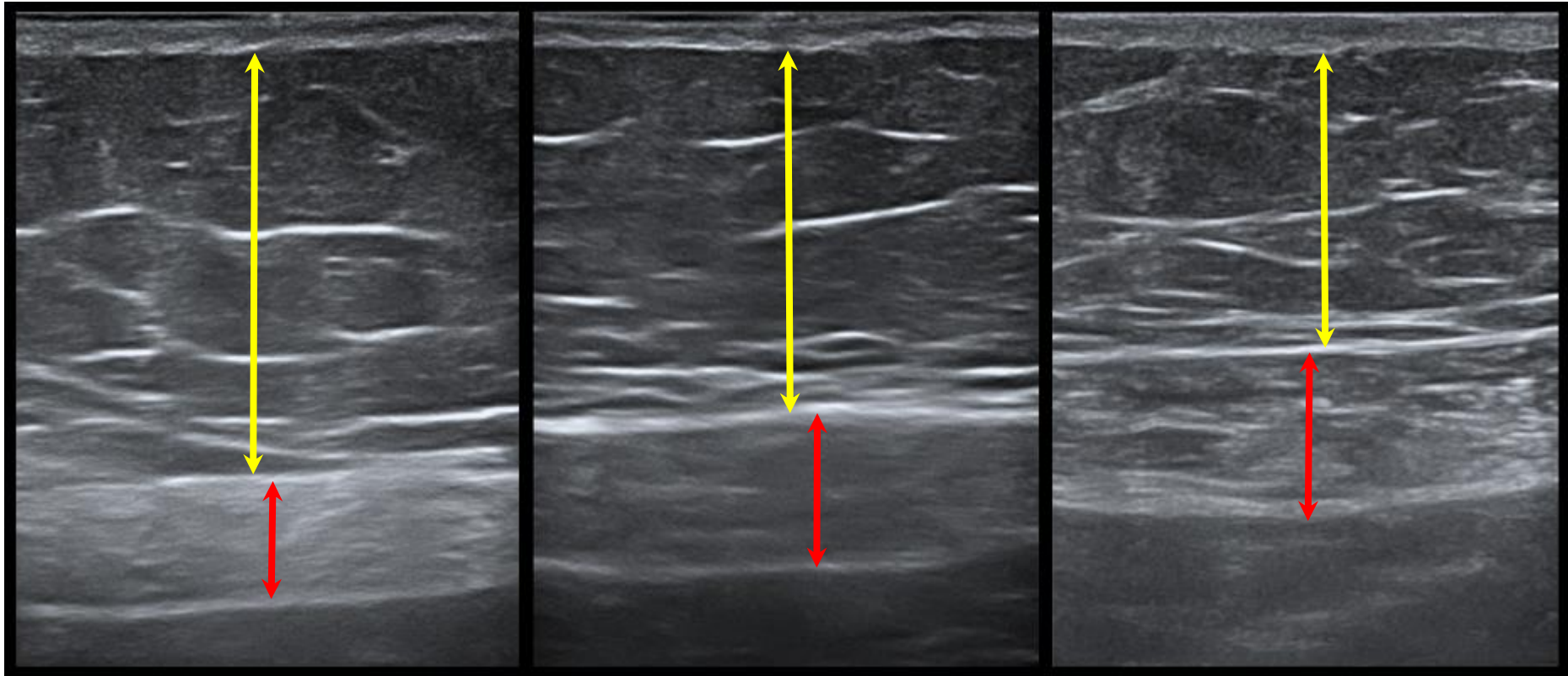
1 MONTH AFTER



MORE FOR LESS

EMSCULPT^{neo}

EXAMPLE OF PATIENT RESULTS



Ultrasound images of a patient from the A group taken at baseline (left), 1 month (center) and at 6 months (right). The images are showing continuously reducing fat layer (yellow) with increasing thickness of rectus abdominis (red).



MORE FOR LESS

EMSCULPT[®] neo

EXAMPLE OF PATIENT RESULTS

- 53-year-old female, BMI of 26.2 kg/m²
- **-32.3% of fat; +35.1% of muscle thickness**



BEFORE

3 MONTHS AFTER

- 38-year-old female, BMI of 22.8 kg/m²
- **-27.8% of fat; +15.8% muscle thickness**



BEFORE

3 MONTHS AFTER



MORE FOR LESS

EMSCULPT^{neo}

CONCLUSION

- The procedure combining RF and HIFEM showed to be highly effective for abdominal body shaping
- Results were consistent, all of the active patients showed fat reduction.
- High patient satisfaction of 93.9% in the HIFEM+RF group
- 36 out of 40 subjects showed a reduction higher than 22% at 3 months.



MORE FOR LESS

EMSCULPT^{neo}

III) SPOT REDUCTION OF LOCALIZED FAT DEPOSITS ON THE LATERAL THIGHS BY SIMULTANEOUS EMISSION OF SYNCHRONIZED RADIOFREQUENCY AND HIFEM ENERGY: MAGNETIC RESONANCE MULTICENTRE STUDY

Melanie Palm, M.D., MBA¹, Yael Halaas, M.D., FACS², Brian Kinney, M.D., FACS, MSME³, Richard Goldfarb M.D., FACS⁴

¹Art of Skin MD, Solana Beach, CA, United States

²Yael Halaas M.D., New York, NY, United States

³Brian M. Kinney M.D., Beverly Hills, CA, United States

⁴Center for SmartLipo & Plastic Surgery, PA, United States

Published in the Dermatologic Surgery, 2023

<https://doi.org/10.1097/DSS.0000000000003663>



MORE FOR LESS

EMSCULPT[®]
neo

STUDY DESIGN

- 93 subjects (21-70 y/o, 19.0-34.5 kg/m²), at four study sites
- Subjects with all skin types were included in this study.
- **Four (4) 30-minute bilateral treatments** combining RF+HIFEM on lateral thighs were performed
- Applicators were placed over the outer thighs on each side (“**Saddlebags**”)
- Treatment intensities (0-100%) were set according to the subject’s tolerance
- Baseline, 1-month, 3-month and 6-month data were analyzed



MORE FOR LESS

EMSCULPT[®] Neo

STUDY DESIGN: EVALUATION

Magnetic resonance imaging (MRI)

- Thickness of adipose tissue measured in the frontal plane

Hip & thigh circumference

- Hip: Widest part of the hip
- Thighs: 0, 5 and 10 cm below the gluteal fold

Satisfaction and comfort questionnaires

- 5-point Likert scale
- 10-point VAS scale

Digital photographs

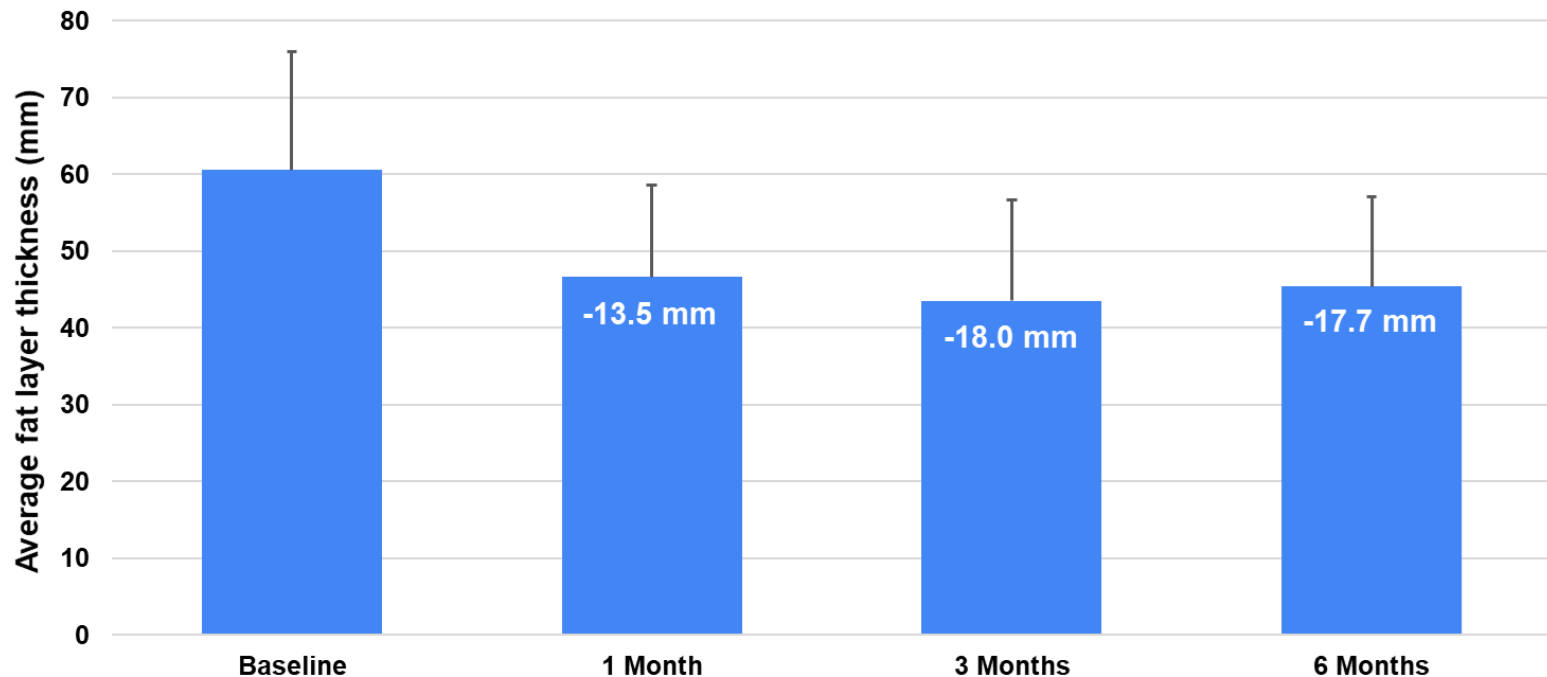
Adverse events monitoring

Localization of fat bulge in MRI



MRI RESULTS

- **60 MRI scans** were reviewed at 1 month, **51** at 3 months and **54** at 6 months
- The **changes** in fat thickness were **highly significant** ($p\text{-value} < 0.001$)
- The average **decrease peaked** at 3 months (-18.0 ± 5.5 mm; $-29.9 \pm 6.8\%$)
- Results were maintained ($-28.4 \pm 5.7\%$) at 6 months follow-up

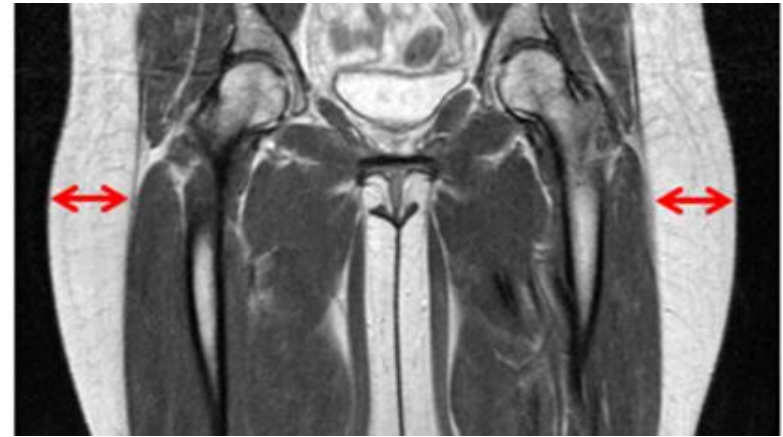
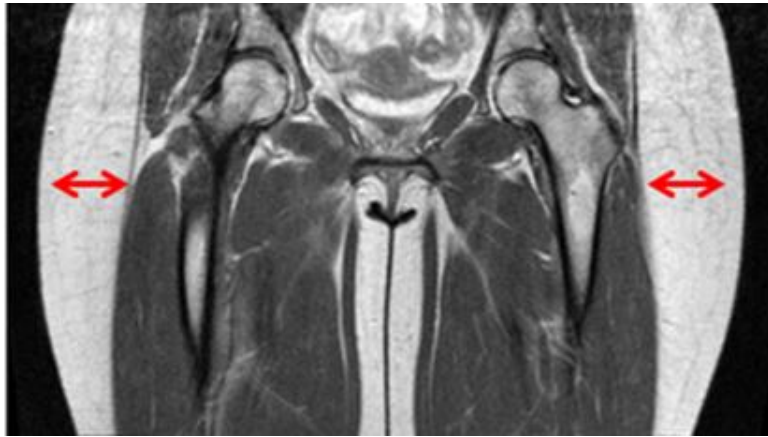


MORE FOR LESS

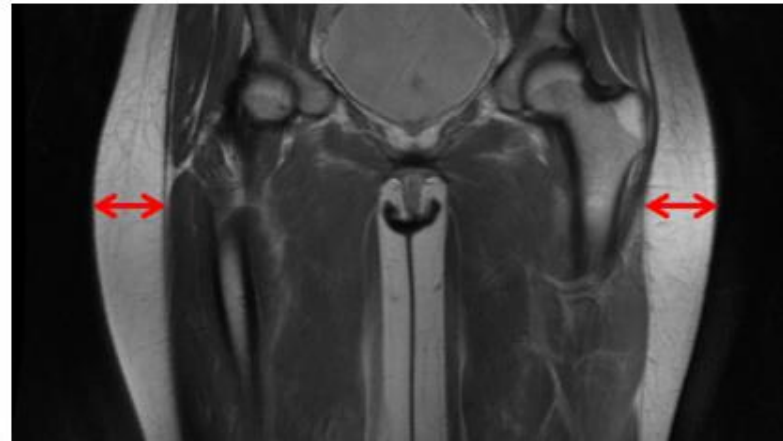
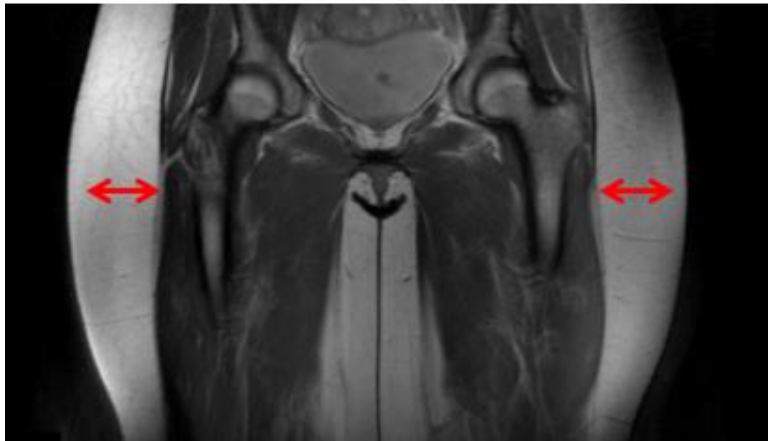
EMSCULPT[®] neo

RESULTS: EXAMPLE OF PATIENT RESULTS

Average fat thickness at baseline (left) of 5.9 cm was reduced at 1 month (right) by 1.3 cm



Average fat thickness at baseline (left) of 6.1 cm was reduced at 3 months (right) by 2.1 cm



MORE FOR LESS

EMSCULPT®

OTHER RESULTS

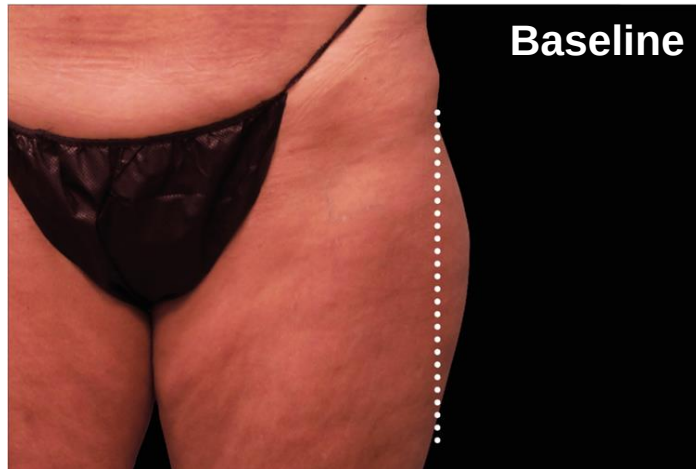
- Thigh **circumference decreased** on average by 2.3 cm at 3 months and by 3.0 cm at 6 months
- Measurements at 10 cm below gluteal fold showed greatest improvement in circumference (**-3.5 cm** at 3 months)
- In general, patients showed **high (82%) satisfaction** with achieved results
- **Therapies** were perceived as **comfortable** (91.0%)
- Noticeable reduction of saddlebags was seen on digital photographs
- **No serious adverse events** occurred



MORE FOR LESS

EMSCULPT^{neo}

EXAMPLE OF PATIENT RESULTS



Courtesy of: Brian Kinney, M.D.



Courtesy of: Melanie Palm, M.D.



MORE FOR LESS

EMSCULPT®

CONCLUSION

The objective data evidenced the effectiveness of the novel HIFEM+RF technology for fat reduction on lateral thighs

- Average 3-month **fat thickness reduction was as high as 30%** (-18.0 mm)
- Thigh **circumference was reduced** as much as -3.5 cm
- **Results were maintained** for 6 months

Patients reported high level of satisfaction with results

Digital photographs showed noticeable improvement

Therapy was well tolerated



MORE FOR LESS

EMSCULPT[®] Neo

IV) SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY FOR FAT DISRUPTION: HISTOLOGICAL AND ELECTRON MICROSCOPY PORCINE MODEL STUDY

Robert A. Weiss M.D., FAAD¹, MVDr Jan Bernardy Ph.D.², Prof MVDr Frantisek Tichy CSc³

¹Maryland Laser Skin, & Vein Institute, Hunt Valley, MD, USA

²Veterinary Research Institute, Brno, CZ

³Department of Anatomy and Histology, Faculty of Veterinary Medicine, University of Veterinary and Pharmaceutical Sciences Brno, CZ

Published in Dermatologic Surgery Journal, 2021

<https://doi.org/10.1097/DSS.0000000000003091>

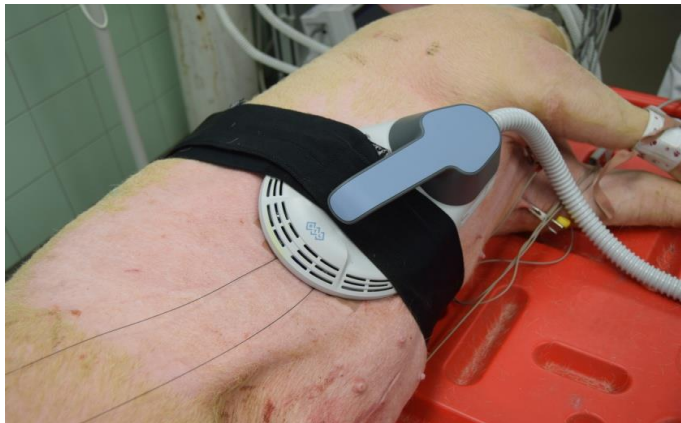


MORE FOR LESS

EMSCULPT[®]
neo

STUDY DESIGN

- **7 Large White pigs** (approximately 6 months old)
- All animals received active treatment procedure: 3x30 minutes on abdomen once a week
- **Biopsy specimens were collected** at baseline, 4 days, 2 weeks, 1 month and 2 months post-treatment
- During treatment and biopsy collection the animals were under anesthesia
- Sample processing resulted in **252 tissue slices**, that were analyzed



MORE FOR LESS

EMSCULPT[®] neo

STUDY DESIGN

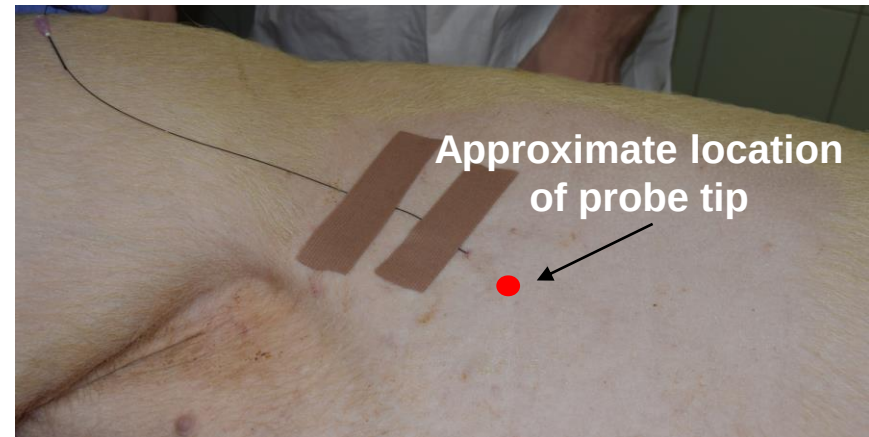
The goal of the study was to investigate the **effect of the treatment on subcutaneous fat**

Collected fat tissue samples were examined by two different approaches:

- **Histology (H&E staining)**
- **Scanning Electron Microscopy (SEM)**

Temperature measurements:

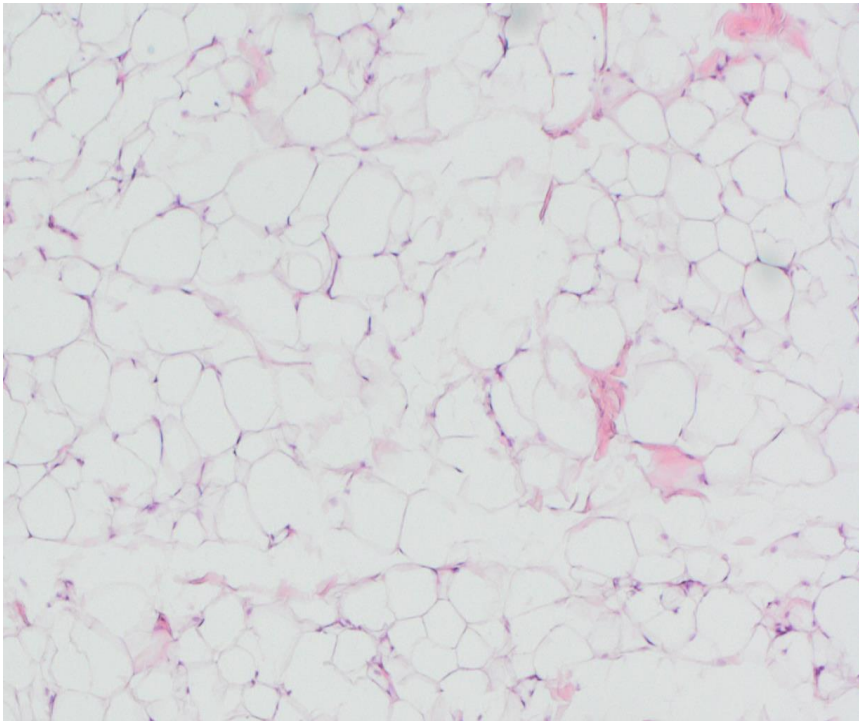
- Thermal imager for **surface temperature**
- In-vivo thermal probes for **fat temperature**



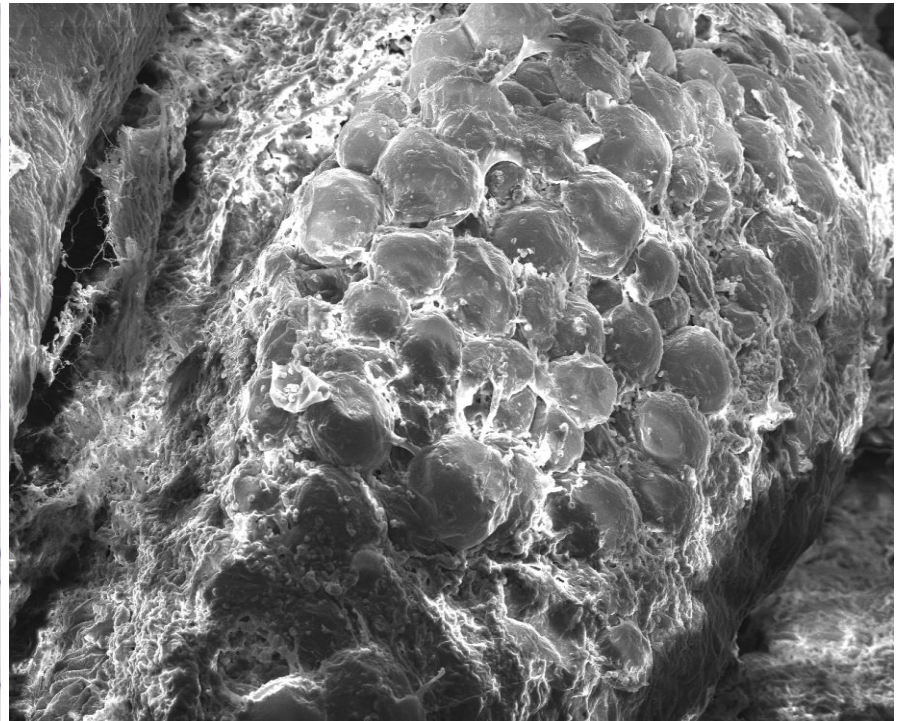
RESULTS: BASELINE

- Healthy fat cell structure
- Intact cells with **well defined shape**, without **any signs of damage**

Histology



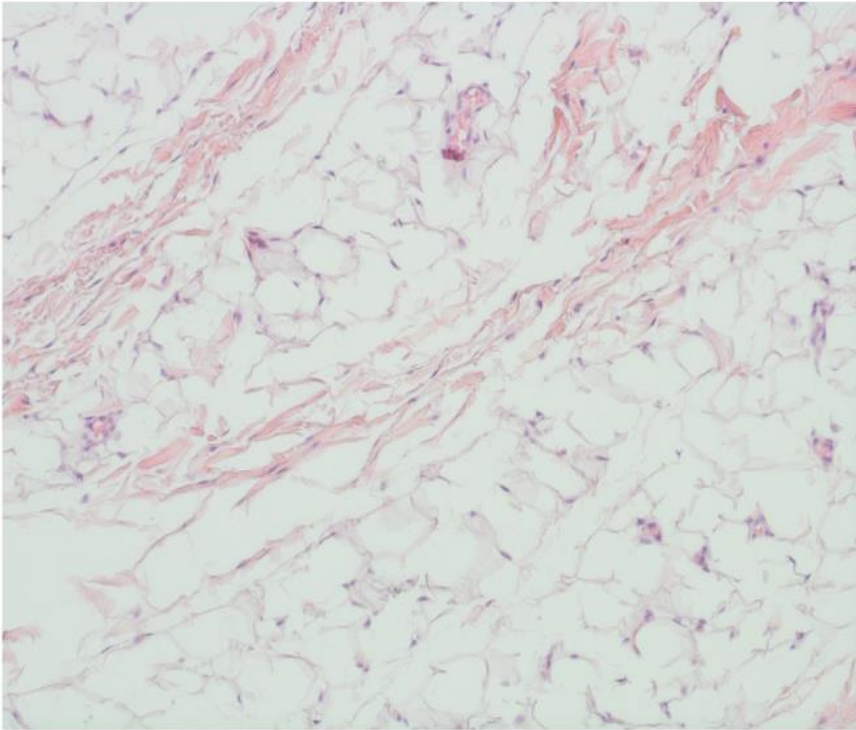
SEM



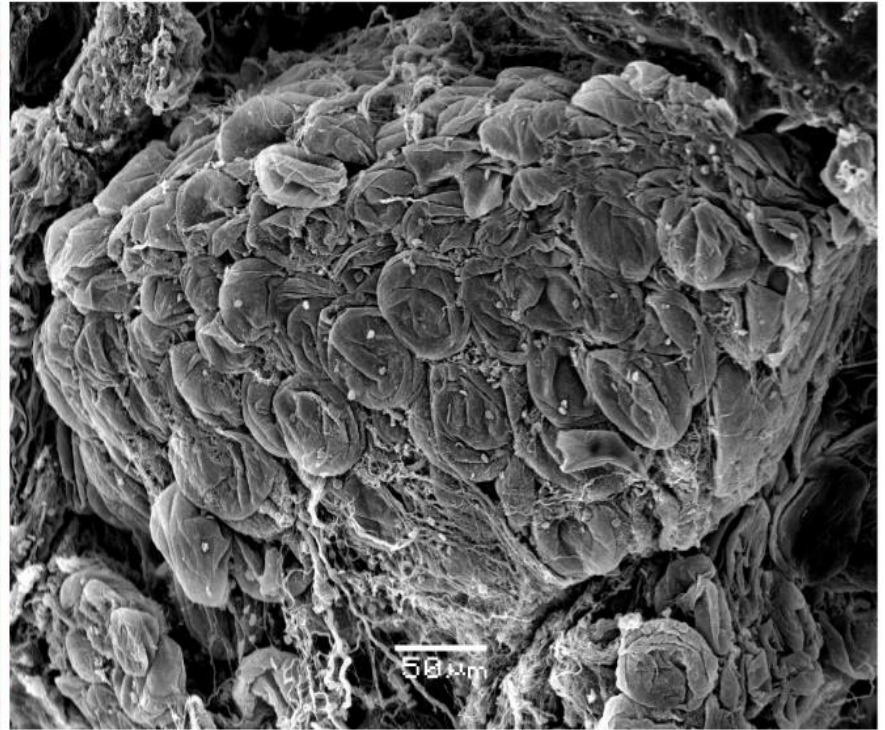
RESULTS: 4 DAYS POST-TREATMENT

- The fat cells are shrunk (lipolysis) with signs of membrane ruptures (apoptosis)
- First presence of pyknotic nuclei (the sign of apoptotic changes)

Histology



SEM



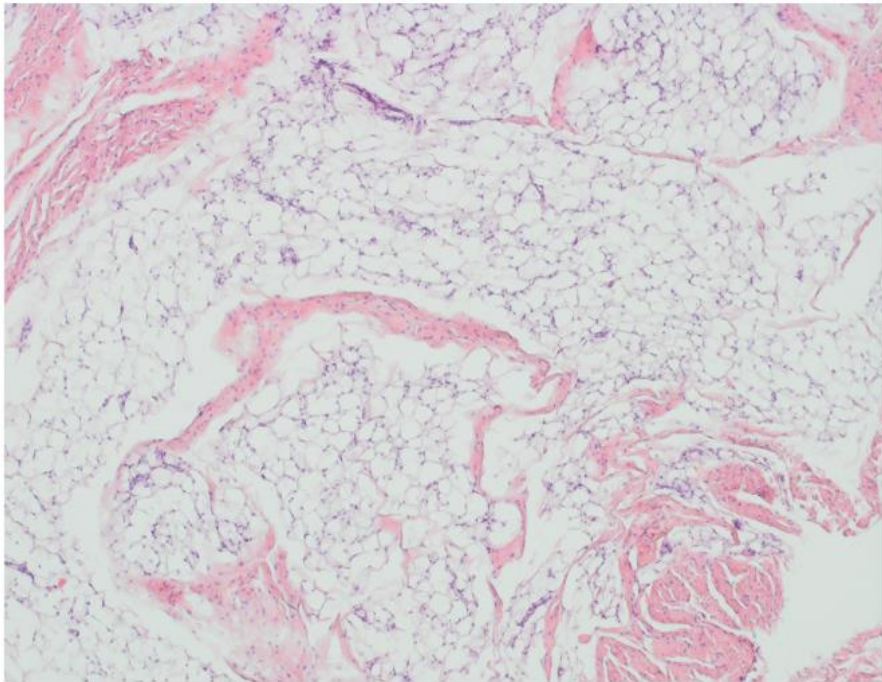
MORE FOR LESS

EMSCULPT^{neo}

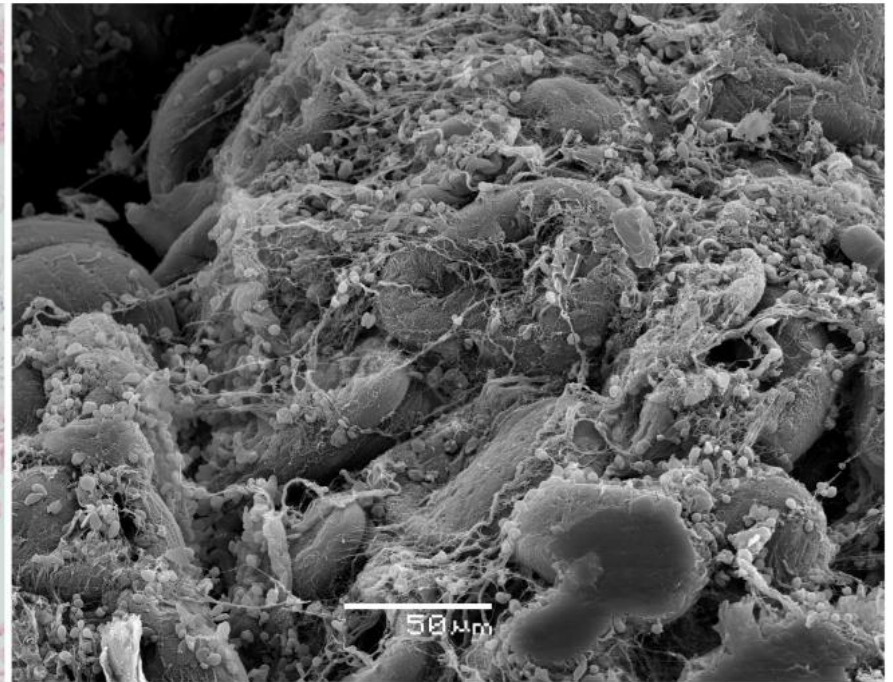
RESULTS: 2 WEEKS POST-TREATMENT

- **Flattened adipocytes of smaller size (-31.1%)**, some membranes manifest ruptures
- Presence of **pyknotic nuclei** (the sign of **apoptotic changes**)
- **Inflammatory cells** and macrophages are present

Histology

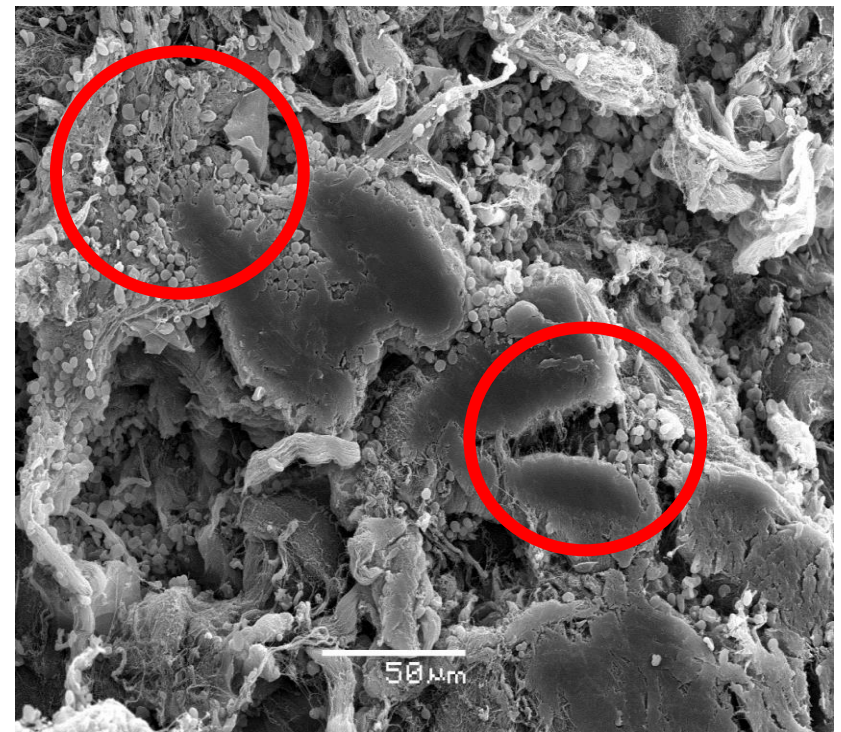
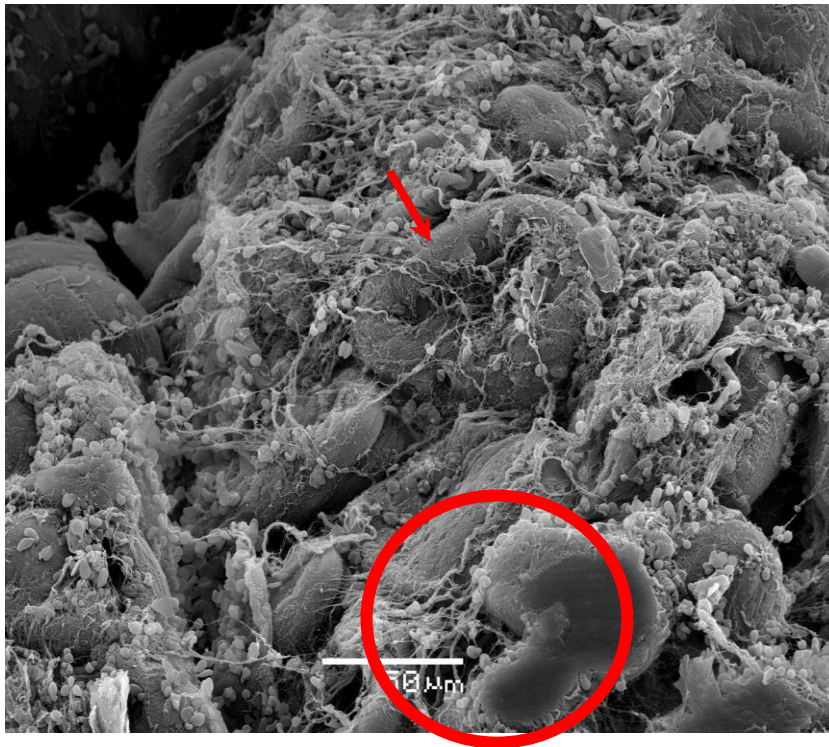


SEM



RESULTS: 2 WEEKS POST-TREATMENT

Cut through the **ruptured and damaged adipocytes** with flooding of the inner content (lipid droplets) out into the environment.



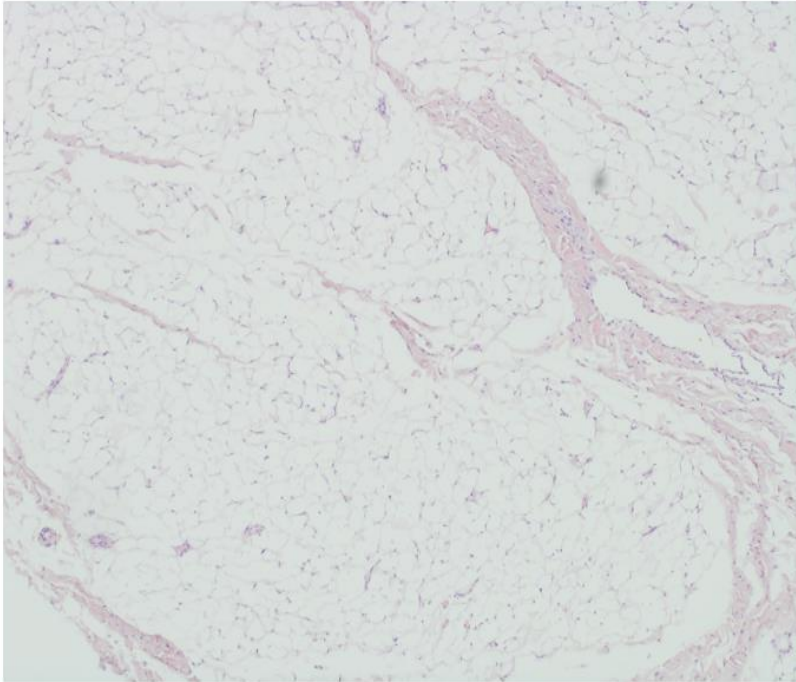
MORE FOR LESS

EMSCULPT®

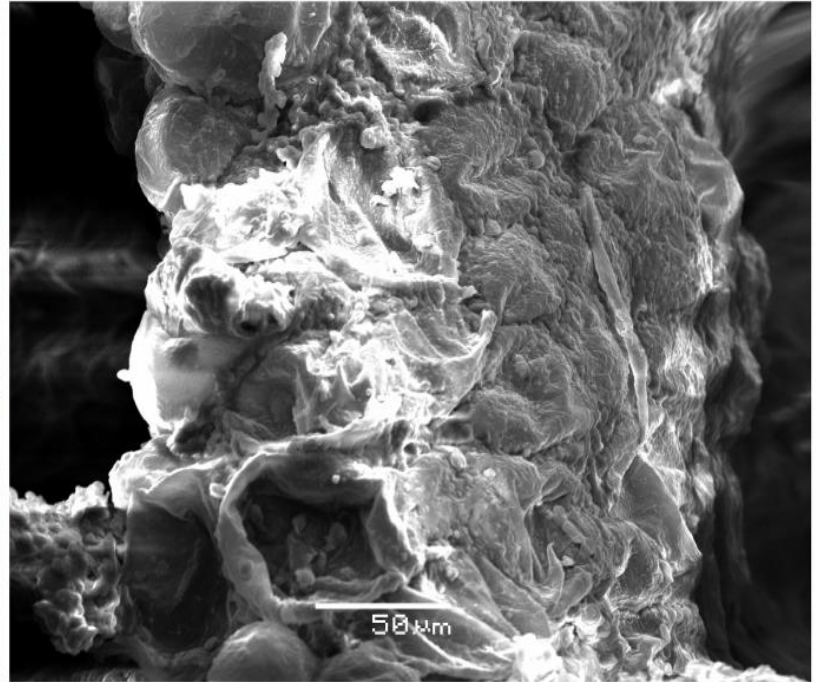
RESULTS: 1 MONTH POST-TREATMENT

- Occasional **ruptures in some adipocyte membranes** still visible
- The inflammatory infiltrate is receding
- Still presence of **damaged fat cells** which have not yet been cleared out

Histology



SEM



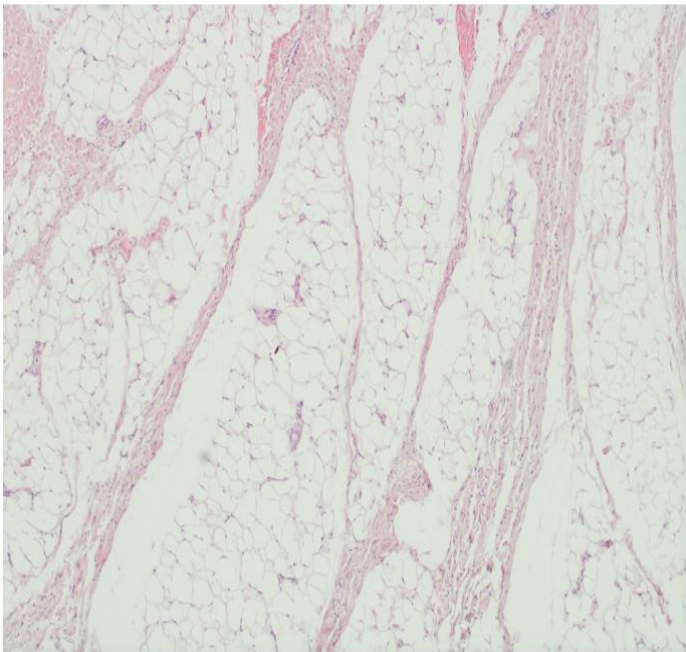
MORE FOR LESS

EMSCULPT®

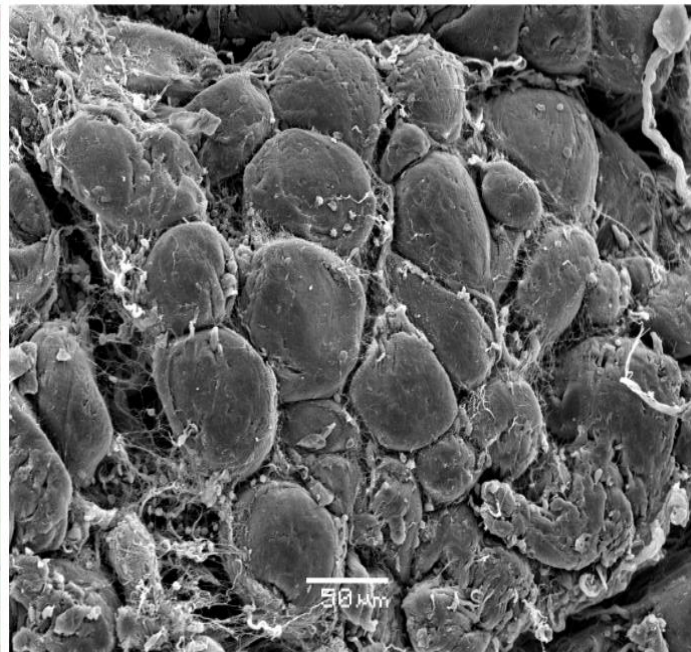
RESULTS: 2 MONTHS POST-TREATMENT

- The surviving adipocytes are nearly recovered, however, still showing some signs of **undergoing stress reaction**
- Macrophages and lymphocytic infiltrate are still occasionally present
- Blood **vessels** suffered **no damage**, **no necrosis** of fat tissue is seen

Histology

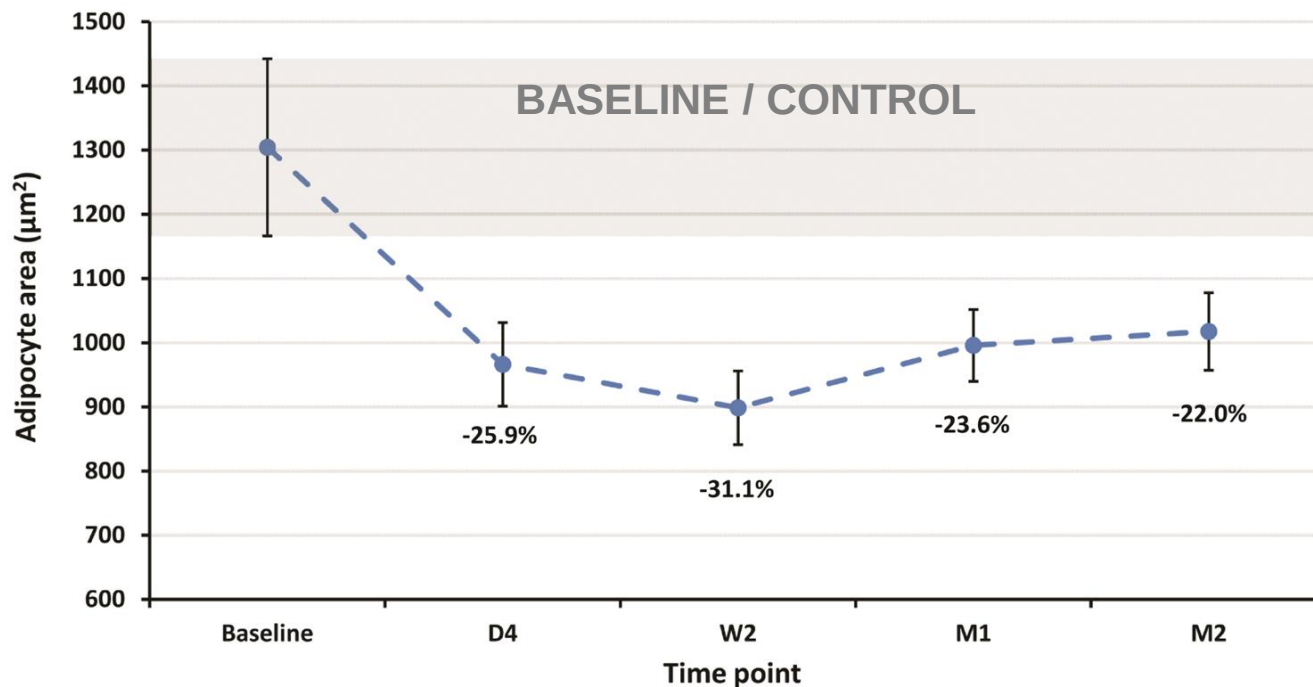


SEM



RESULTS: ADIPOCYTES SIZE MEASUREMENT

- A considerable **reduction of adipocytes area**
- **Greatest reduction** was observed **4 days** and **2 weeks** after the last procedure
- The adipocytes size **remains** smaller at **follow-ups** compared to baseline



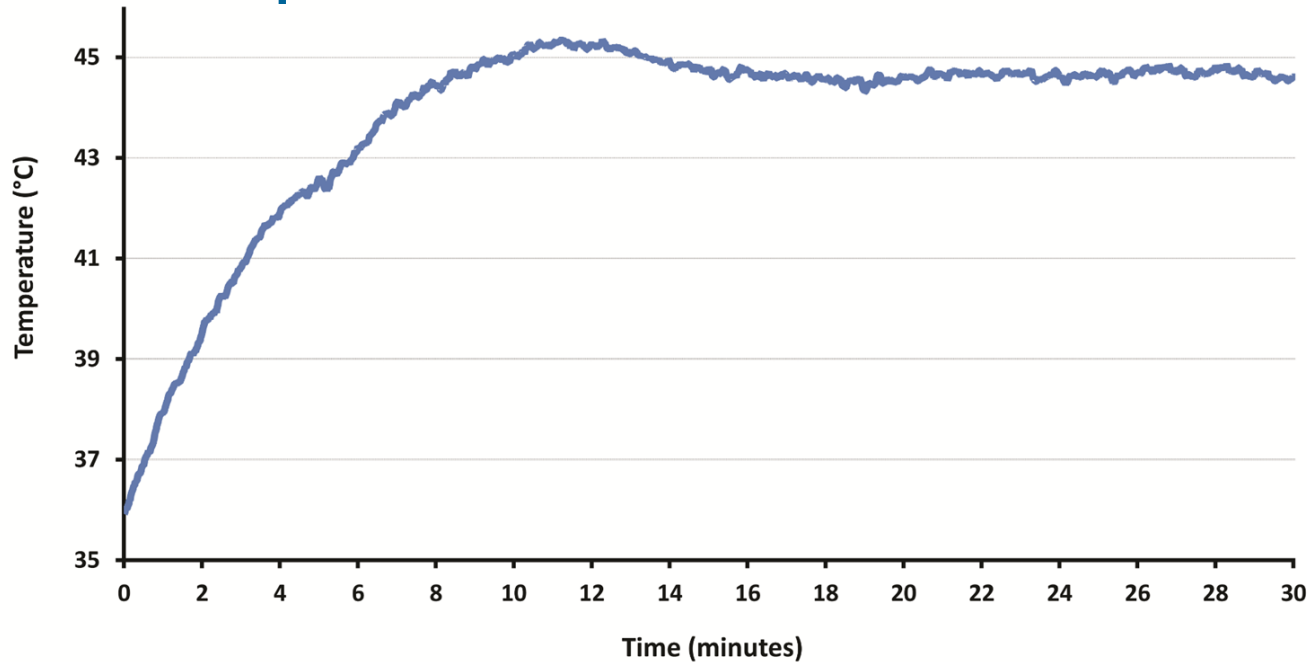
MORE FOR LESS

EMSCULPT^{neo}

RESULTS: TEMPERATURE MEASUREMENTS

- Apoptotic temperatures in fat proven by in-vivo measurements
- The skin surface temperatures were **between 42°C and 43°C**
- In fat tissue the temperature was maintained **just below 45°C** for more than **20 minutes**

Temperature in subcutaneous tissue



MORE FOR LESS

EMSCULPT®

CONCLUSIONS

- Post-treatment the adipocytes **were damaged** (apoptosis) and/or **shrunk** (lipolysis)
- **Mild inflammatory response** was present to promote the **apoptotic death cells removal**
- Histology and SEM showed efficacy of the procedure for **disruption of adipocytes**
- The procedure **elevates the temperature** in fat to levels necessary for **apoptosis induction**
- **No burns, necrosis or other serious adverse events were observed.**



MORE FOR LESS

EMSCULPT[®] Neo

V) DELETION OF ADIPOCYTES INDUCED BY A NOVEL DEVICE SIMULTANEOUSLY DELIVERING SYNCHRONIZED RADIOFREQUENCY AND HIFEM: HUMAN HISTOLOGICAL STUDY

David J. Goldberg M.D., JD¹

¹Icahn School of Medicine, New York, NY, USA

Published in the Journal of Cosmetic Dermatology, 2021
<https://doi.org/10.1111/jocd.13970>



MORE FOR LESS

EMSCULPT[®]
neo

STUDY DESIGN

- Three 30-minute abdominal treatments once a week
- Five patients in two groups:

ACTIVE TREATMENT (4 subjects)

Age: 46-57 (Avg 51.50±6.35) years

BMI: 19.2-26.8 kg/m²

HIFEM: Maximum tolerable intensity

RF: Maximum tolerable intensity

SHAM TREATMENT (1 subject)

Age: 57 years,

BMI: 23.60 kg/m²

HIFEM: 5% of device's output

RF: 5% of device's output

- Evaluation baseline, at 1-week and 1-month follow-ups
- Adverse events were monitored



STUDY DESIGN: EVALUATION

- **Histology:**
 - Fat tissue changes
 - Measurement of adipocytes size
- **In-vivo temperature measurement**
- Waist circumference
- Comfort and satisfaction

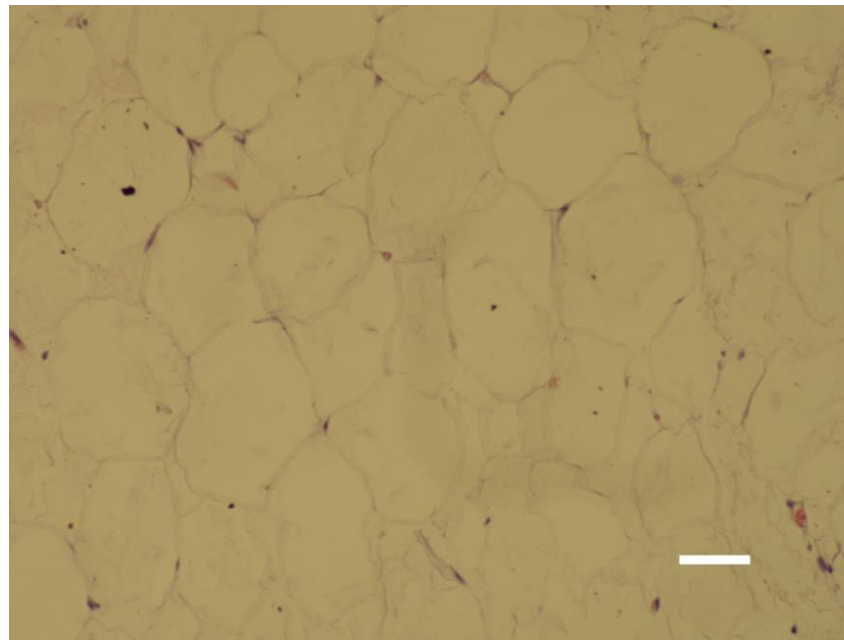


Incision mark after the punch biopsy

RESULTS: FAT TISSUE HISTOLOGY

BASELINE/CONTROL

- **Healthy unilocular cells** of round/polygonal shape, no deviations in adipocytes shape and **no signs of elevated apoptosis**

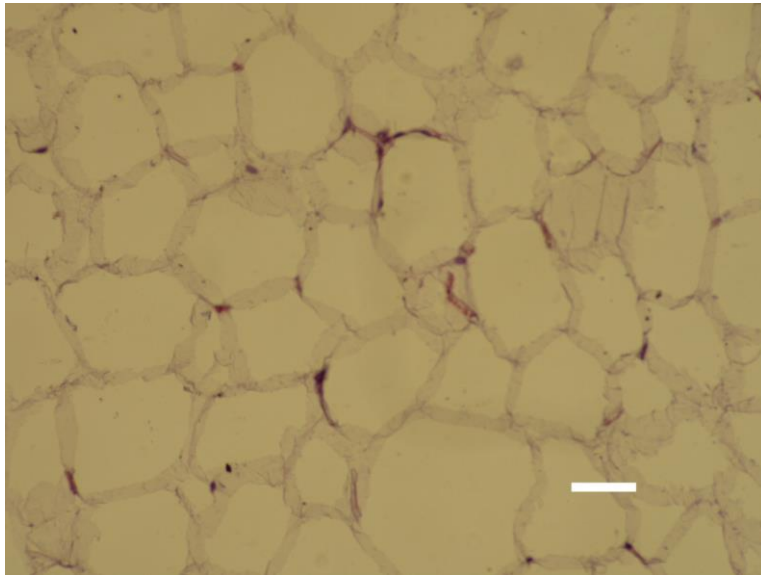


Baseline fat tissue histology, H&E
stained, bar = 40 μ m

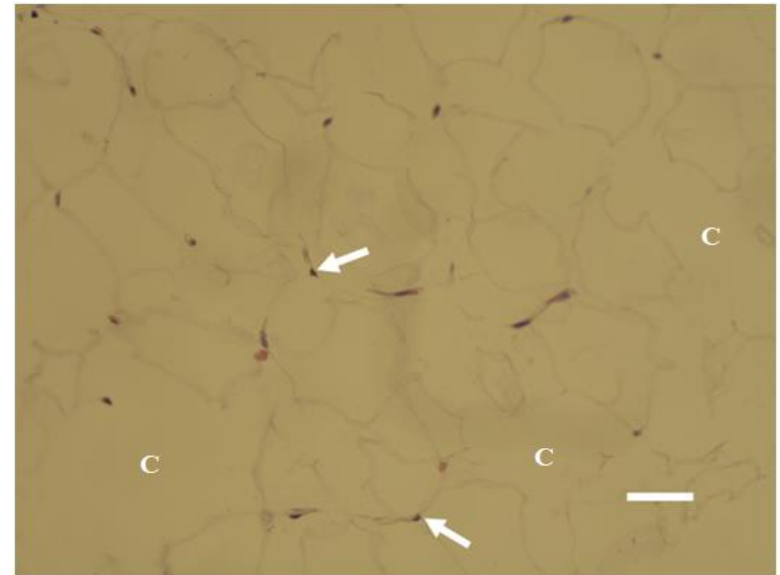
RESULTS: FAT TISSUE HISTOLOGY

1 WEEK POST-TREATMENT

- Elimination of fat cells (C) and **alternations** of adipocytes **shape** were found
- **Pyknotic nuclei** (sign of **apoptosis**) were observed (indicated by arrows)



Control, 1 week, bar = 30 μ m

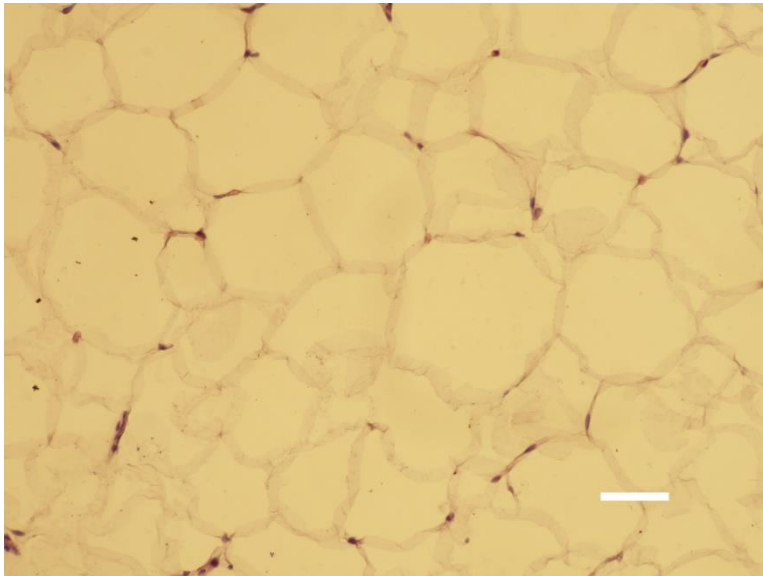


Active treatment, 1 week, bar = 30 μ m

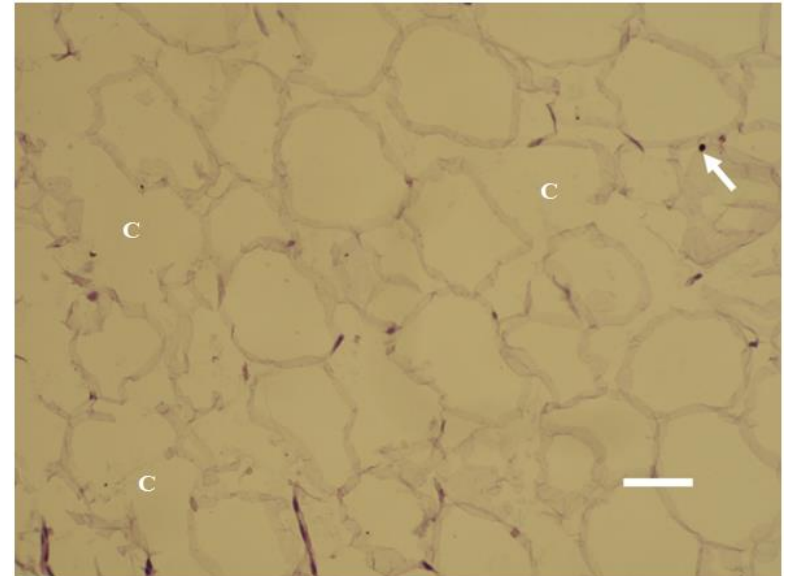
RESULTS: FAT TISSUE HISTOLOGY

1 MONTH POST-TREATMENT

- **Elimination of fat cells (C), no necrosis is present**
- **Destructive fragmentation of nuclei resulting from pyknosis (arrow)**



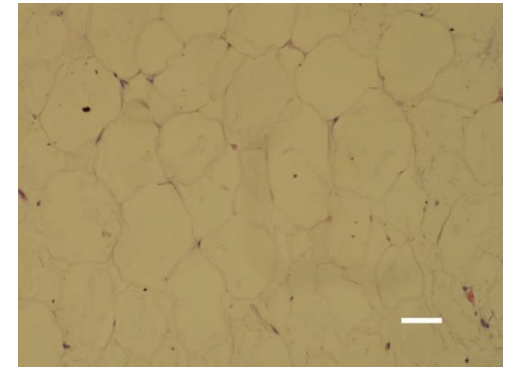
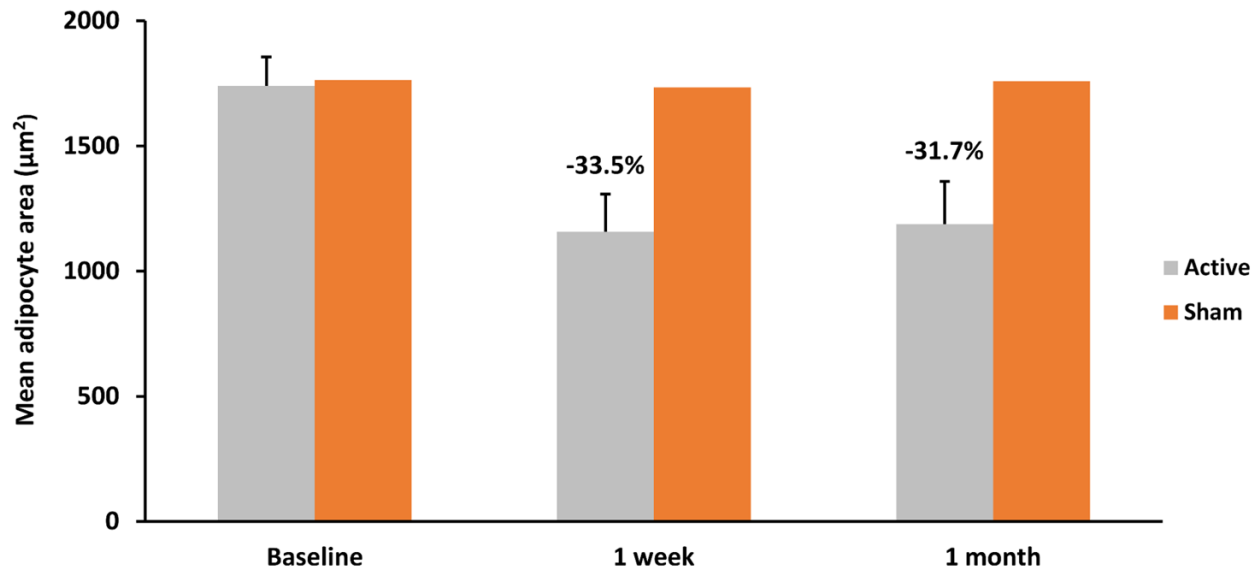
Control, 1 month, bar = 30 μ m



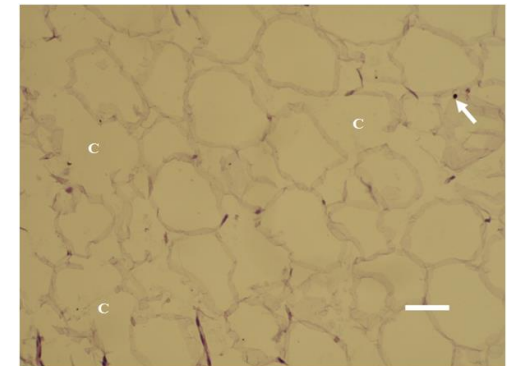
Active treatment, 1 month, bar = 30 μ m

RESULTS: ADIPOCYTES SIZE

- Significant ($P < 0.05$) decrease in adipocytes area
- **Control** subject showed **no change** over time



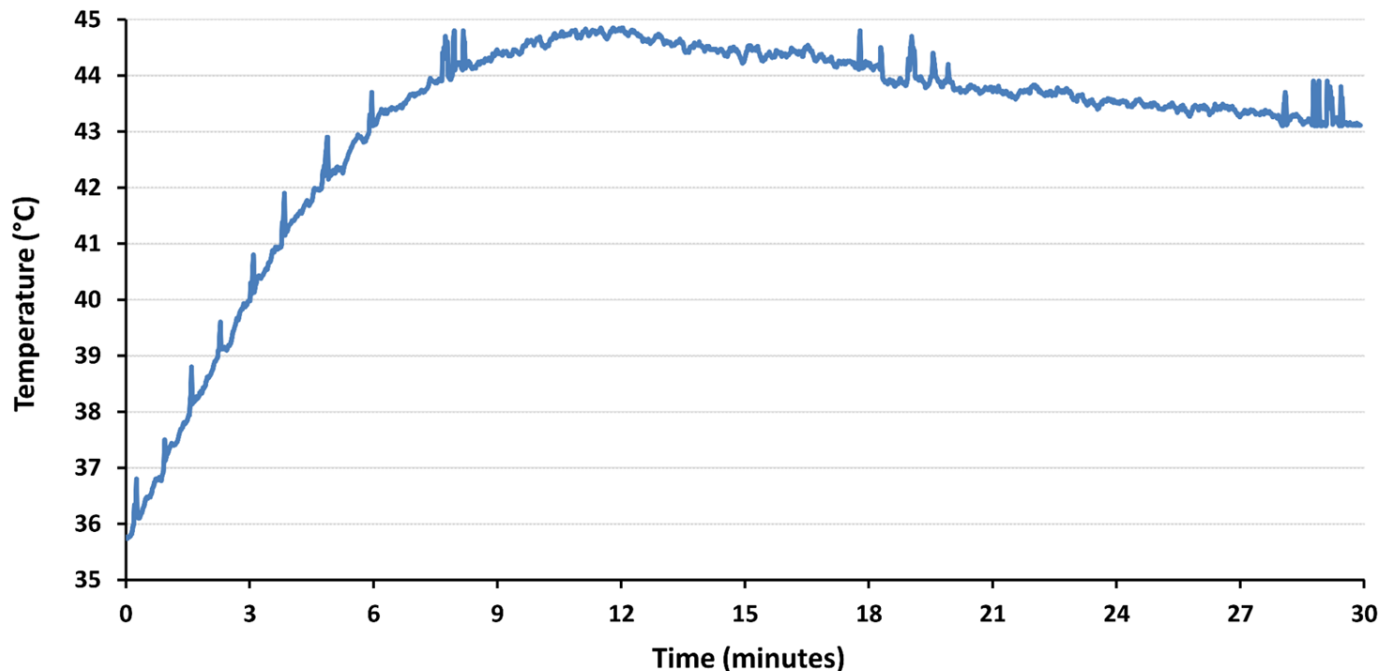
Baseline, bar = 40 μm



1 month, bar = 40 μm

RESULTS: TEMPERATURE IN FAT TISSUE

- Effective temperature of **42°C** was achieved in four minutes
- Temperature stayed between **43-45°C** throughout most of the therapy
- Measurement confirmed **lethal thermal damage** to adipose tissue¹



1) Franco W, Kothare A, Ronan SJ, Grekin RC, McCalmont TH. Hyperthermic injury to adipocyte cells by selective heating of subcutaneous fat with a novel radiofrequency device: Feasibility studies. *Lasers Surg Med.* 2010;42(5):361-370.



MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS

Patient digital photographs (57 years, 22.98 kg/m²) showing the improved body contour



BASELINE



AFTER 1 MONTH



MORE FOR LESS

EMSCULPT®
neo

OTHER RESULTS:

- Waist circumference reduction **in active group: -2.20 cm**
 - **Maximum circumference reduction of -5.4 cm**
- **No change in sham subject**
- **All subjects** found the treatments **comfortable**
- Active group was more satisfied with the results than sham



MORE FOR LESS

EMSCULPT[®] neo

CONCLUSION

- Histology suggested **apoptotic elimination** of adipocytes
- Fat **cell size was reduced** due to lipolysis
- **No necrosis** was seen
- **Therapy reaches effective temperatures** for apoptosis
- Procedure is **comfortable** with **high patient satisfaction**



MORE FOR LESS

EMSCULPT^{neo}

VI) ACTIVATION OF SKELETAL MUSCLE SATELLITE CELLS BY A DEVICE SIMULTANEOUSLY APPLYING HIGH-INTENSITY FOCUSED ELECTROMAGNETIC TECHNOLOGY AND NOVEL RF TECHNOLOGY: FLUORESCENT MICROSCOPY FACILITATED DETECTION OF NCAM/CD56

Yael Halaas M.D.¹, Diane Duncan, M.D.², MVDr. Jan Bernardy Ph.D³, MVDr. Petra Ondrackova Ph.D.³, Ivan Dinev DVM, Ph.D., DSc⁴

¹Facial Plastic and Reconstructive Surgery, New York, NY, USA

²Plastic Surgical Associates, Fort Collins, CO, USA

³Veterinary Research Institute, Brno, CZ

⁴General and Clinical Pathology, Faculty of Veterinary Medicine, Trakia University, Stara Zagora, BG

Published in the Aesthetic Surgery Journal, 2021

<https://doi.org/10.1093/asj/sjab002>



MORE FOR LESS

EMSCULPT[®] neo

BACKGROUND

What are satellite cells?

- Muscle-derived **stem cells**¹
- Responsible for **myofiber development and renewal**
- In resting muscles, satellite cells remain in quiescent (inactive) state¹
- However, **exercise can alter the state and trigger the differentiation**^{2,3}
- SCs have the ability to re-enter the cell cycle to **generate new muscle fibers** or to **provide new myonuclei** during postnatal growth^{2,3}
- SCs play an important role in **regenerating overloaded muscles** and in **adaptation** of skeletal muscles to exercise⁴

1. Mauro A. Satellite cell of skeletal muscle fibers. *J Biophys Biochem Cytol.* 1961;9:493-495. .

2. Moss FP, Leblond CP. Satellite cells as the source of nuclei in muscles of growing rats. *Anat Rec.* 1971;170(4):421-435.

3. Schultz E, McCormick KM. Skeletal muscle satellite cells. *Rev Physiol Biochem Pharmacol.* 1994;123:213-257.

4. Hawke TJ, Garry DJ. Myogenic satellite cells: physiology to molecular biology. *J Appl Physiol (1985).* 2001;91(2):534-551.



OBJECTIVE

- **HIFEM procedure** induces muscle fiber hypertrophy through **supramaximal contractions**
- **Radiofrequency heating promotes the hypertrophic effect** of HIFEM contractions
- **Combination treatment should synergistically affect the levels of satellite cells**

The aim of this study is to examine the effect of combined HIFEM and RF procedure on the level of satellite cells



STUDY DESIGN

- **5 Large White Swine**, age approximately 6 months
- All animals received **3 thirty-minute treatments** applied on abdomen (1tx per week)
- **The opposite site of the abdomen was used as a control area**
- 2 biopsy specimen (ø 6mm) from the treatment site and 2 from control site
- In total, **275 tissue slices** were analyzed



MORE FOR LESS

EMSCULPT[®] neo

STUDY DESIGN: EVALUATION

Immunofluorescence:

- For **satellite cell** analysis by **NCAM/CD56** - the marker labeling satellite cells
- The tissue samples were cut to **four 5–10µm thick slices**

Conventional Histology:

- For histological analysis of any treatment related structural changes
- Samples were cut to **5–10µm thick slices** and colored using **H&E staining**

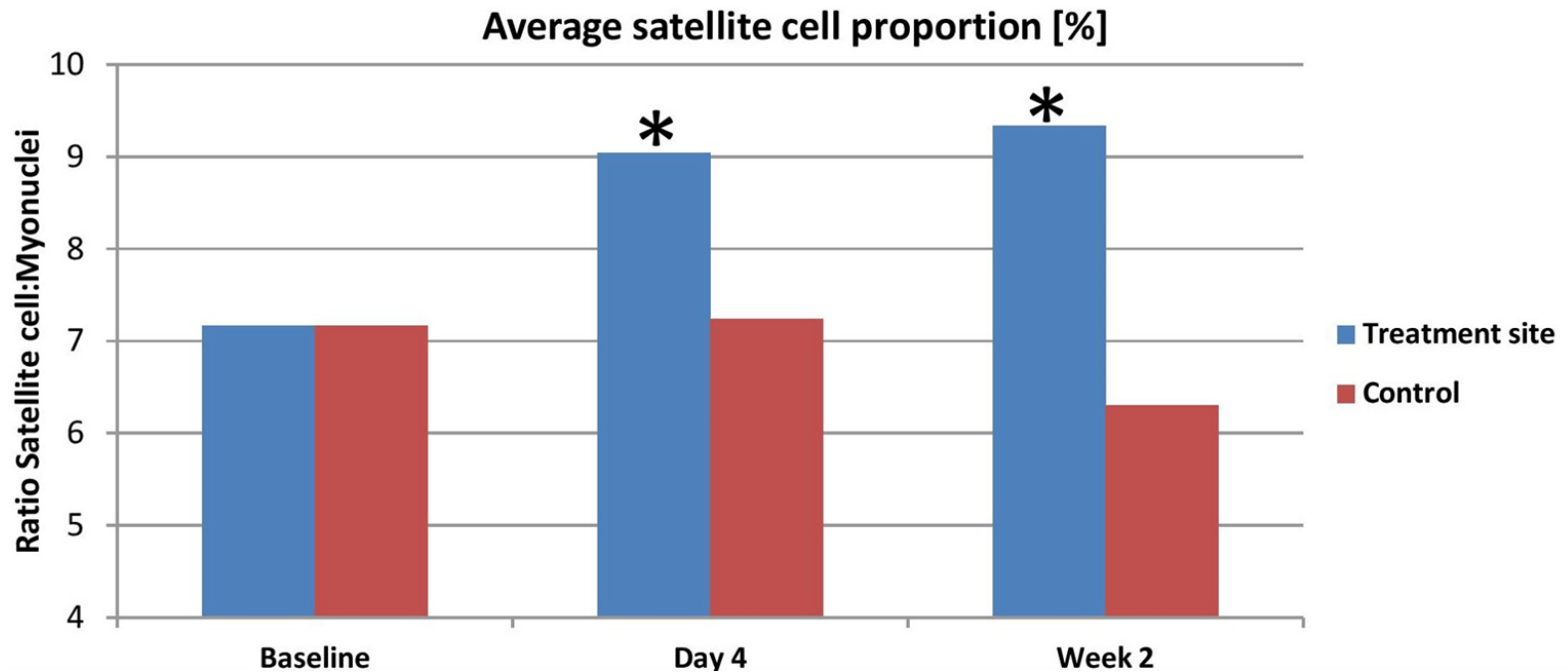
Muscle Temperature Monitoring:

- Temperature monitoring by fiber optic probe during the treatment for safety reasons and to rule out any possibility of muscle tissue overheating



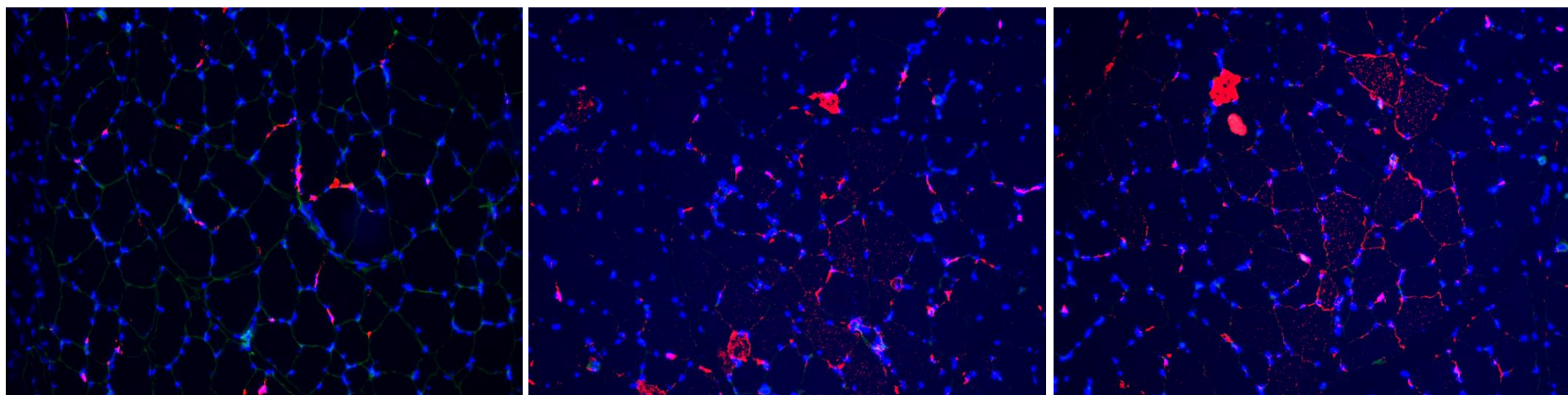
RESULTS: IMMUNOFLUORESCENCE

- The proportion of satellite cells increased by **26.1% at day 4** ($p < 0.05$)
- **2 weeks post-treatment** the **satellite cell proportion** was elevated by **30.2%** from baseline ($p < 0.05$)
- **No changes were seen for the control samples** ($p > 0.05$)



IMMUNOFLUORESCENCE RESULTS

Satellite cells (red) and myonuclei (blue)



Baseline

4 days after

2 weeks after

The levels of satellite cells are growing over time

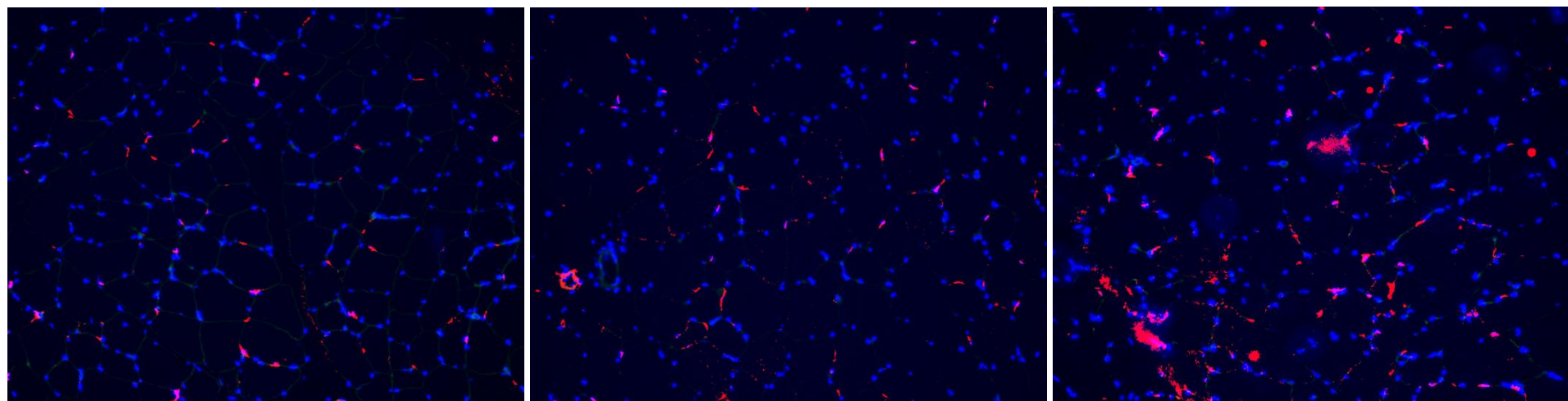


MORE FOR LESS

EMSCULPT[®] neo

IMMUNOFLUORESCENCE RESULTS

Satellite cells (red) and myonuclei (blue)



Baseline

4 days after

2 weeks after

The levels of satellite cells are growing over time



MORE FOR LESS

EMSCULPT^{neo}

COMPARISON WITH EXERCISE PROGRAMS

STUDY	PROGRAM	SATELLITE CELL CONTENT
Mackey et al.	12 weeks exercise (males)	+36%
Kadi et al.	90 days exercise	+ 31%
CURRENT STUDY	3 sessions HIFEM+RF	+30.2%
Olsen et al.	16 weeks exercise	+ 27%
Olsen et al.	4 weeks exercise	+ 22%
Kadi et al.	30 days exercise	+ 19%
Mackey et al.	12 weeks exercise (females)	+ 18%

HIFEM+RF induces satellite cell response similar as seen after 12-16 week exercise programs



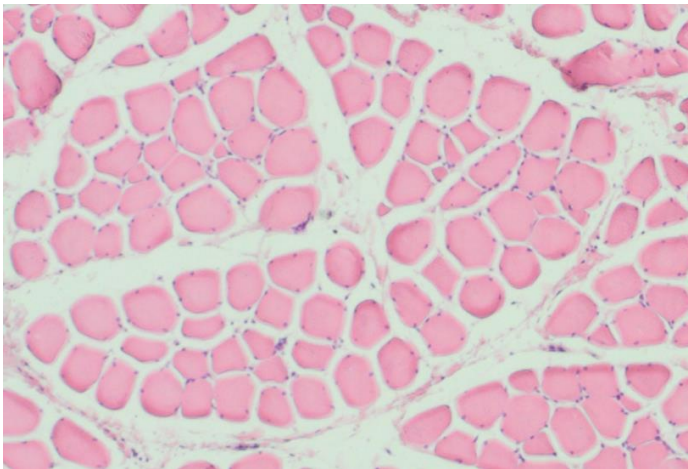
MORE FOR LESS

EMSCULPT®

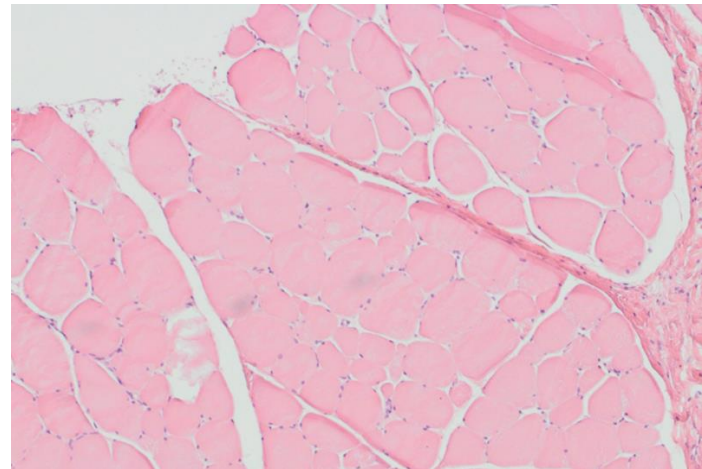
RESULTS: HISTOLOGICAL OBSERVATIONS

- Post-treatment slices showed **hypertrophic fibers**
- **Signs of newly formed myofibers** were present at several post-treatment slices
- No deviations from normal healthy muscle structure was seen
- **No signs of muscle damage** or treatment related serious adverse events were observed

Baseline



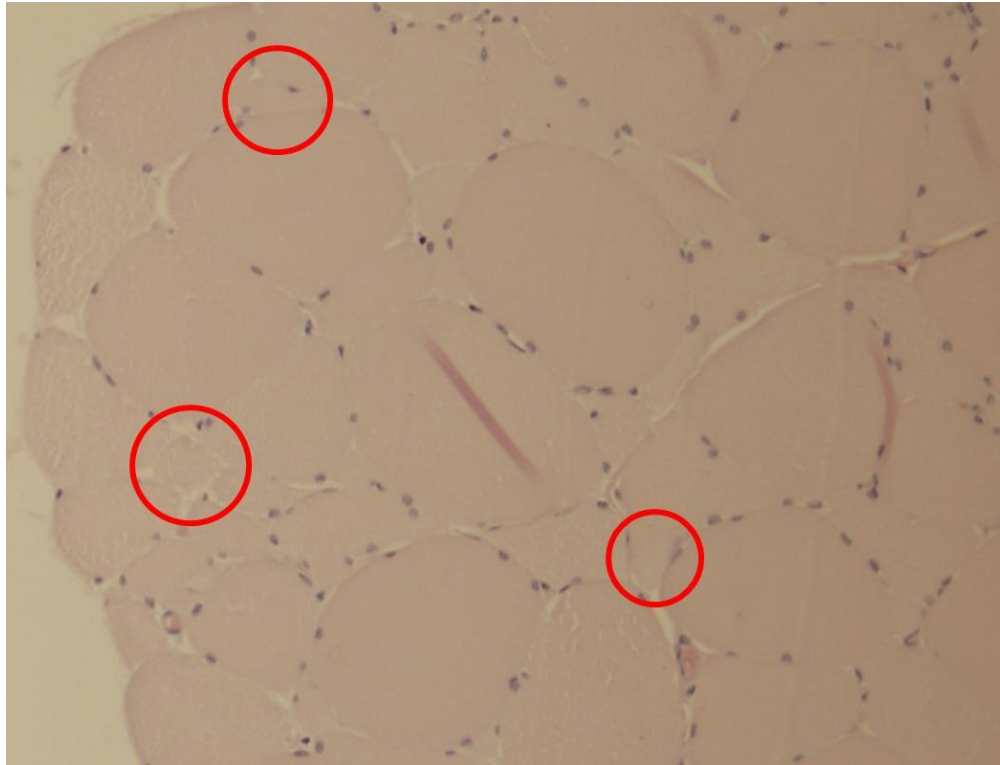
1M after last TX



Comment: The post-treatment tissue shows **hypertrophic fibers** and a noticeable increase in the muscle tissue with decreased intramuscular sheaf space.

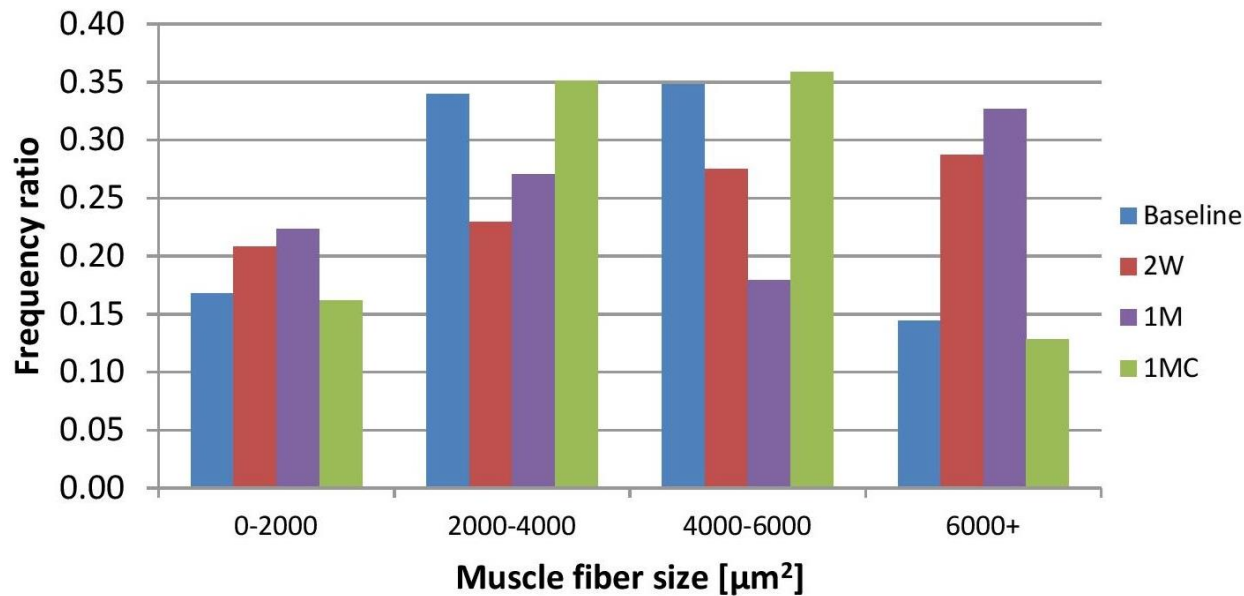
RESULTS: NEWLY FORMED MUSCLE FIBERS

Red circles mark area with small diameter muscle fibers that may be **newly formed muscle fibers** at post-treatment slice (1 month)



RESULTS: MUSCLE FIBER SIZE

- The results showed an increased number of large **hypertrophic fibers** post-treatment
- The frequency ratio of **large fibers** increased by **135.7%** at 1 month.
- Aside from fiber growth, the number of **small-diameter fibers** was **increased** as well
- The frequency ratio of **small fibers** increased by **29.4%** at 1 month.
- This finding strongly suggests muscle fiber hyperplasia



RESULTS: TEMPERATURE MEASUREMENTS

Muscle temperature during treatment

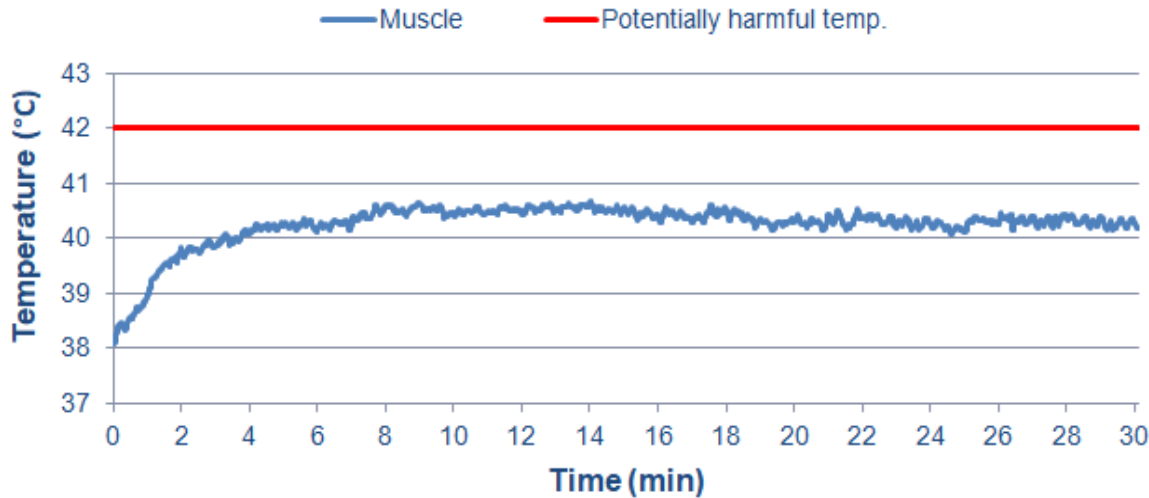


Illustration of thermal probe installation

- Muscle temperature was elevated to **40°C during the first 2 minutes**
- Then the temperature was maintained between **40 and 41°C for the rest of the treatment**
- The **temperature in muscle was in safe levels** for the entire treatment without any risks for the muscle tissue

CONCLUSIONS

- HIFEM+RF therapy significantly **increases the levels** of labeled **satellite cells** by **30.2%**
- **The effect is comparable with 12-16 weeks long exercise programs**
- Together with histological observations satellite cells appear to:
 - **Incorporate** into the existing muscle fibers and **create new myonuclei**
 - **Muscle** fibers can **grow more** and SC thus support **muscle fiber hypertrophy**
 - Differentiate and **form new muscle fibers**
- **Procedure** based on stimulating and heating muscle tissue **is safe** and does **not cause** any muscle **damage**
- **The muscle temperature was maintained on a safe level** without any potential risks to the muscle tissue



MORE FOR LESS

EMSCULPT^{neo}

VII) HIFEM WITH SYNCHRONIZED RADIOFREQUENCY ACHIEVES SUPERIOR GLUTEAL MUSCLE CONTOURING THAN HIFEM PROCEDURE ALONE

Barry DiBernardo M.D.¹, David J. Goldberg M.D., JD², Bruce Katz M.D.³, JD McCoy NMD⁴, Suneel Chilukuri M.D., FAAD, FACSM⁵,

¹New Jersey Plastic Surgery, New Jersey, NY, United States

²Icahn School of Medicine, New York, NY, United States

³Juva Skin and Laser Center, Manhattan, NY, United States

⁴Contour Mecal, Gilbert, AZ, United States

⁵Refresh Dermatology, Houston, TX, United States

Published in the Aesthetic Surgery Journal Open Forum, 2023

<https://doi.org/10.1093/asjof/ojac087>



MORE FOR LESS

EMSCULPT®
neo

STUDY DESIGN

- **67 subjects** were recruited and were divided into:

Group A:

- Simultaneous HIFEM+RF therapy
- 34 subjects (21-57 years, 16-34.0 kg/m²)

Group B:

- Standalone HIFEM treatment
- 33 subjects (23-67 years, 17.4-31.7 kg/m²)

Treatment:

- Four (4) 30-minute bilateral treatments on the buttocks spaced by 5-10 days
- HIFEM at maximum tolerable level, RF energy set to 100% of gentle preset (in group A only)



STUDY DESIGN: EVALUATION

Magnetic resonance imaging (MRI; axial plane images)

Thickness of gluteal muscles and adjacent fat layer were measured:

- Just above the femoral head - gluteus maximus
- At the inferior point of the sacroiliac joint - gluteus medius and minimus

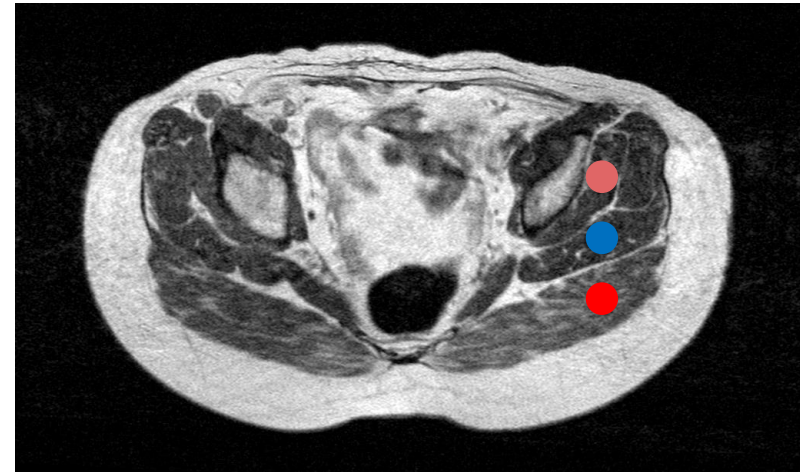
Satisfaction and comfort questionnaires

- 5-point Likert scale
- 10-point VAS scale

Digital photographs

Adverse events monitoring

Illustrative MRI above the femoral head



g. maximus, g. medius and g. minimus

RESULTS

Muscle Tissue	Group A (HIFEM + RF)	Group B (HIFEM)
<i>Gluteus maximus</i>	+8.5±1.9 mm	+5.2±1.1 mm
<i>Gluteus medius</i>	+6.0±1.1 mm	+3.6±1.0 mm
<i>Gluteus minimus</i>	+2.9±0.8 mm	+1.6±0.4 mm

Fat thickness

- **Changes** in fat were **negligible and clinically insignificant** in both groups (-0.2%, p-value > 0.05)



MORE FOR LESS

EMSCULPT[®] Neo

RESULTS: SATISFACTION & COMFORT

Subject satisfaction

- Subjects in both groups were **highly satisfied** with the therapy results (over **84%** in both groups)
- All **subjects agreed or strongly agreed** that their appearance in the treated area is more toned after the therapies in both groups (over **93%** in both groups)

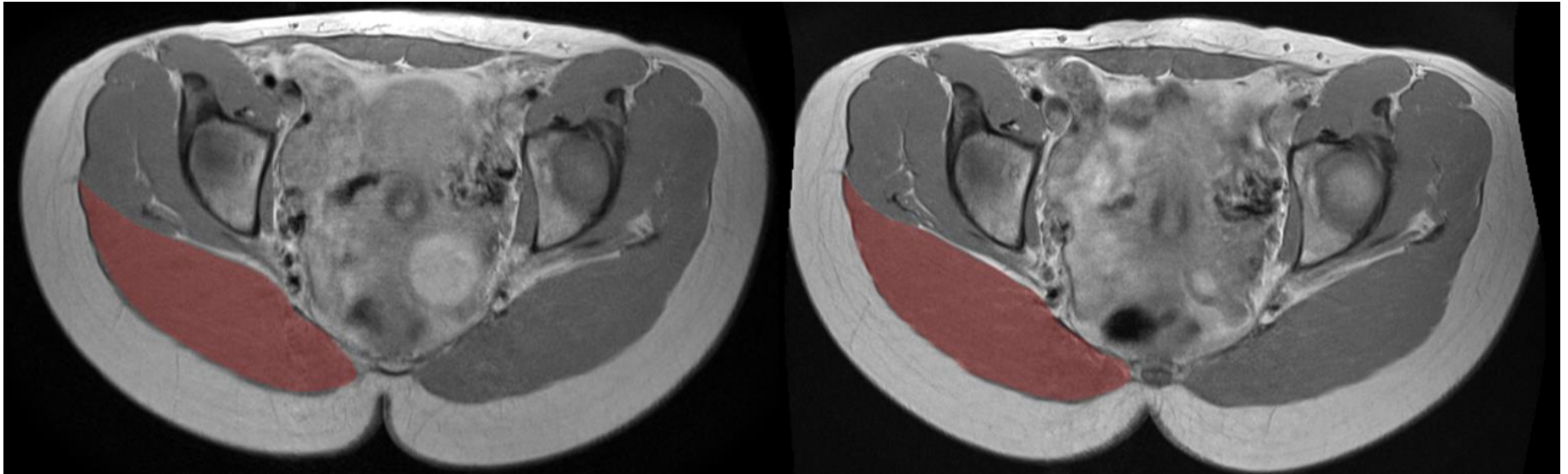
Therapy comfort

- Group A: 4.4 ± 0.7 (1-5 scale); VAS score of 1.2 ± 1.9 (0-10 scale)
- Group B: 4.2 ± 0.7 (1-5 scale); VAS score of 1.3 ± 1.7 (0-10 scale)

The slight difference in the therapy comfort may be attributed to radiofrequency heating. Both groups however, perceived the therapy as **highly comfortable**



EXAMPLE OF PATIENT RESULTS (GROUP A)



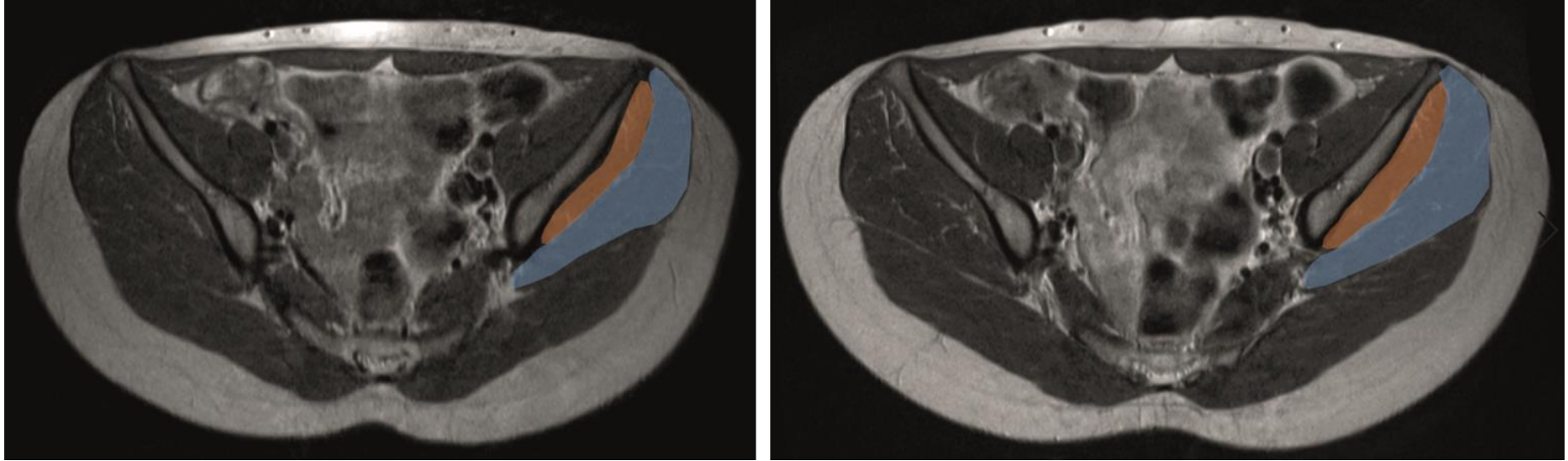
MRI scans taken at baseline (left) and at 3-month follow-up (right), the highlights are depicting the contour of **gluteus maximus** showing noticeable enlargement of the muscle.



MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS (GROUP A)



MRI scans taken at baseline (left) and at 3-month follow-up (right), the highlights are depicting the contour of **gluteus medius** and **gluteus minimus**, showing noticeable enlargement of the each muscle.



MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS

BASELINE



POST TREATMENT



Courtesy of: David Goldberg, M.D.



MORE FOR LESS

EMSCULPT[®] neo

EXAMPLE OF PATIENT RESULTS

BASELINE



POST TREATMENT



Courtesy of: JD McCoy, NMD



MORE FOR LESS

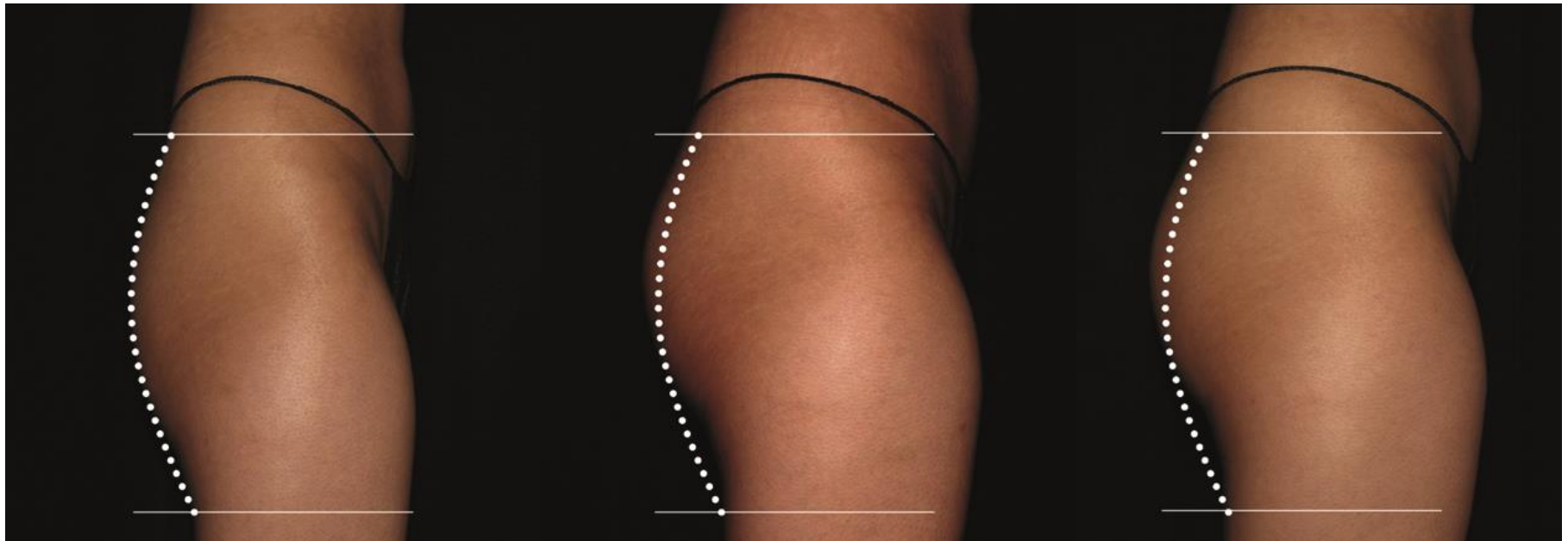
EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS

BASELINE

POST TREATMENT

3-MONTH FOLLOW-UP



Courtesy of: Suneel Chilukuri, M.D.



MORE FOR LESS

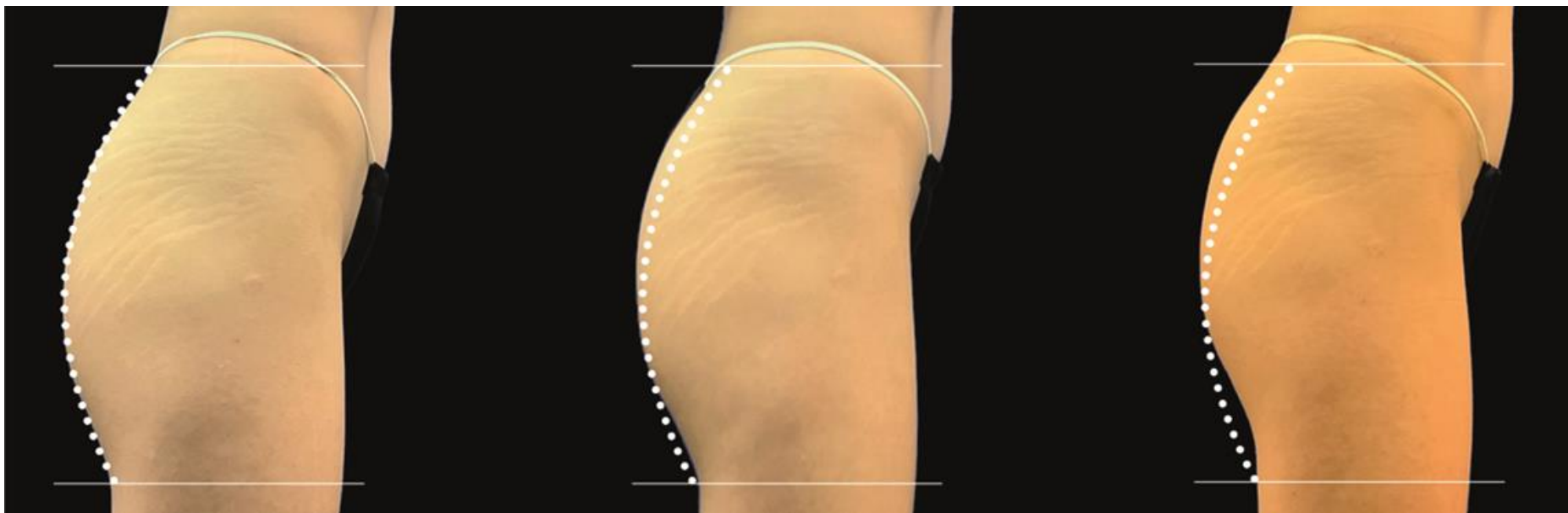
EMSCULPT[®] neo

EXAMPLE OF PATIENT RESULTS

BASELINE

POST TREATMENT

3-MONTH FOLLOW-UP



Courtesy of: JD McCoy, NMD



MORE FOR LESS

EMSCULPT[®] neo

CONCLUSION

Results suggest that simultaneous use of **HIFEM+RF is significantly more effective** for gluteal contouring than standalone HIFEM

- Average increment of muscle thickness after **HIFEM+RF is 24.7%** at 3 month
- **Standalone HIFEM** procedure resulted in just **15.9%** improvement rate
- The highest magnitude of muscle mass increments were seen in gluteus maximus in both groups (+8.5 mm and +5.2 mm, respectively)
- **Changes in fat were negligible and clinically insignificant**



MORE FOR LESS

EMSCULPT[®] Neo

VIII) SAFETY AND EFFICACY OF SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY FOR NON-INVASIVE FAT REDUCTION AND MUSCLE TONING IN INNER THIGHS: MAGNETIC RESONANCE IMAGING EVALUATION

Diane Duncan M.D., FACS¹

¹Plastic Surgical Associates, Fort Collins, CO, United States

Published in the Journal of Clinical and Aesthetic Dermatology, 2022
<https://jcadonline.com/efficacy-non-invasive-electromagnetic-thighs-magnetic/>



MORE FOR LESS

EMSCULPT[®] neo

STUDY DESIGN

- **16 subjects (24-69 y/o, BMI 21.3-35.0 kg/m²)**
- All Fitzpatrick skin **phototypes (I-VI)** were represented in the study group
- **Four (4) bilateral treatments** combining RF+HIFEM on inner thighs lasting for 30 minutes each were applied each week
- Small applicators designed to treat more localized body areas were placed over both inner thighs
- Treatment intensities (0-100%) were set according to the subject's tolerance
- **1-month and 3-month data** were analyzed



MORE FOR LESS

EMSCULPT[®] Neo

STUDY DESIGN: EVALUATION

Magnetic resonance imaging (MRI; axial plane images)

- Adipose tissue thickness
- Muscle thickness (hip adductors located at the measured level; m. gracilis, m. adductor longus and magnus)

Thigh circumference

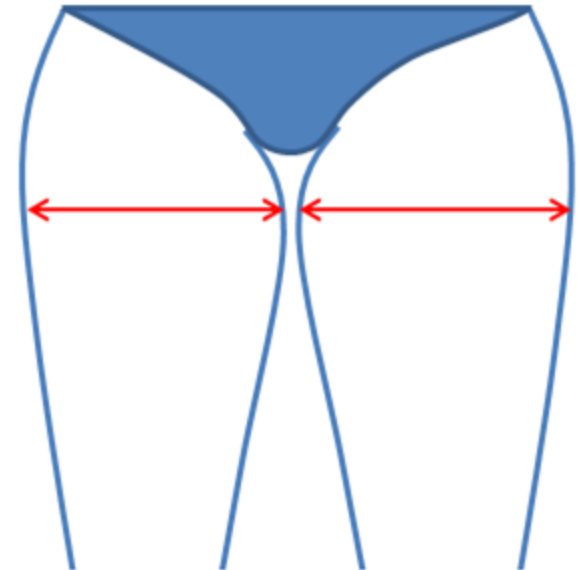
- 0.5 and 10 cm below the pelvic crease

Satisfaction and comfort questionnaires

- 5-point Likert scale and 10-point VAS scale

Digital photographs

Adverse events monitoring



Red lines indicate the level of MRI measurement



MORE FOR LESS

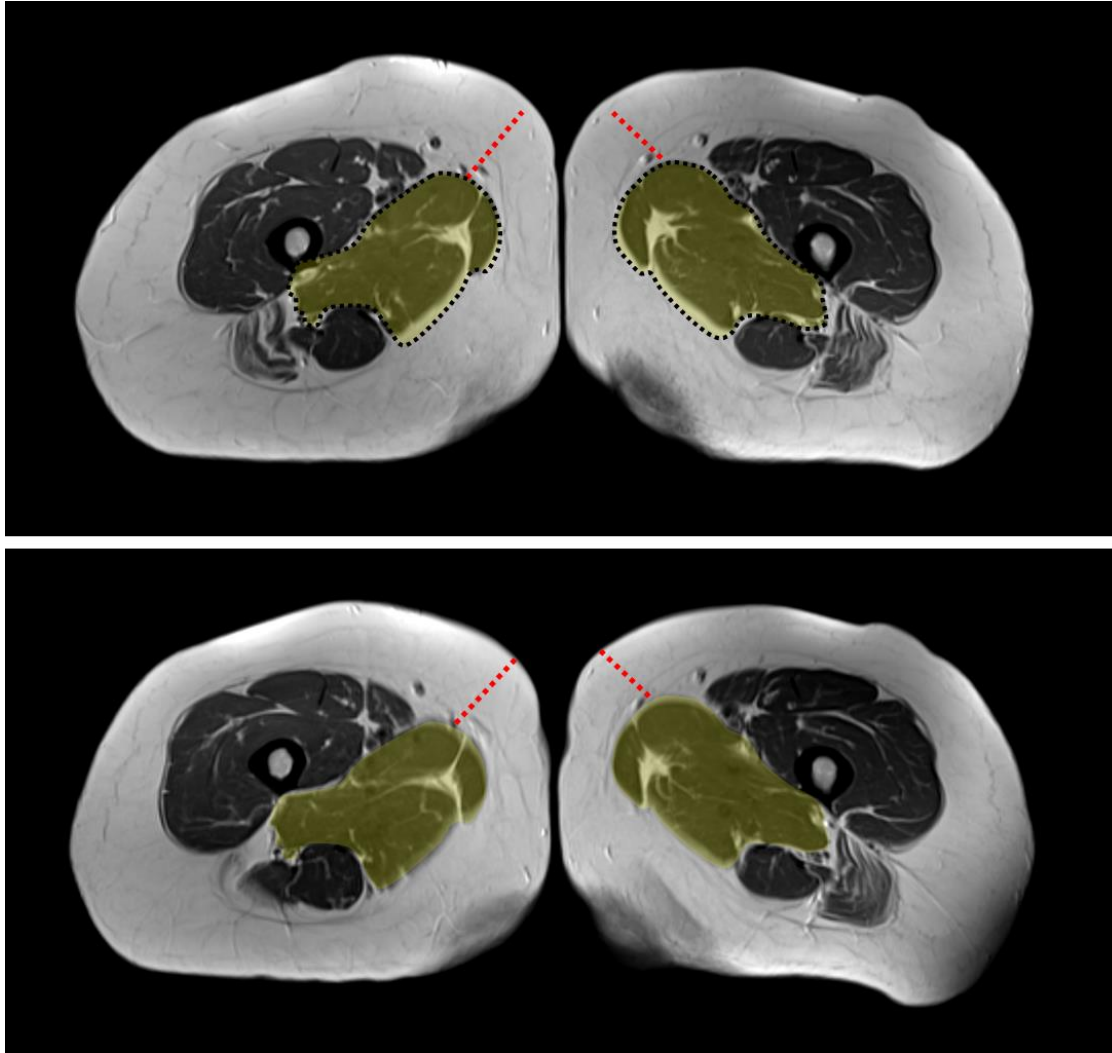
EMSCULPT[®] neo

RESULTS

- **All examined subjects** showed significant decrease in fat thickness
- **Fat thickness** was reduced significantly by **0.84 ± 0.15 cm** at 1 month and by **1.01 ± 0.17 cm** at 3 months (**27.4%**)
- The average increase in **muscle thickness** at 3 months was **23.2%**
- Average thigh **circumference reduction (per leg, 5 cm below pelvic crease)** was **-1.8 cm**
- **94%** of subjects expressed **satisfaction** with treatment results
- Therapy caused none to minimum discomfort (VAS score of 1.5 points)



EXAMPLE OF PATIENT RESULTS



Illustrative fat and muscle changes seen in MRI scans. The **highlighted muscle area** and **fat thickness** corresponds to the 3-month data, overlaying the baseline scans.



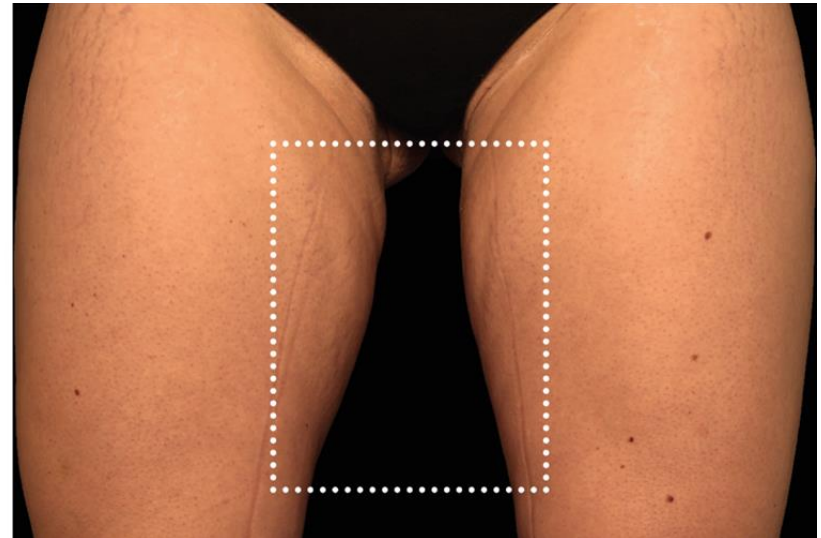
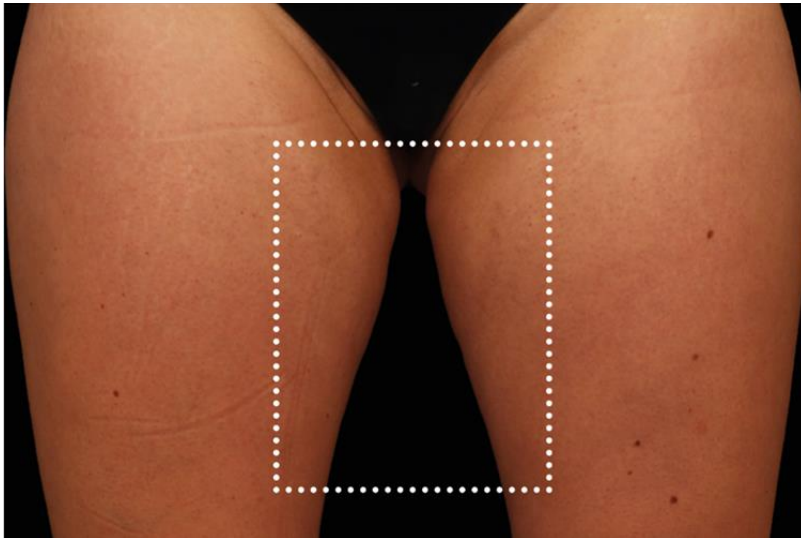
MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS

Baseline

1 month



Courtesy of: Diane Duncan M.D.

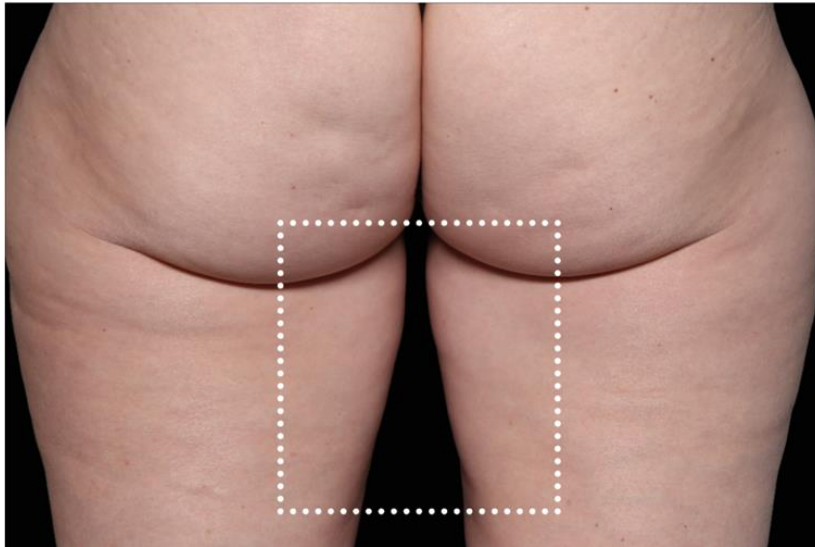


MORE FOR LESS

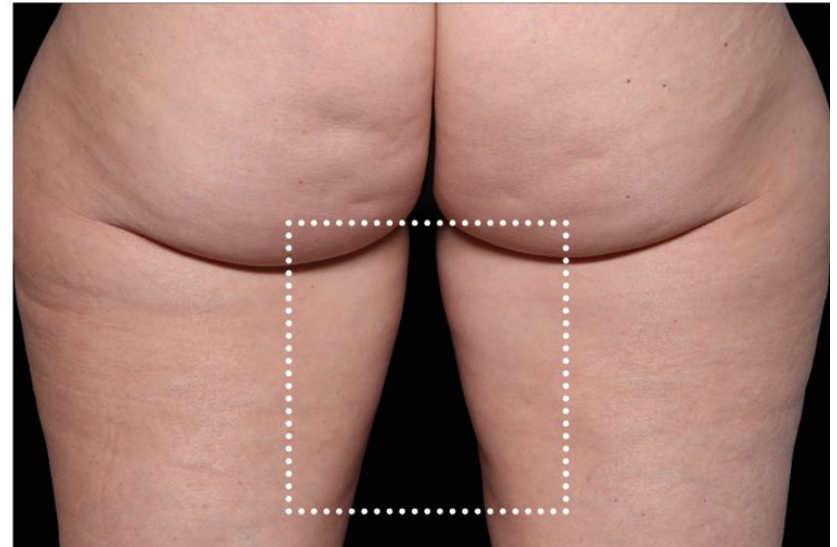
EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS

Baseline



1 month



Courtesy of: Diane Duncan M.D.



MORE FOR LESS

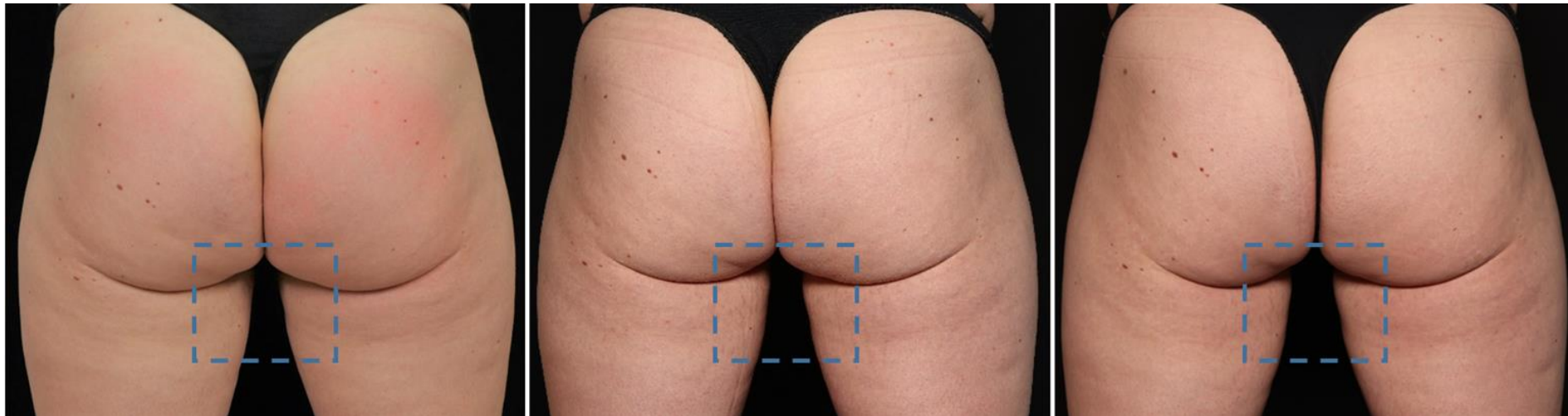
EMSCULPT®

EXAMPLE OF PATIENT RESULTS

Baseline

1 month

3 months



Courtesy of: Diane Duncan M.D.



MORE FOR LESS

EMSCULPT®
neo

CONCLUSION

- Therapy was comfortable with **high patient satisfaction (94%)**
- Changes of the inner thigh contour were noticeable on digital photographs and MRI
- **Improvement in fat and muscle** thickness was gradually increasing up to 3 months
- On average fat **thickness was decreased by 27.4% (-1.01 cm)**
- At 3 months, inner thigh **circumference** declined by **1.8 cm per leg**



MORE FOR LESS

EMSCULPT[®] Neo

IX) CONCOMITANT USE OF RADIOFREQUENCY AND HIGH INTENSITY FOCUSED ELECTROMAGNETIC FIELD ENERGIES FOR FULL-BODY REMODELING: MRI-EVIDENCE BASED PREFATORY TRIAL

Bruce Katz, M.D.¹

¹Juva Skin and Laser Center, Manhattan, NY, USA

Published in the Journal of Cosmetic Dermatology, 2022
<https://doi.org/10.1111/jocd.14736>



MORE FOR LESS

EMSCULPT[®]
neo

STUDY DESIGN

- **Three female subjects**
 - Age: 19-23 years
 - BMI: 26-35 kg/m²
- **4 treated areas** (abdomen, inner thighs, lateral thighs, buttocks)
 - All areas were treated consecutively **in the same day**
 - Each area was treated with HIFEM+RF applied for 30-minute
 - Therapy settings were HIFEM 80-100%, RF 100%
 - Gentle protocol preset was used for buttocks treatment
 - **In total, 4 treatment visits** (once per week) were scheduled
- Abdomen & Inner thighs treated in **supine position**; Lateral thighs & Buttocks in **prone position**



MORE FOR LESS

EMSCULPT^{neo}

STUDY DESIGN: EVALUATION

Safety

- The occurrence of **adverse events** during/post multiple body-part therapy was followed throughout the whole study

Effectiveness

- Outcomes were evaluated at 3 months post treatments
- Changes in muscle and adipose tissue were evaluated using objective tools:
 - **Magnetic resonance imaging (MRI) in axial plane**
 - Circumference measurements (waist, hip and thigh)
 - Digital photographs

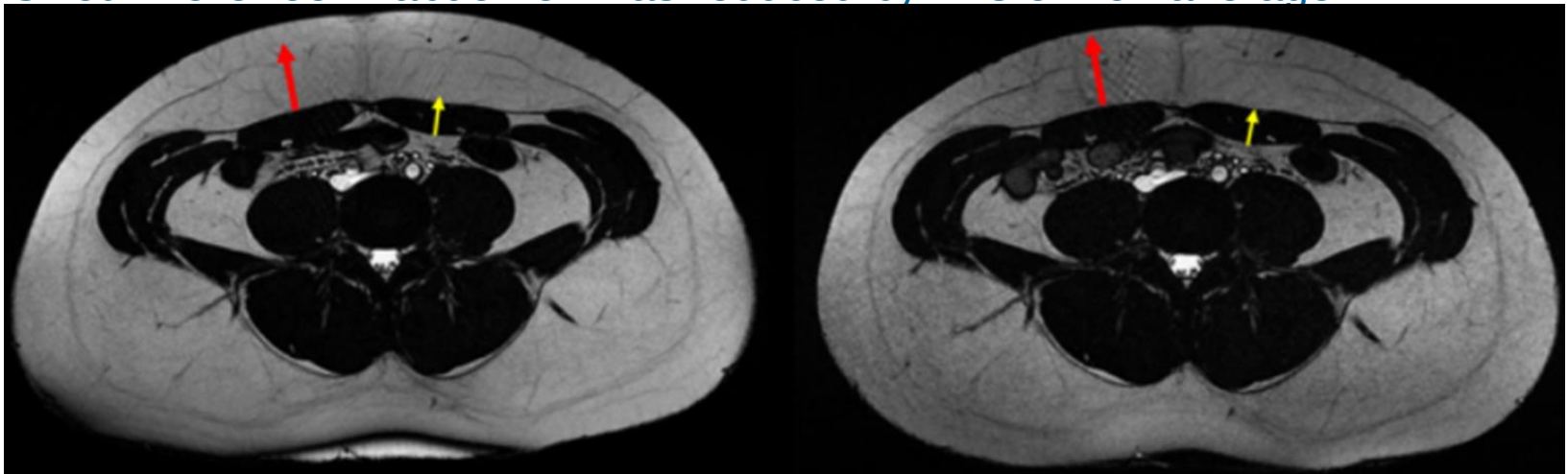


MORE FOR LESS

EMSCULPT[®] Neo

RESULTS: ABDOMEN

- **Fat and muscle thickness, and width of abdominal separation** was measured approximately 2 inches above and below the umbilicus.
- At 3 months post treatment, improvement reached on average:
 - **-28.7%** of fat thickness decrease
 - **+24.3%** of muscle thickness increase
 - **-18.9%** of abdominal separation width decrease
- **Circumference** in abdomen was reduced by **-7.8 cm** on average



MRI images showing reduction in **fat thickness** while rectus abdominis **muscle** is visibly thicker

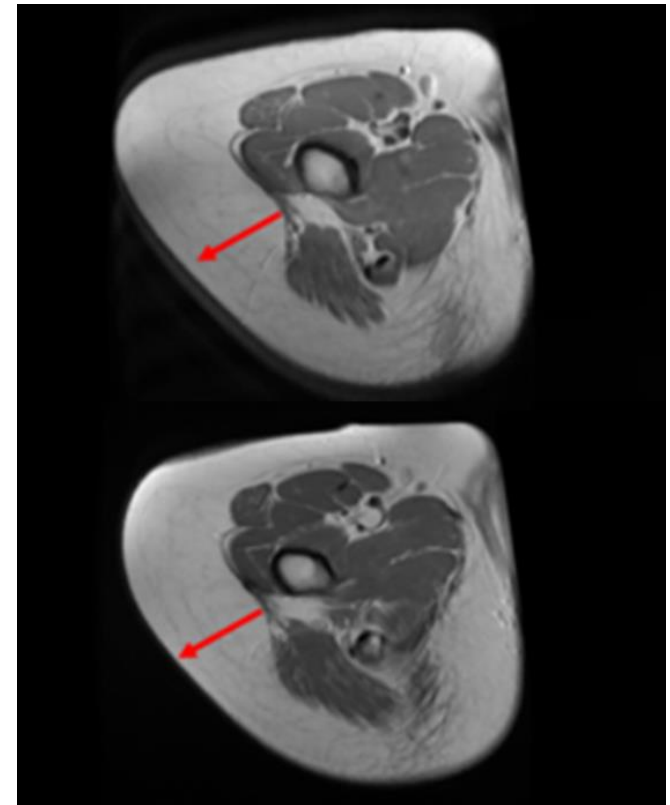


MORE FOR LESS

EMSCULPT®
neo

RESULTS: THIGHS

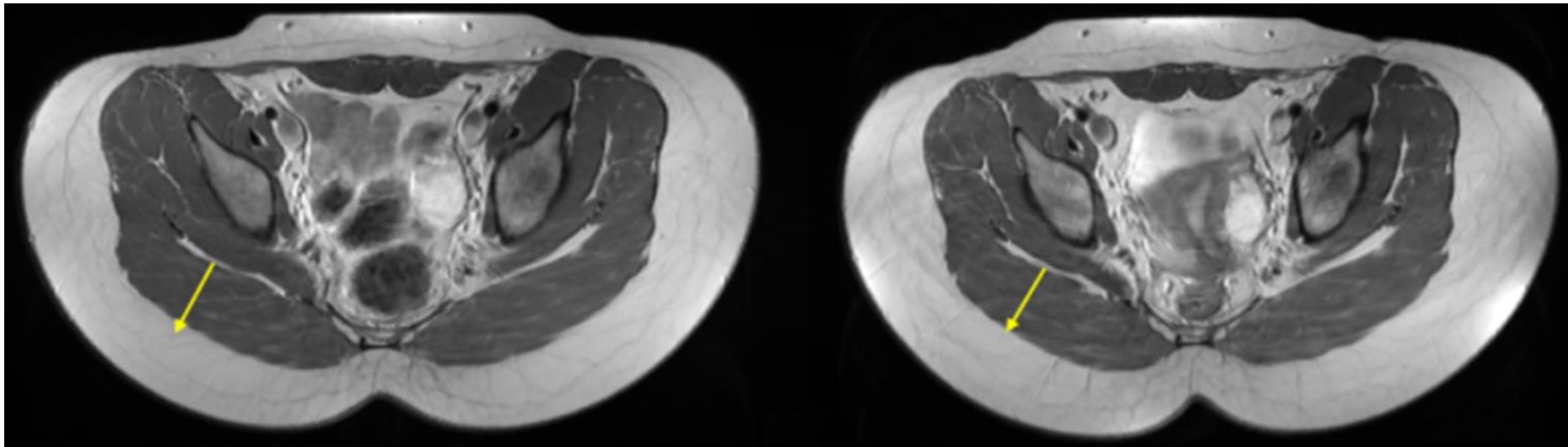
- Fat thickness on the outer and inner thighs was assessed at the corresponding levels where fat bulge had the greatest thickness
- **Both inner and outer thigh** measurements showed substantial fat reduction
 - **Outer -1.8 cm** in fat layer thickness
 - **Inner: -1.2 cm** in fat layer thickness
- **Circumference** measured in the thigh area decreased considerably as well
 - **Outer: -2.8 cm**
 - **Inner: -3.6 cm**



MRI images pre (up) and post (down) treatment showing reduction of **fat thickness** in lateral thigh

RESULTS: BUTTOCKS

- Measurement at **three levels** was performed (middle, upper and lower quarter of m. gluteus maximus) to obtain **average change** in fat and muscle thickness
- At 3 months, the average thickness of **gluteus maximus increased by +24.6%**
- **Buttock adipose tissue was unaffected** by the treatments
 - **Gentle treatment protocol** was used
 - Negligible changes of +0.3% in fat thickness were documented



MRI images showing increased thickness of **gluteus maximus** muscle at 3 months



MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS



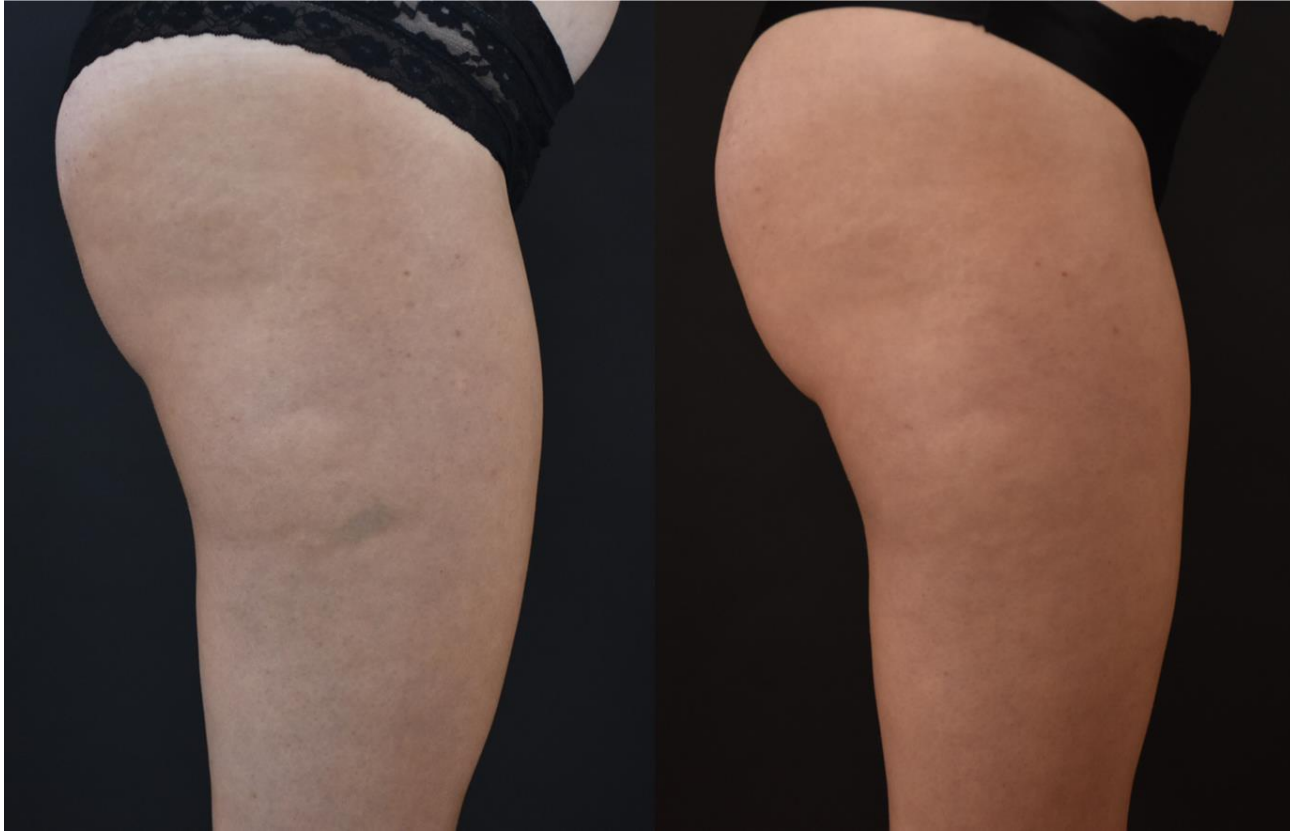
Baseline (left) and 3 months (Right). Abdominal remodeling.



MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS



Baseline (left) and 3 months (Right). Improved appearance of buttocks.



MORE FOR LESS

EMSCULPT®
neo

CONCLUSION

Treating **multiple body areas at the same day** by HIFEM+RF technology provides safe and effective tool for **full body remodeling**

- Therapies were safe as **no adverse event** occurred
- **Fat reduction at 3 months** was seen in each examined body part, except for buttocks due to the use of gentle protocol
 - Abdomen: **-28.7%**
 - Inner thighs: **-1.2 cm**
 - Outer thighs: **-1.8 cm**
- Considerable increases in thickness of **rectus abdominis (+24.3%)** and **gluteus maximus (+24.6%)** were observed
 - Muscle changes on abdomen resulted in reduced abdominal separation
- Digital photographs documented the favourable changes in body appearance



MORE FOR LESS

EMSCULPT^{neo}

X) SIMULTANEOUS HIFEM AND SYNCHRONIZED RF PROCEDURE CAN BE EFFECTIVELY USED FOR UPPER ARM TONING AND STRENGTHENING

Carolyn Jacob, M.D.¹, Robert A. Weiss, M.D.²

¹Chicago Cosmetic Surgery and Dermatology, Chicago, IL

²Maryland Laser Skin and Vein Institute, Hunter Valley, MD

Published in the Journal of Clinical and Aesthetic Dermatology, 2023

<https://jcadonline.com/increasing-muscle-mass-decreasing-fat/>



MORE FOR LESS

EMSCULPT[®]

STUDY DESIGN

- **34 subjects (23-72 y/o, BMI 18.5-33.9 kg/m²)**
- Fitzpatrick skin **phototypes (II-VI)** were represented in the study group
- **Four (4) bilateral treatments** combining RF+HIFEM on upper arms lasting for 30 minutes each were applied each week
- Small applicators designed to treat more localized body areas were placed over both arms
- Treatment intensities (0-100%) were set according to the subject's tolerance
- **1-month and 3-month data** were analyzed



MORE FOR LESS

EMSCULPT^{neo}

STUDY DESIGN: EVALUATION

Magnetic resonance imaging (MRI; axial plane images)

- Adipose tissue thickness
- m. triceps muscle thickness

Satisfaction and comfort questionnaires

- 5-point Likert scale and 10-point VAS scale

Digital photographs

Adverse events monitoring



RESULTS

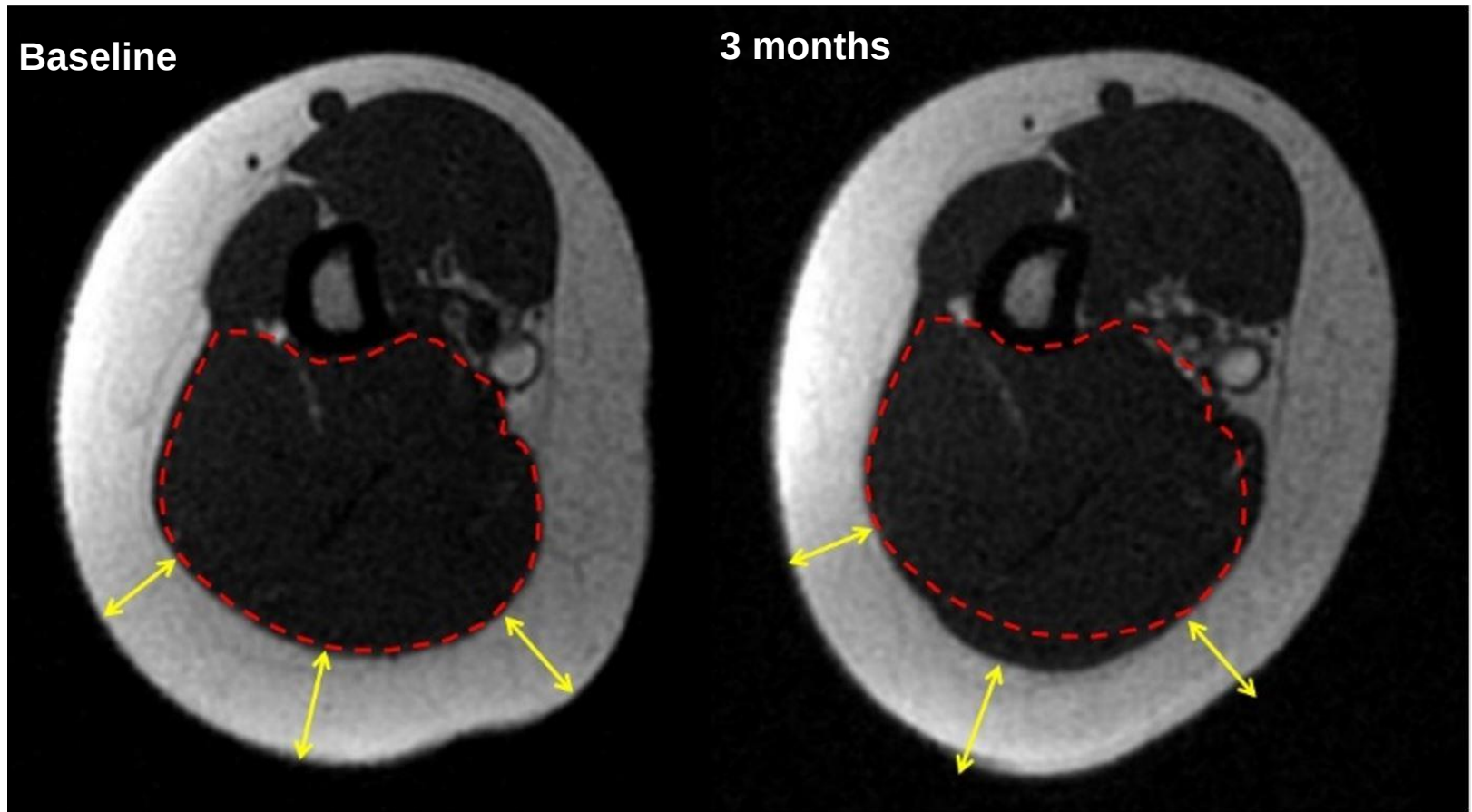
- The overall **thickness of m. triceps muscle increased significantly** ($p < 0.001$) at the follow-up visits
 - Average muscle thickness increase at **1 month** was **+21.5%** (+0.8 cm)
 - Average muscle thickness increase at **3 months** was **+23.9%** (+0.9 cm)
- **Fat thickness** was reduced significantly ($p < 0.001$) by
 - **-22.3%** (-0.4 cm) at 1 month
 - **-25.5%** (-0.5 cm) at 3 months follow-up
- **87%** of subjects expressed **satisfaction** with treatment results
- Therapy caused **none to minimal discomfort** (VAS score of 1.6 points). 91% of subjects found treatment comfortable
- **No serious adverse events occurred**



MORE FOR LESS

EMSCULPT^{neo}

EXAMPLE OF PATIENT RESULTS



MRI illustration of the difference in **triceps muscle** (red outlined area) and subcutaneous **fat layer** (yellow arrows) before (left) and 3 months after (right) treatment. The muscle increased in volume noticeably, whereas the fat layer thickness reduced.



MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS

Baseline



3 months



Courtesy of: Carolyn Jacob, M.D.



MORE FOR LESS

EMSCULPT[®] neo

EXAMPLE OF PATIENT RESULTS

Baseline



3 months



Courtesy of: Carolyn Jacob, M.D.



MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS

Baseline

3 months



Courtesy of: Carolyn Jacob, M.D.



MORE FOR LESS

EMSCULPT^{neo}

CONCLUSION

- Therapy was comfortable with **high patient satisfaction (87%)**
- Changes of the upper arm contour were noticeable on digital photographs and MRI
- **Improvement in fat and muscle** thickness was gradually increasing up to 3 months
- On average, **fat thickness was decreased by 25.5% (-0.5 cm)**
- Average **triceps muscle thickness increased by 23.9% (+0.9cm)**



MORE FOR LESS

EMSCULPT^{neo}

XI) SAFETY EVALUATION OF SIMULTANEOUS APPLICATION OF RADIOFREQUENCY SYNCHRONIZED WITH HIFEM PROCEDURE FOR FAT REDUCTION IN MULTIPLE BODY PARTS TREATED ON THE SAME DAY VERIFIED BY PLASMA ANALYSIS OF LIVER AND LIPID PROFILES

Robert A. Weiss, M.D., FAAD¹

¹Maryland Laser Skin, & Vein Institute, Hunt Valley, Maryland

Accepted for publication in the Dermatologic Surgery



MORE FOR LESS

EMSCULPT[®] neo

STUDY DESIGN

- **Ten patients** were enrolled
 - Eight women and two men
 - 24-59 years, BMI 22.4-30.6 kg/m²
- All patients received four 30-minute sessions spaced 1 week apart
- In one session, patients received three consecutive 30-minute **treatments in different body parts**
 - **Women:** abdomen, inner and outer thigh
 - **Men:** abdomen, front and back thigh
- The intensity of the HIFEM energy was set to maximally tolerated level, with RF energy set at 100% in all therapies



MORE FOR LESS

EMSCULPT^{neo}

STUDY DESIGN: EVALUATION

Blood samples taken at **baseline**, **1 hour** after the last treatment, at **24-48 hours** follow-up visit, and **1-month** follow-up visit were analyzed

Analysis included:

Liver function test

- To detect liver damage, analytes:
 - Alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyltransferase (GGT)

The lipid profile

- Indicates cardiovascular health, analytes:
 - Total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglycerides (TG)



MORE FOR LESS

EMSCULPT^{neo}

STUDY DESIGN: EVALUATION

The secondary outcomes were:

- **Abdominal circumference**
 - Taken at baseline, after the last treatment, and 1-month follow-up
- **Digital photographs**
 - Taken at baseline, after the last treatment, and 1-month follow-up
- **Subject satisfaction questionnaire**
 - 5-point Likert scale
 - Collected after the last treatment and 1-month follow-up
- **Comfort questionnaire**
 - 5-point Likert scale
 - 10-point visual analogue scale
 - Collected after the last treatment



RESULTS: BLOOD ANALYSIS

- After three consecutive treatments delivered on the same day, patients were able to resume their daily routine
- **No adverse event** or side effect occurred
- **40 blood samples** were collected and analyzed
 - Any of the analyte showed any significant changes during the study (p-value > 0.05)
 - In general, **no analyte showed fluctuation** above normal range

Table of normal ranges

	ALT	AST	ALP	GGT	Cholesterol	LDL	HDL	TG
Normal Range	7-56 U/l ¹	0-35 U/l ¹	20-140 U/l ²	9 - 85 U/l ³	below 5.2 mmol/l ⁴	below 3.4 mmol/l ⁴	above 1.0 mmol/l ⁴	below 1.8 mmol/l ⁵

1. Gowda S, Desai PB, Hull VV, Math AAK, Vernekar SN, Kulkarni SS. A review on laboratory liver function tests. *Pan Afr Med J.* 2009;3:17.

2. Sharma U, Pal D, Prasad R. Alkaline Phosphatase: An Overview. *Indian J Clin Biochem.* 2014;29(3):269-278.

3. Tierney LM, McPhee SJ, Papadakis MA. *Current Medical Diagnosis & Treatment 2004 43rd Edition.*; 2003.

4. *High Cholesterol: Overview.* Institute for Quality and Efficiency in Health Care (IQWiG); 2017. Accessed February 18, 2022. <https://www.ncbi.nlm.nih.gov/books/NBK279318/>

5. Hui D. Common Laboratory Values and Unit Conversion. In: Hui D, ed. *Approach to Internal Medicine: A Resource Book for Clinical Practice.* Springer US; 2011:437-440.



RESULTS: BLOOD ANALYSIS

- Measured analytes demonstrated **no substantial fluctuation**

	AST (U/l)	ALT (U/l)	GGT (U/l)	ALP (U/l)	Total cholesterol (mmol/l)	HDL (mmol/l)	LDL (mmol/l)	TG (mmol/l)
Baseline	16.7±3.1	13.4±6.8	12.7±6.5	74.3±19.2	5.1±1.1	1.7±0.4	3.0±1.2	1.0±0.4
1 hour after last Tx	16.3±2.6	12.3±4.9	12.0±5.2	72.2±20.4	5.1±1.0	1.7±0.5	3.0±1.1	1.0±0.4
24/48h FU	16.1±2.6	11.9±4.6	11.6±5.3	71.4±22.0	5.0±1.0	1.7±0.5	3.0±1.0	1.0±0.6
1M FU	15.7±3.2	12.5±6.9	13.8±6.6	77.2±26.3	5.1±1.1	1.7±0.5	3.0±1.1	1.1±0.9
Normal Range	0-35	7-56	9 - 85	20-140	below 5.2	above 1.0	below 3.4	below 1.8

mean±SD, Tx=treatment, M=month, FU=follow-up

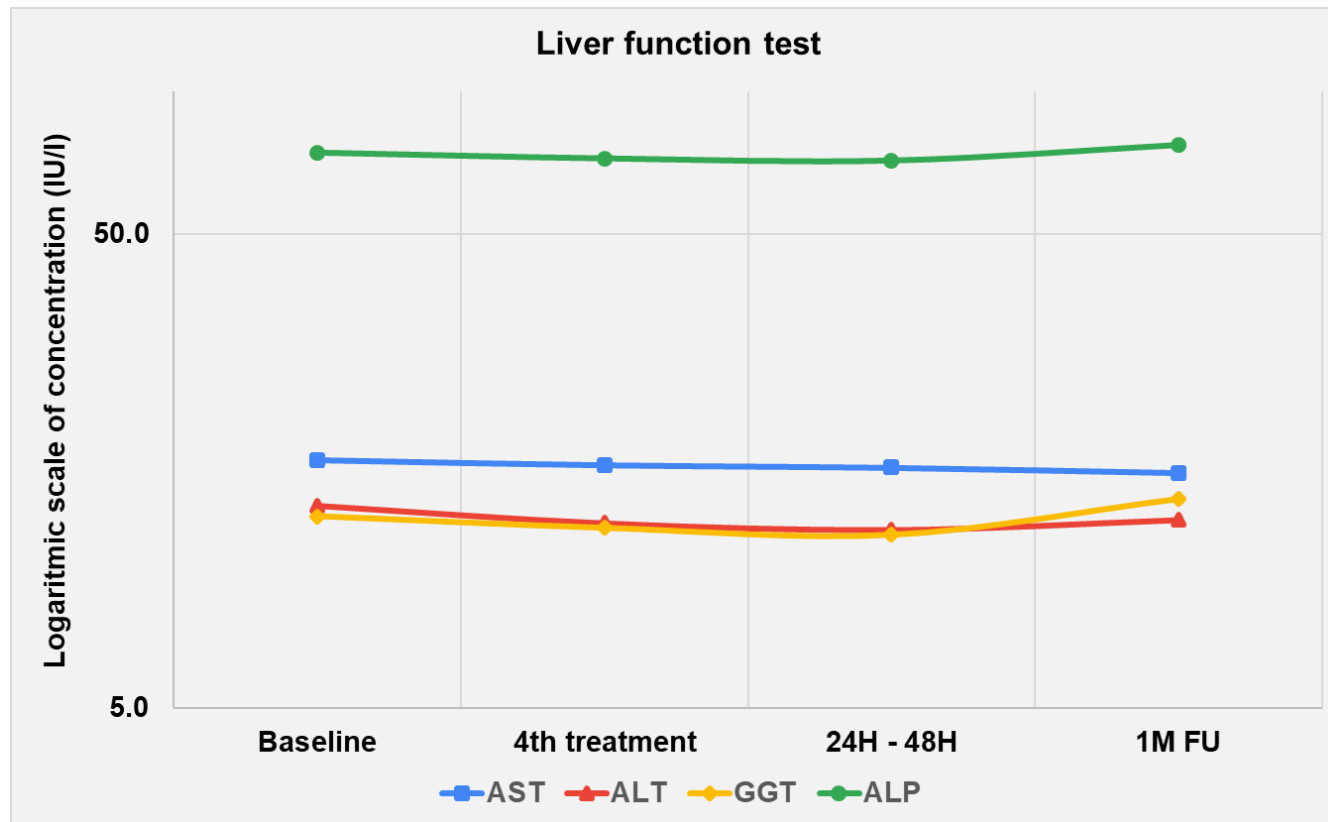


MORE FOR LESS

EMSCULPT^{neo}

RESULTS: BLOOD ANALYSIS

- No significant fluctuation of the liver analytes indicates safe use of consecutive HIFEM+RF treatments



alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyltransferase (GGT)

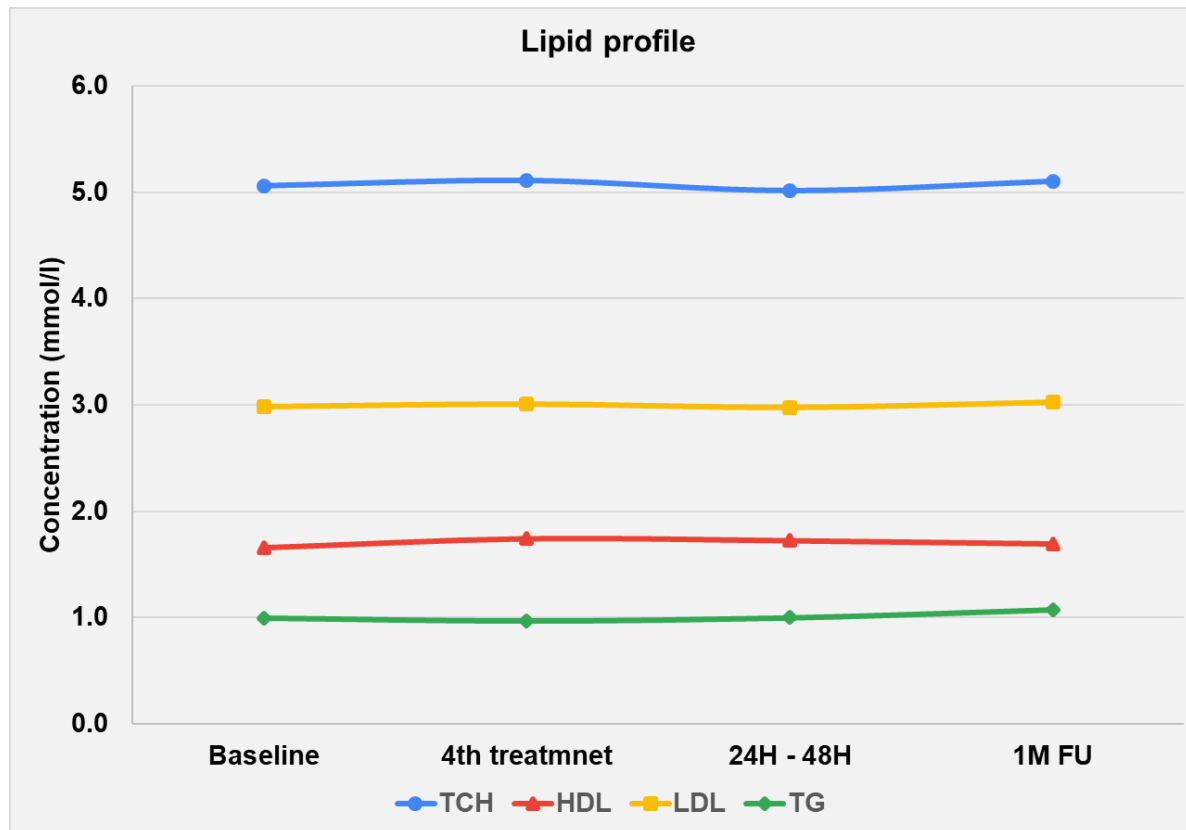


MORE FOR LESS

EMSCULPT[®] Neo

RESULTS: BLOOD ANALYSIS

- No significant fluctuation of the lipid profile indicates that the HIFEM+RF treatment does not impair lipid metabolism or cardiovascular health



total cholesterol (TCH), low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglycerides (TG)



MORE FOR LESS

EMSCULPT^{neo}

RESULTS: SECONDARY OUTCOMES

- The average abdominal **circumference reduction**
 - -2.20 ± 1.92 cm after the last treatment
 - **-2.45 ± 2.34** cm at the 1-month follow-up
 - maximal reduction of -6 cm
- Satisfaction questionnaire (1-5 scale; 1 strongly disagree - 5 strongly agree)
 - Patients were **highly satisfied** with the results (**4.7 ± 0.5**)
 - Patients noticed **improvement in appearance** of the treated areas (**4.6 ± 0.5**)
 - Patients noticed improvement in muscle tone and fat thickness (**4.7 ± 0.5**)
- The treatment was comfortable and painless (**VAS = 0.4 ± 0.5**)



EXAMPLE OF PATIENT RESULTS

A 29-year-old female, photographs take at baseline (left), after last treatment (middle) and at 1 mont (right; -3 cm in circumference)

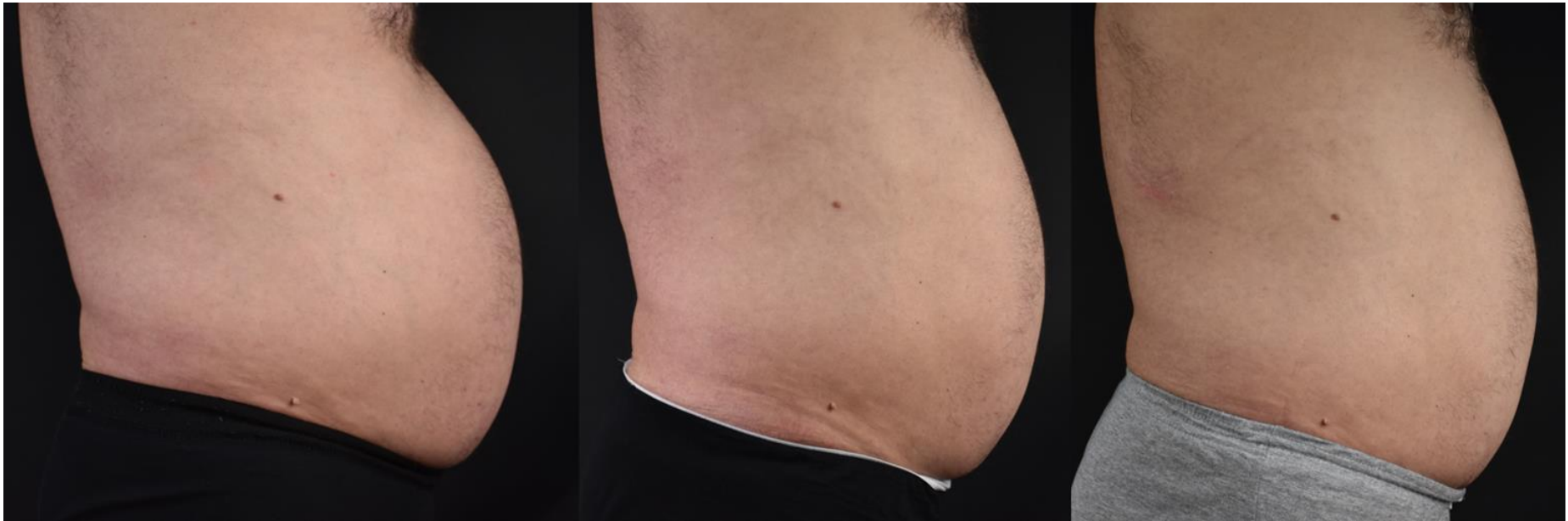


MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS

A 59-year-old male, photographs take at baseline (left), after last treatment (middle) and at 1 mont (right; -6 cm in circumference)



MORE FOR LESS

EMSCULPT®
neo

CONCLUSION

This study demonstrated the **safe use of the HIFEM+RF procedure** for consecutive treatments as:

- In any of the eight studied analytes, **no significant change nor fluctuation above normal and safe levels** were observed

The secondary outcomes showed:

- Significant reduction in **abdominal circumference** (-2.45 ± 2.34 cm)
- High **overall satisfaction** (4.7 ± 0.5)
- Comfortable and painless procedure ($VAS = 0.4 \pm 0.5$)



MORE FOR LESS

EMSCULPT^{neo}

XII) VISCERAL FAT REDUCTION WITH SIMULTANEOUS APPLICATION OF HIFEM AND RADIOFREQUENCY ENERGIES RETROSPECTIVELY ASSESSED FROM MRI SCANS

David E. Kent, M.D.¹, Carolyn Jacob, M.D.², Brian M. Kinney, M.D., FACS³

¹Skin Care Physicians of Georgia, Macon, Georgia

²Chicago Cosmetic Surgery and Dermatology, Chicago, Illinois

³Brian M. Kinney M.D., Beverly Hills, CA, USA

Accepted for publication in the Journal of Cosmetic Dermatology



MORE FOR LESS

EMSCULPT[®]

STUDY DESIGN

- **Retrospective analysis of MRI scans**, collected in the study by Jacob et al¹, was performed to evaluate changes in the visceral adipose tissue (VAT) after the HIFEM+RF treatment
- **40 subjects** (22-62 years, BMI 21.2-34.3 kg/m², skin type I-VI)
 - 16 men and 24 women
- Patients received three 30-minute treatments on the abdomen
 - HIFEM intensity set at maximally tolerated level
 - RF intensity set at 100%
- MRI scans were collected at baseline, 1-, 3- and 6-month follow-up visits

I. Jacob C, Kent D, Ibrahim O. Efficacy and Safety of Simultaneous Application of HIFEM and Synchronized Radiofrequency for Abdominal Fat Reduction and Muscle Toning: A Multicenter Magnetic Resonance Imaging Evaluation Study. *Dermatol Surg Off Publ Am Soc Dermatol Surg Al.* 2021;47(7):969-973.

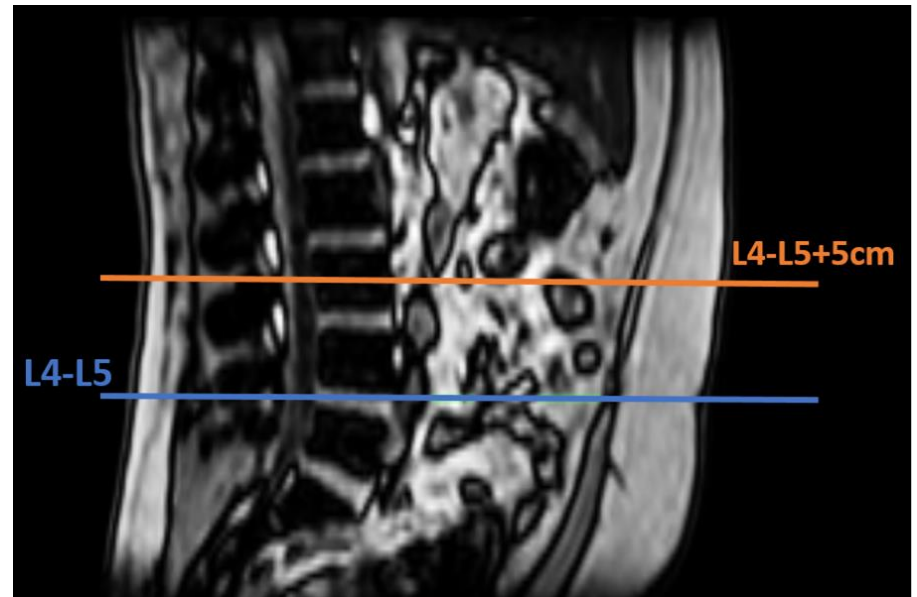


MORE FOR LESS

EMSCULPT^{Neo}

STUDY DESIGN: EVALUATION

- Only the MRI scans from the original study were used, no additional data were collected. **Visceral adipose tissue (VAT)** was analyzed.
- **Semi-automatic segmentation** was performed
 - First an automatic analysis via the threshold method to detect the VAT
 - Then the results of automatic segmentation were manually corrected to include only VAT in the evaluation
- **The cross-sectional area (CSA)** corresponding to the VAT was calculated on two levels separately and averaged
- Digital photographs from the original study were also evaluated



RESULTS: AVERAGE VAT REDUCTION

- The results showed **highly significant** ($p < 0.001$) decrease of VAT cross sectional area throughout the study
- The average VAT reduction was - **$17.9 \pm 15.4 \text{ cm}^2$ ($-17.8 \pm 2.0\%$)** peaking at 3-month follow-up with maintaining the reduction at 6-month follow-up ($-17.6 \pm 17.3 \text{ cm}^2$)
- The inspection of MRI scans unveil **no other changes in the abdominal cavity** or organs in the proximity to the treatment area

	Average	
	cm ²	%
Baseline	100.2 ± 73.3	-
Difference at 1 month (n=40)	-15.8 ± 12.7	-15.3 ± 2.4
Difference at 3 months (n=29)	-17.9 ± 15.4	-17.8 ± 2.0
Difference at 6 months (n=20)	-17.6 ± 17.3	-17.3 ± 1.9



RESULTS: REDUCTION AT INDIVIDUAL LEVELS

	L4-L5		L4-L5+5cm	
	cm ²	%	cm ²	%
Baseline	93.5 ± 54.1	-	106.9 ± 88.7	-
1-month follow-up (n=40)	-14.6 ± 9.3	-15.2 ± 2.4	-17.1 ± 15.5	-15.3 ± 2.5
3-month follow-up (n=29)	-16.7 ± 10.5	-17.7 ± 2.1	-19.1 ± 19.3	-17.9 ± 1.8
6-month follow-up (n=20)	-15.3 ± 9.7	-17.2 ± 1.9	-19.9 ± 22.6	-17.3 ± 1.8

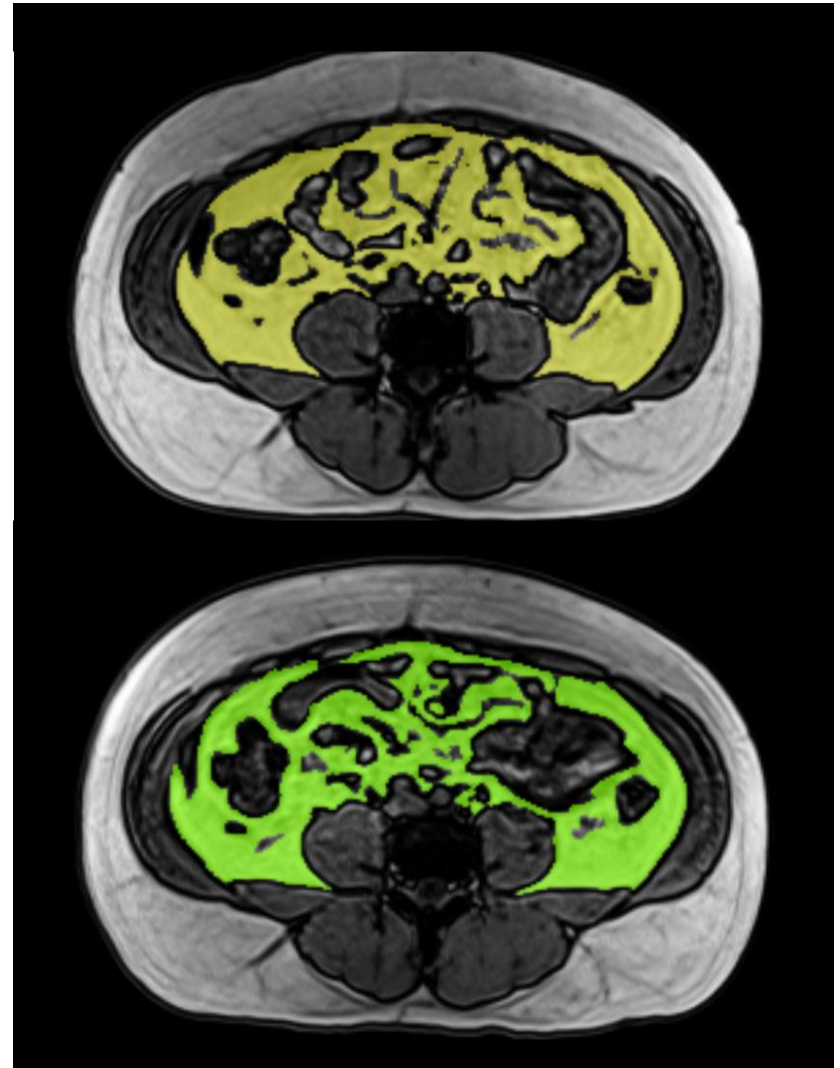


MORE FOR LESS

EMSCULPT[®] neo

SAMPLE RESULTS

- A visualization of the segmented VAT area at baseline (yellow) and 3-month follow-up (green)
- A 34-year-old male subject with BMI 29.5 kg/m², L4-L5+5cm level in the axial plane
- Baseline CSA of 159.6 cm² was **reduced by 17.4%** to 131.9 cm² after the HIFEM+RF procedure



MORE FOR LESS

EMSCULPT®
neo

RESULTS: HIGH-VAT PATIENTS

- VAT **area exceeding 100 cm²** is associated with elevated risks of coronary heart disease (CHD) or metabolic problems such as diabetes mellitus, further increasing the risk when the VAT area exceeds 160cm²

100 cm² threshold

- At baseline 21 subjects showed the VAT area above 100 cm² while **at the end of the study it was only 9 patients**

160 cm² threshold

- At baseline 12 subjects showed VAT above 160 cm² while **at the end of the study, it was only 3 patients**



MORE FOR LESS

EMSCULPT[®] Neo

EXAMPLE OF PATIENT RESULTS

A 57-year-old male with a BMI of 32.8 kg/m² (an average VAT reduction of 17.0%)



Courtesy of: David Kent, M.D.

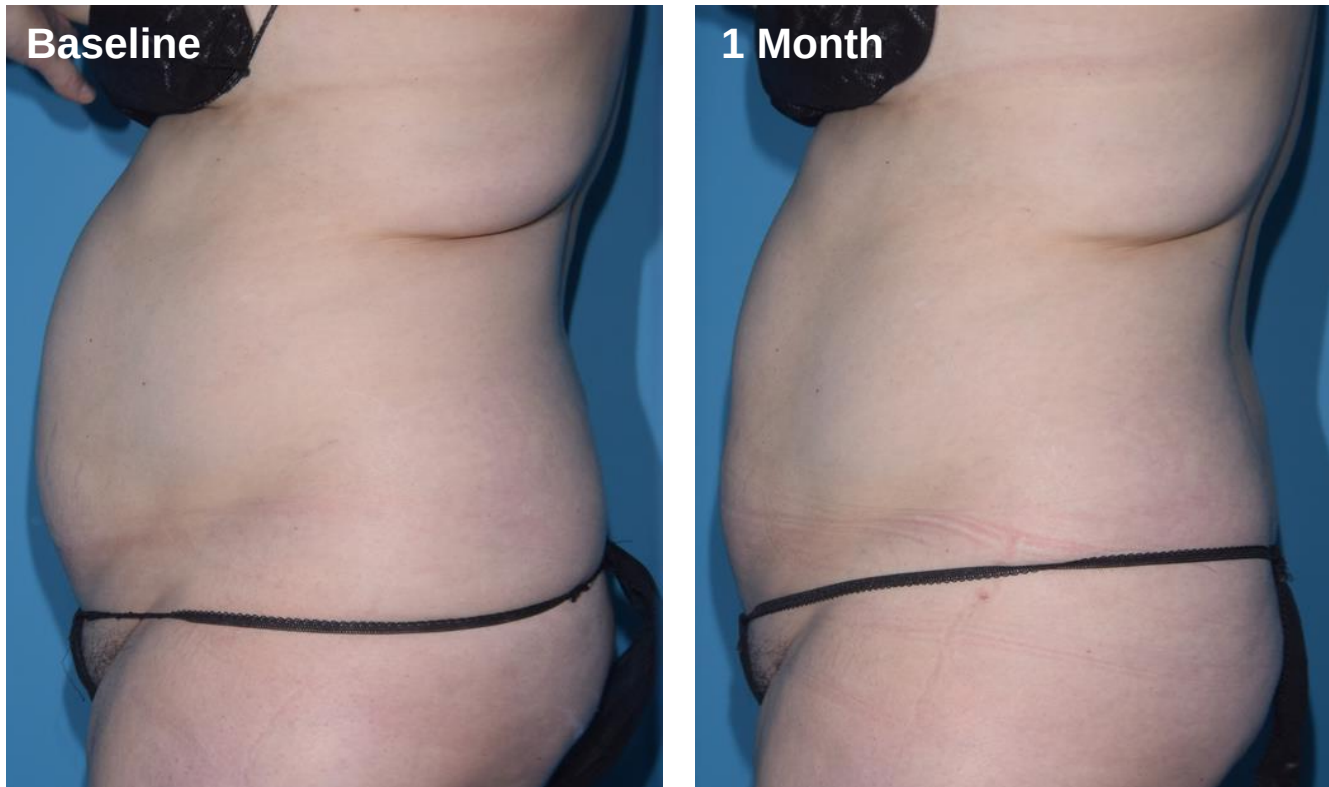


MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS

A 34-year-old female with a BMI of 28.9 kg/m² (an average VAT reduction of 19.7%)



Courtesy of: Carolyn Jacob, M.D.



MORE FOR LESS

EMSCULPT®
neo

CONCLUSION

- This retrospective analysis demonstrates the **efficiency of the HIFEM+RF** treatment for visceral fat reduction
 - The average VAT reduction was **-17.9 ± 15.4 cm² (-17.8 ± 2.0%)**
 - The changes were significant significant regardless of gender
 - The results were **maintained at 6-month** follow-up
- **Safety of the procedure** was documented of the HIFEM+RF procedure:
 - The MRI evaluation showed no other changes in the abdominal cavity except for VAT reduction



XIII) ADIPOCYTE APOPTOSIS INDUCED BY TREATMENT WITH SYNCHRONIZED RADIOFREQUENCY AND HIGH-INTENSITY FOCUSED ELECTROMAGNETIC PROCEDURE: HUMAN HISTOLOGIC ANALYSIS

David J. Goldberg M.D., JD¹, Karan Lal, M.D.¹

¹Icahn School of Medicine, New York, NY, USA

Presented at 41st ASLMS annual conference, San Diego, 2022



MORE FOR LESS

EMSCULPT[®]

STUDY DESIGN

Nine (n=9) subjects were **divided into two groups:**

Active group

- **Six subjects** (23-59 years, BMI = 24.6-34.7 kg/m², skin type I-V)
- Received one 30-minute HIFEM+RF treatment in the abdominal area
- **HIFEM intensity was set according to the patient's feedback**
- **RF was set at 100% intensity**

Control group

- **Three subjects** (28-61 years, BMI = 25.6-31.9 kg/m², skin type II-III)
- Received one 30-minute treatment with **both energies set at 5% intensity**



MORE FOR LESS

EMSCULPT^{neo}

STUDY DESIGN: EVALUATION

- **Punch biopsies (5 mm in diameter)** were collected from the treatment area at baseline (1 week prior to the treatment), 8h and 24 hours after the treatment
- Additionally, all patients underwent 7-day safety follow-up
- Collected samples were processed, immunohistochemically stained with **apoptosis** detection kit (**detecting activated Caspase-3**) and Calleja stain for visualization of collagen structures (septae)
- **The apoptotic index (AI)** was calculated - dividing the number of stained apoptotic nuclei found in the fat tissue by the total number of nuclei and multiplied by 100
- **Two subjects were withdrawn** (one from each group) for unsuitable histology samples for evaluation



RESULTS

- There was no significant difference between the groups at baseline (p-value = 0.36)
- **In the active group**, the changes occurring 8 and 24 hours after the treatment were **significant compared to baseline** (p-value < 0.001)
- The changes in the control group were insignificant through the study (p-value > 0.05)

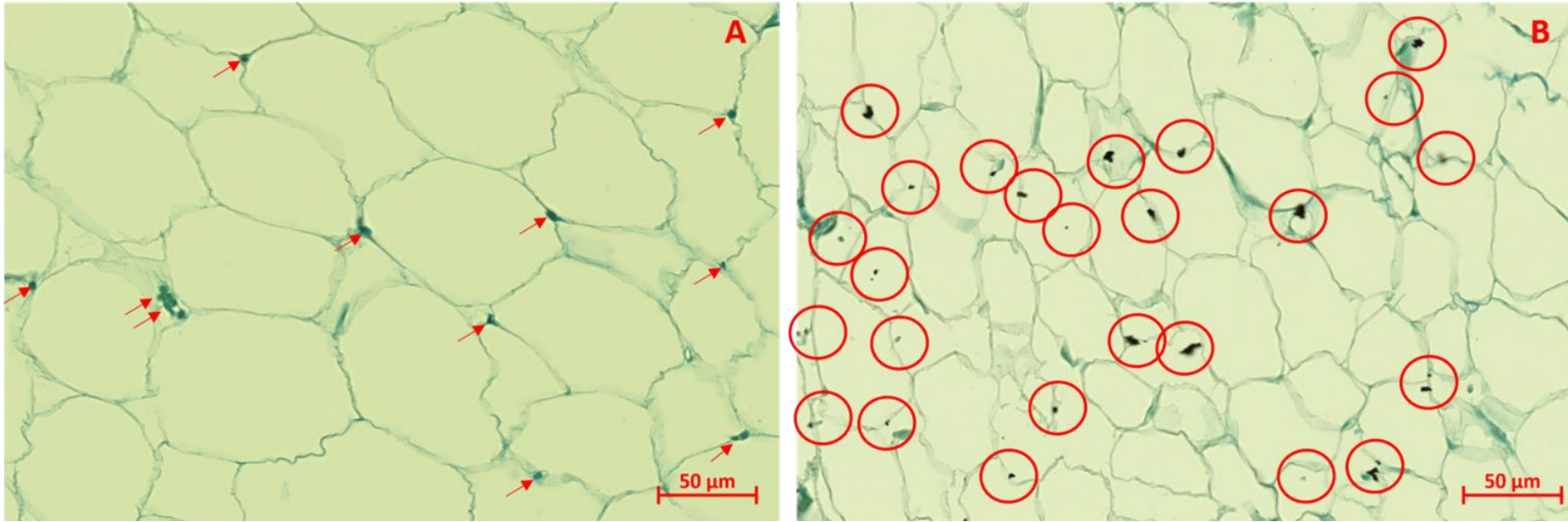
APOPTOTIC INDEX	Baseline	8 hours after the Tx	24 hours after the Tx
Active group (n=5)	7.34 ± 2.34%	47.01 ± 10.56%	43.72 ± 6.10%
Control group (n=2)	7.63 ± 3.06%	7.24 ± 1.88%	7.36 ± 3.34%



MORE FOR LESS

EMSCULPT^{neo}

SAMPLE RESULTS



Left side (A) represents untreated adipose tissue with a healthy nuclei (red arrows), while the right side (B) represents adipose tissue 8 hours after the HIFEM+RF treatment with **numerous apoptotic nuclei (red circles)**

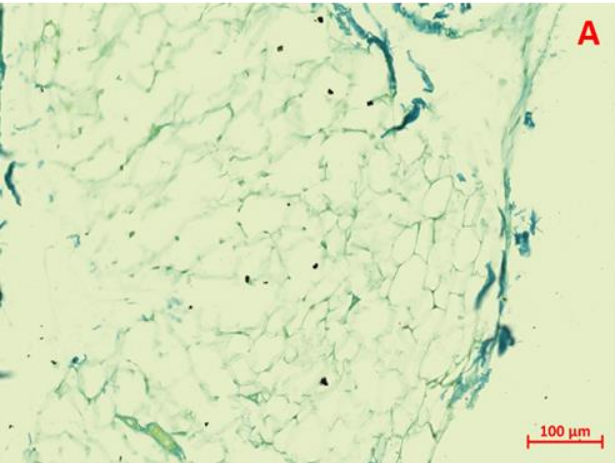


MORE FOR LESS

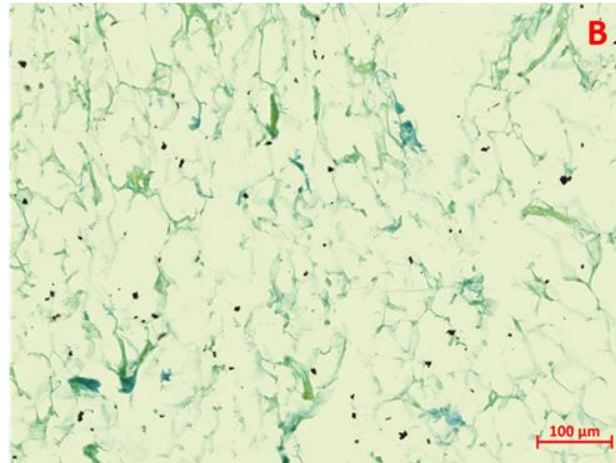
EMSCULPT®

SAMPLE RESULTS

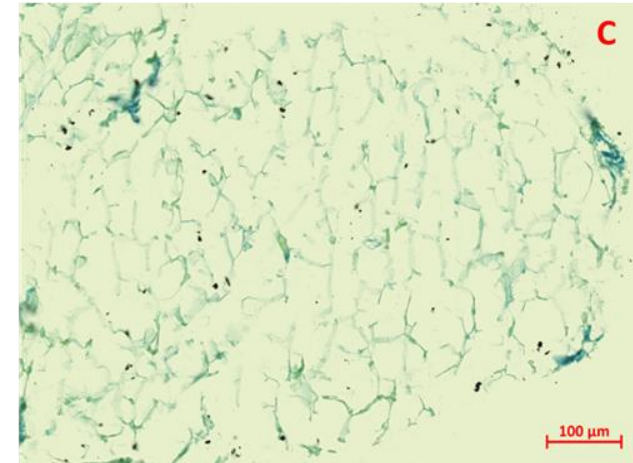
BASELINE



8 HOURS AFTER TX



24 HOURS AFTER TX



- Visualization of the changes in the adipose tissue morphology in the active group after the treatment
- **The number of apoptotic nuclei peaked 8 hours** after the treatment with AI reaching **+47% on average**

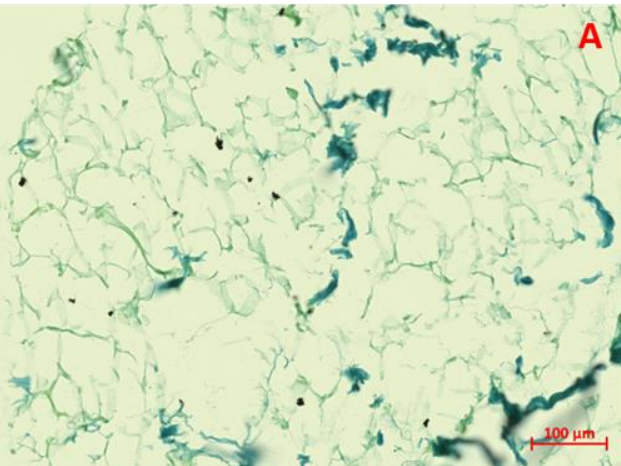


MORE FOR LESS

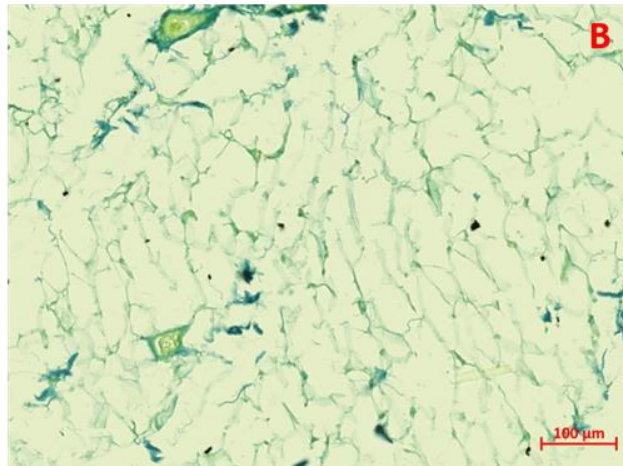
EMSCULPT^{neo}

SAMPLE RESULTS

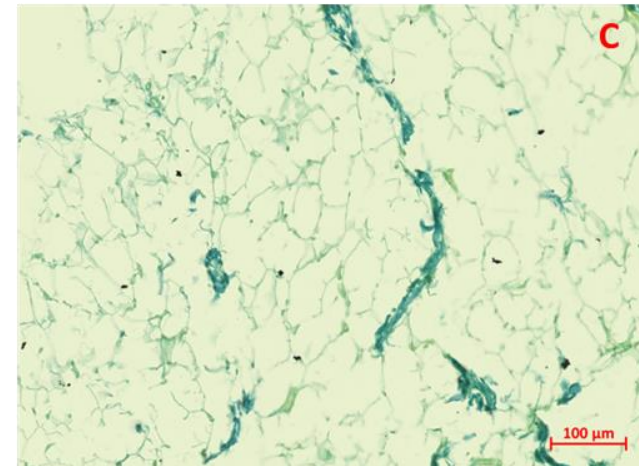
BASELINE



8 HOURS AFTER THE TX



24 HOURS AFTER THE TX



- On average, in the **control group**, the number of apoptotic nuclei **did not change** since AI was $7.63 \pm 3.06\%$ (Baseline), $7.24 \pm 1.88\%$ (8 Hours after), $7.36 \pm 3.34\%$ (24 hours after)

CONCLUSION

- The results show the **efficiency and safety** of the HIFEM+RF procedure for **adipose tissue reduction** as:
 - The treatment induced safe **elimination of fat cells via apoptosis**
 - Highly significant changes occurred only in the active group
 - The effect of treatment peaked after 8 hours, when **apoptotic index reached 47% from 7% at baseline (an increase of +540% against the baseline)**
 - **No adverse events** or side effect were observed



MORE FOR LESS

EMSCULPT[®] Neo

XV) EFFECTIVENESS OF COMBINED USE OF TARGETED PRESSURE ENERGY, RADIOFREQUENCY AND HIGH INTENSITY FOCUSED ELECTROMAGNETIC FIELDS TO IMPROVE SKIN QUALITY AND APPEARANCE OF FAT AND MUSCLE TISSUE IN DIFFERENT BODY PARTS

Diane Duncan M.D., FACS¹, Mariano Busso, M.D.²

¹Plastic Surgical Associates, Fort Collins, CO, United States

²Dr. Busso Cosmetic Dermatology, Miami, FL

Published in the Journal of Cosmetic Dermatology, 2022

<https://doi.org/10.1111/jocd.15280>



MORE FOR LESS

EMSCULPT[®]

STUDY DESIGN

- **32 subjects (21-64 y/o, BMI 17.4-33.5 kg/m²)**
- **Four (4) bilateral treatments** combining RF+HIFEM lasting for 30 minutes each followed by 20 minutes of simultaneous RF+TPE applied weekly
- Thighs, buttocks (saddlebags), abdomen, and upper arms treated
- All treatment intensities (HIFEM, RF or TPE) were set according to the subject's tolerance
- **1-month and 3-month data** were analyzed



MORE FOR LESS

EMSCULPT[®] Neo

STUDY DESIGN: EVALUATION

Circumference of the treated body part measured pre- & post-treatment:

- Using a stretch-resistant tape

Satisfaction and Comfort questionnaire

- 5-point Likert scale
- Assessment of overall appearance of treatment area considering the role & quality of different tissues – skin, fat and muscle
- Improvement of cellulite and skin laxity

Digital photographs

Adverse events monitoring



MORE FOR LESS

EMSCULPT^{neo}

RESULTS

- Improvement in all treated areas from 1-month follow-up, and more pronounced results at 3 months.
- **Significant circumference reduction** of the thighs ($p < 0.01$), saddlebags ($p < 0.05$) and abdomen ($p < 0.01$) 1 month and 3 months post-treatment.

Treatment area	1 month	3 months
Abdomen	-6.1 cm	-5.2 cm
Thighs	-1.5 cm	-3.0 cm
Saddlebags	-5.3 cm	-5.5 cm
Upper arms	-0.2 cm	-2.5 cm

- **94 % satisfaction** with overall treatment results
 - **93%** of subjects had an **improved appearance of cellulite**
 - **93%** of subjects had **improved skin laxity**
- Majority (88%) found therapy comfortable
- No adverse events occurred



EXAMPLE OF PATIENT RESULTS



The subject achieved considerable fat reduction accompanied by core muscle enhancement. The umbilical area appears tighter suggesting possible shortening of diastasis (abdominal muscle separation).



MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS



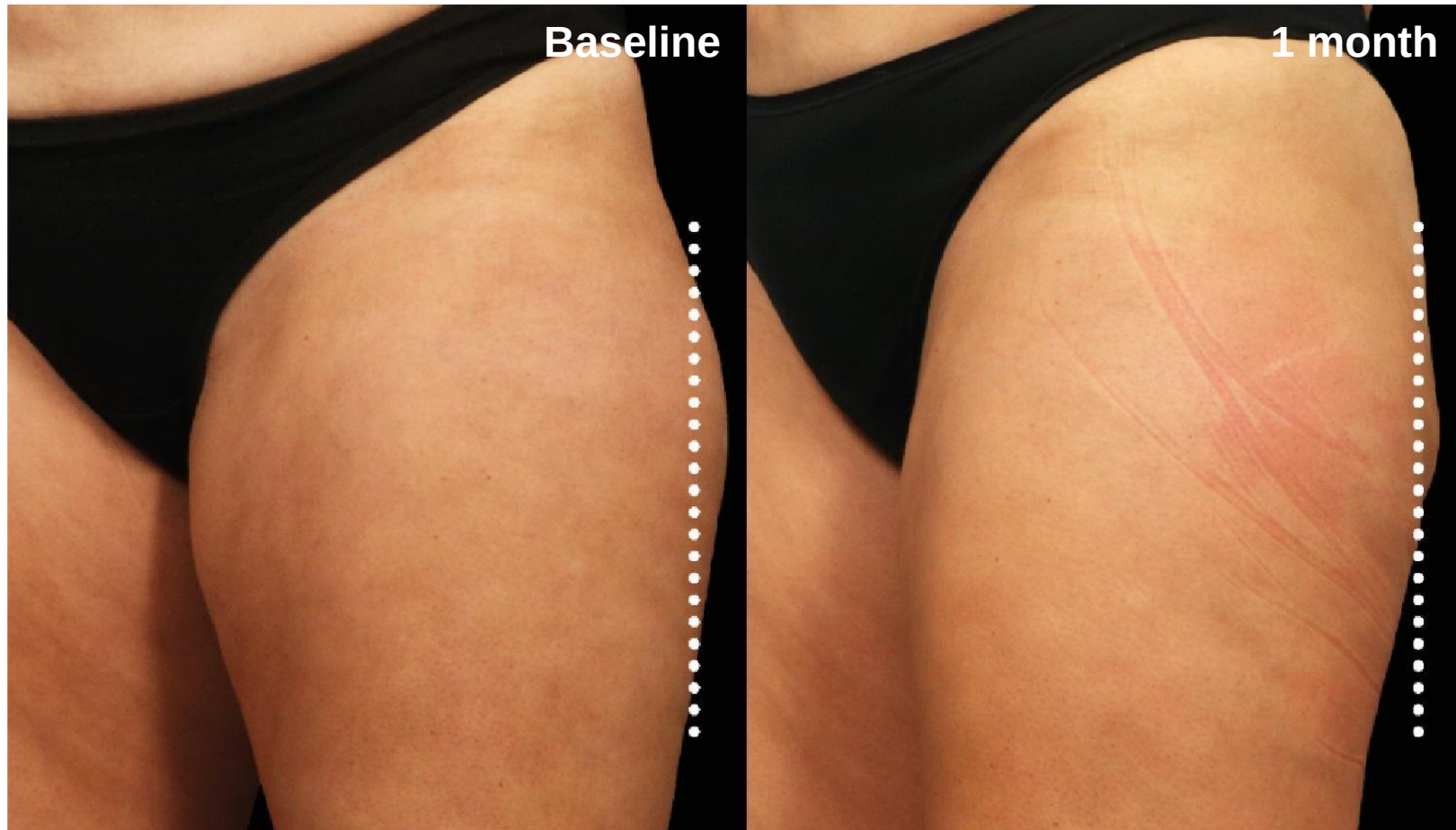
After the treatments, there is a better abdominal muscle definition. Skin texture appears smoother, the fine lines have reduced and the skin looks tighter.



MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS



The fat pocket is not protruding after the treatments. The outer thigh is more toned and shapely.



MORE FOR LESS

EMSCULPT[®] neo

EXAMPLE OF PATIENT RESULTS



After treatments, buttock contour is rounder and lifted. Cellulite bumps and dimples evened out, improving the skin condition.



MORE FOR LESS

EMSCULPT®
neo

CONCLUSION

- Therapy was comfortable with **high patient satisfaction (94%)**
- **Noticeable changes of the fat, muscle and skin** tissue were observable from 1-month follow-up
- **Circumference reduction** in the different body parts was **maintained or gradually improved at 3 months**
- **Skin quality** - laxity and cellulite appearance - **improved in 93% patients**
- Consecutive HIFEM+RF and RF+TPE therapy considerably enhances visual appearance by altering fat, muscle, and skin tissue



MORE FOR LESS

EMSCULPT[®] Neo

XVI) THE IMPROVEMENT IN QUALITY OF LIFE AND CORE MUSCLE STRENGTH IN ELDERLY PATIENTS BY SIMULTANEOUS APPLICATION OF HIFEM WITH SYNCHRONIZED RADIOFREQUENCY

Diane Duncan, M.D., FACS¹, David Kent, M.D.², Evan Appelbaum, M.D., FAAC³

¹Plastic Surgery Associates, Fort Collins CO, USA

²Skin Care Physicians of Georgia, Macon, Georgia

³Men's Health Boston, 200 Boylston St a309, Chestnut Hill, MA, United States

Presented at IMCAS world congress, Paris, 2023



MORE FOR LESS

EMSCULPT[®]

STUDY DESIGN

- **39 elderly patients** were enrolled
 - 60-79 years, 19.7-33.9 kg/m², skin type I-V
- All patients were scheduled for **7 treatments sessions**:

Study Devices	Study Treatment Visit						
	1	2	3	4	5	6	7
HIFEM+RF Treatment on Abdomen	X		X		X		X
Standalone HIFEM Treatment on Pelvic Floor	X	X	X	X	X	X	

- **The pressure biofeedback**, waist circumference, comfort and satisfaction questionnaires, and digital photographs were collected
- The data were collected at baseline, after the last treatment, at 1-month and 3-month follow-up visit



STUDY DESIGN: BIOFEEDBACK MEASUREMENT

- The air-filled pressure pad was placed beneath the patient's lower back
- The patients were instructed to **contract their core muscles** without lifting their shoulders or neck and squeezing their buttocks
- **This results in a change of pressure** is measured in mmHg
- An increase in the **pressure corresponds with increased muscle strength**



The biofeedback device



Patient's position during the measurements

RESULTS

- **38 patients completed** the treatment sessions, 38 patients attended the 1-month follow-up visit, and 38 patients finished the 3-month follow-up visit
- **Highly significant increase** in the biofeedback pressure measurements peaking at 3-month follow-up **(+28.3 mm Hg, p-value<0.001)**
- The average circumference reduction at 3 months was 0.93 inches **(-3.1 cm, p<0.05)** with maximum reduction of -12.1 cm

	Baseline	After 4th TX	1-month FU	3-month FU
Biofeedback measurements (mm Hg; N=21)	84.1 ± 47.2	100.0 ± 49.0	107.2 ± 51.7	112.4 ± 47.2
Waist circumference (inch; N=21)	35.6 ± 4.2	34.8 ± 4.0	34.5 ± 4.2	34.4 ± 4.5

Average ± standard deviation, TX= treatment, FU = follow-up

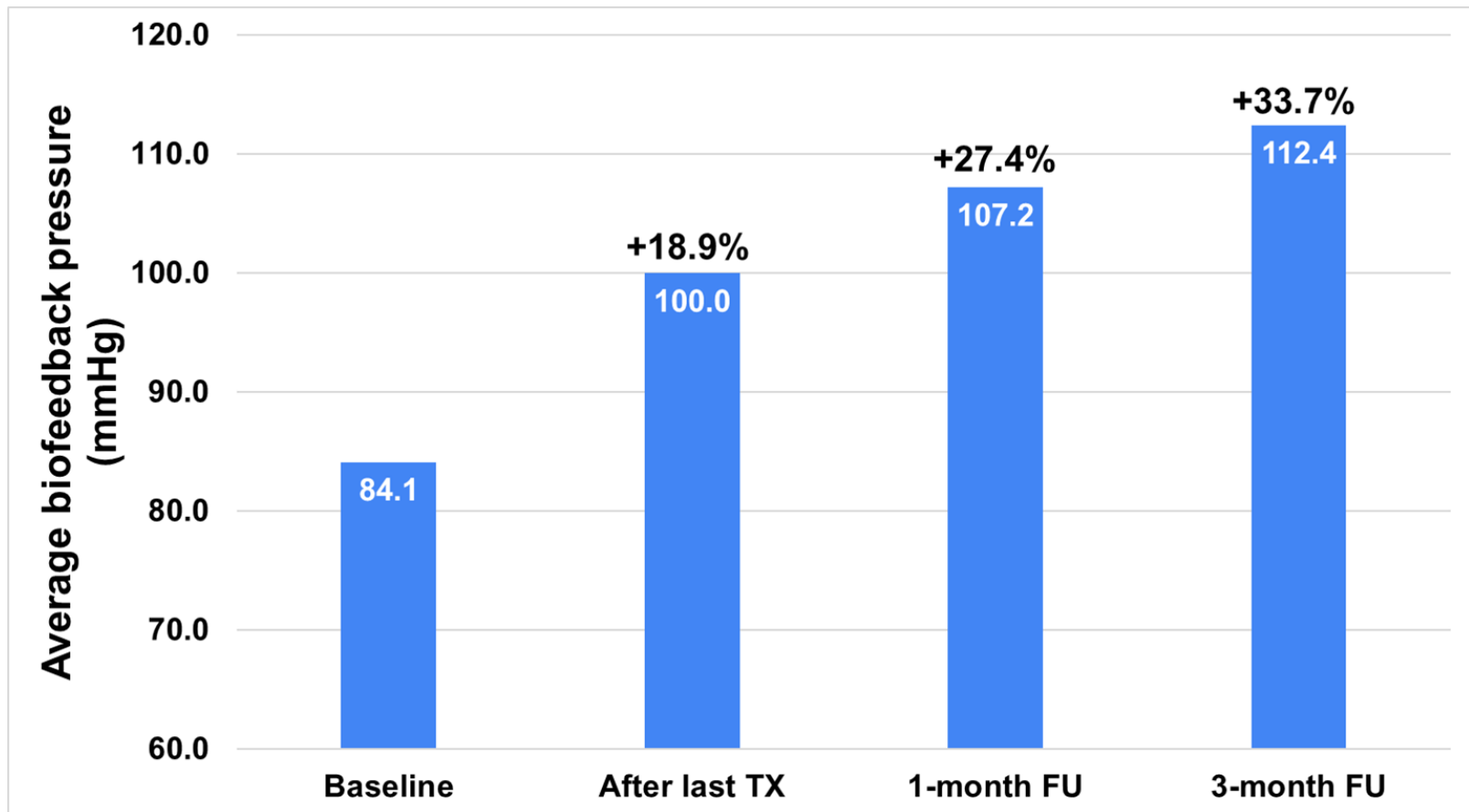


MORE FOR LESS

EMSCULPT^{neo}

RESULTS: BIOFEEDBACK

The relative increase in the biofeedback measurements peaked at 3-month follow-up with **33.7%** increase in core muscle strength



MORE FOR LESS

EMSCULPT^{neo}

RESULTS: QUESTIONNAIRES

Comfort

- Patients found the treatment comfortable and reported none to minimal pain (VAS = **2.45 ± 2.11**)

Satisfaction

- 5-point Likert scale questionnaire consisting of 21 questions regarding patients satisfaction and quality of life. **Results show that, on average, more than:**
 - **92%** of patients **would recommend** the treatment to family and friends
 - **89%** of patients **can get up easily** from a sedentary position
 - **76%** of patients were able to **perform the daily activities** better
 - **68%** of patients have **better posture & stability** together with their back discomfort, **workout performance and form improved**

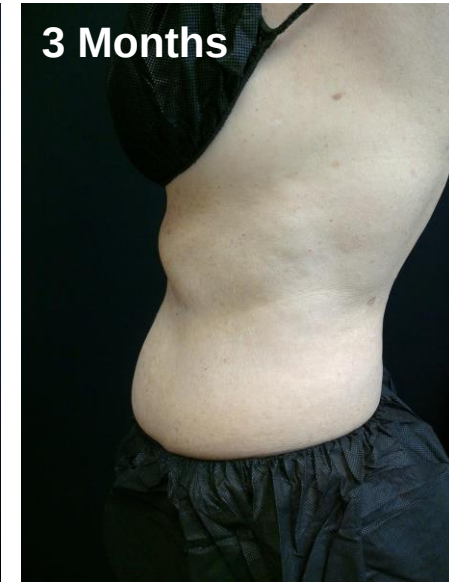
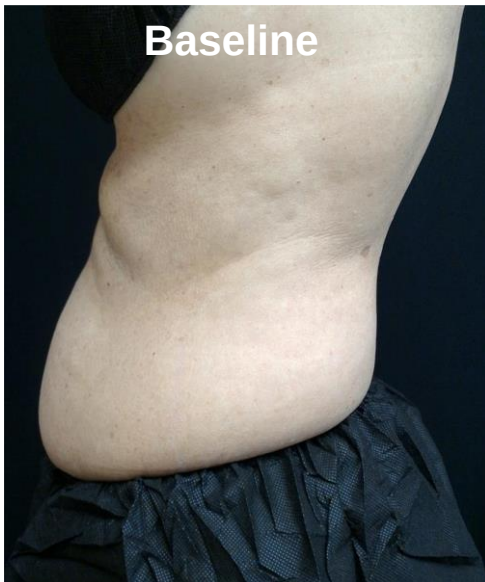


MORE FOR LESS

EMSCULPT[®]

EXAMPLE OF PATIENT RESULTS

60-year-old female (BMI of 22 kg/m²). At 3 months the core muscle strength increased by **+55.6%**.



Courtesy of: David Kent, M.D.

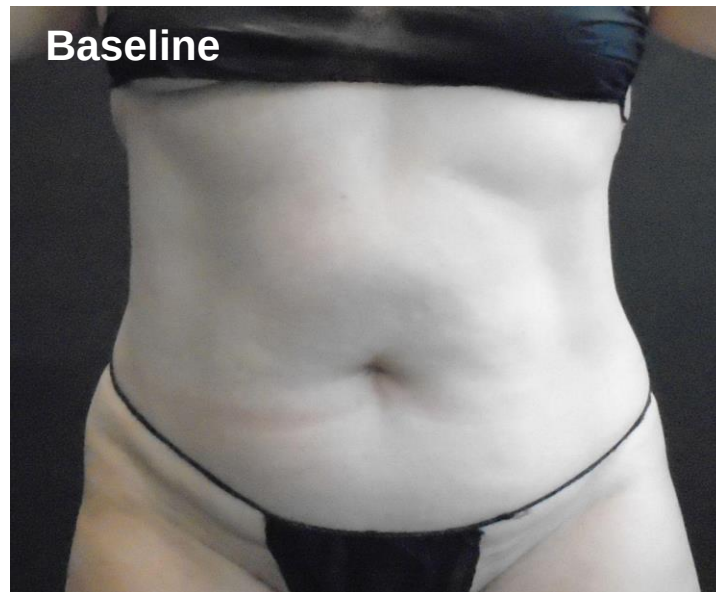


MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS

61-year-old female (BMI of 29.7 kg/m²). At 3-month the core muscle strength increased by **+30.8%**.



Courtesy of: Evan Appelbaum M.D.



MORE FOR LESS

EMSCULPT®

CONCLUSION

- This data analysis showed that the **combined use of the abdominal HIFEM+RF and standalone HIFEM pelvic** procedures improves the quality of life in elderly patients
- The average core strength increased by **33.7%** (+28.3 mm Hg)
- The average waist circumference was reduced by **-3.1 cm**
- On average, more than **92%** of patients were satisfied with the results
- Patients found therapies comfortable
- No serious adverse events or side effects were observed



MORE FOR LESS

EMSCULPT[®] Neo

XVII) THE IMPROVEMENT OF QUALITY OF LIFE IN FEMALE PATIENTS AFTER CHILDBIRTH BY HIFEM WITH SYNCHRONIZED RADIOFREQUENCY FOR THE STRENGTHENING OF CORE MUSCLES

**JD McCoy, M.D.¹, Andrea Pezzella, M.D., FACOG, FPMRS²,
Julene B. Samuels, M.D., FACS³**

¹Contour Medical, Gilbert, AZ, USA

²Lexington Medical Center, West Columbia, SC, USA

³Julene B. Samuels MD, FACS, Prospect, KY, USA

Presented at IMCAS world congress, Paris, 2023



MORE FOR LESS

EMSCULPT[®] neo

STUDY DESIGN

- **36 women** (27-44 years, 19.4-34.5 kg/m², skin type I-V) who gave birth within 6-60 months prior to the study start were enrolled
- All were scheduled for **7 treatments sessions**:

Study Devices	Study Treatment Visit						
	1	2	3	4	5	6	7
HIFEM+RF Treatment on Abdomen	X		X		X		X
Standalone HIFEM Treatment on Pelvic Floor	X	X	X	X	X	X	

- **The biofeedback pressure**, waist circumference, comfort and satisfaction questionnaires, and digital photographs were collected
- The data were collected at baseline, after the last treatment, at 1-month and 3-month follow-up visit



STUDY DESIGN: BIOFEEDBACK MEASUREMENT

- The air-filled pressure pad was placed below the patient's lower back
- The patients were instructed to **contract their core muscles** without lifting their shoulders or neck and squeezing their buttocks
- This results in a change of pressure is measured in mmHg
- An increase in the **pressure corresponds with increased muscle strength**



The biofeedback device



Patient's position during the measurements

RESULTS

- **34 patients completed** the treatment sessions, 33 patients attended the 1-month follow-up, with 33 patients finished the 3-month follow-up visit
- **Significant increase** in the biofeedback pressure measurements (**+26.6 mm Hg, $p<0.001$**) at three months
- The average waist circumference reduction was -1.82 inch (**-4.61 cm, $p<0.05$**) at 3-month follow-up, with maximal reduction of -11.43 cm

	Baseline	After 4th TX	1-month FU	3-month FU
Biofeedback measurements (mm Hg, N=12)	104.5 ± 18.0	121.9 ± 25.8	129.5 ± 22.5	132.0 ± 23.3
Waist circumference (inch, N=12)	35.2 ± 3.6	34.5 ± 3.5	33.9± 3.8	33.3 ± 4.2

Average ± standard deviation, TX= treatment, FU = follow-up

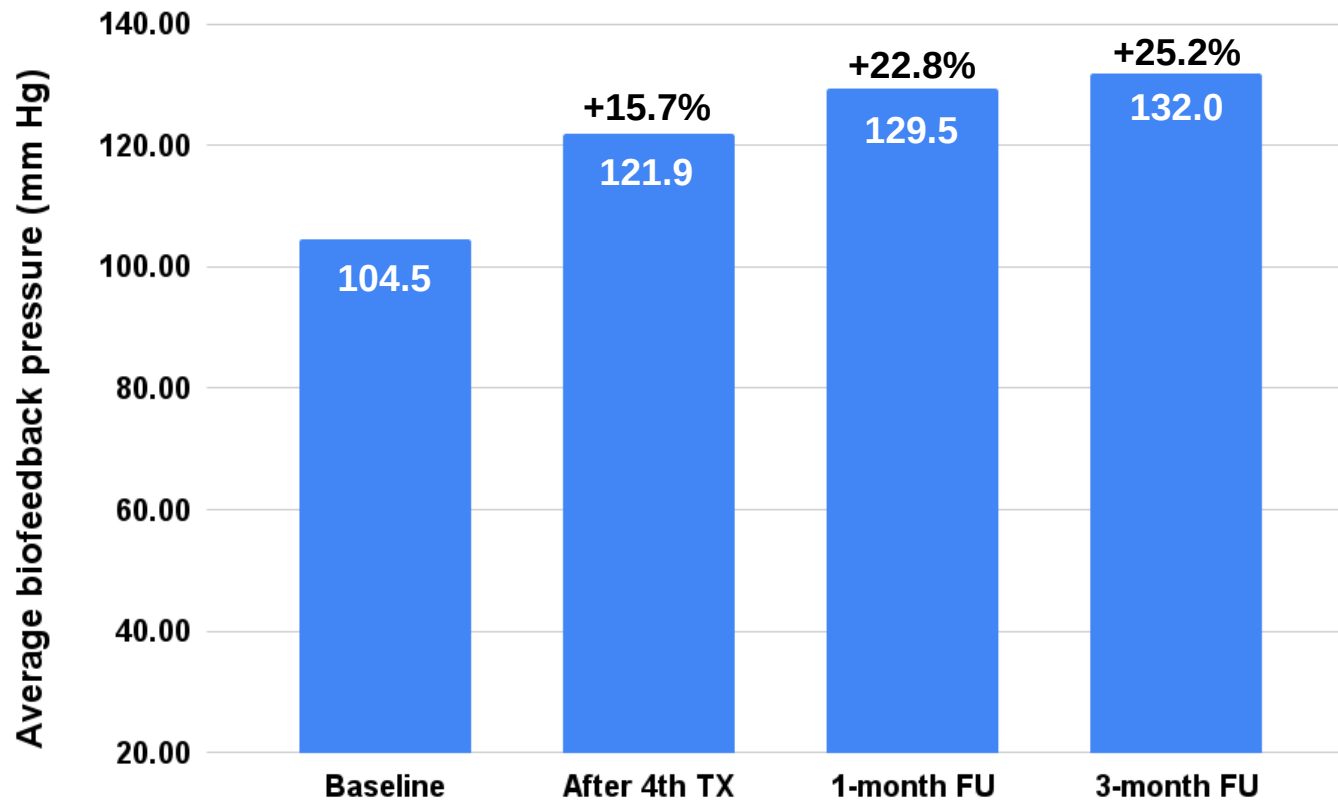


MORE FOR LESS

EMSCULPT^{neo}

RESULTS: BIOFEEDBACK

The data shows gradual increments in biofeedback measurements up to 3-month follow-up with **25.2%** increase in core muscle strength



MORE FOR LESS

EMSCULPT^{neo}

EXAMPLE OF PATIENT RESULTS

33-year-old female (BMI of 24.2 kg/m²). At 3 month the core muscle strength increased by **+53.85%**.



Courtesy of: Julene B. Samuels, M.D., FACS



MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS

38-year-old female (BMI of 20.8 kg/m²) at baseline (left), after the treatments (middle), and at the 3-month follow-up (right, waist reduction of -6.3 cm).

At 3 months, the core muscle strength increased by **21.5%**.



Courtesy of: JD. McCoy, NMD



MORE FOR LESS

EMSCULPT^{neo}

RESULTS: QUESTIONNAIRES

Comfort

- Patients found the treatment comfortable and reported only mild pain overall (VAS = **2.56 ± 2.20**)

Satisfaction

- A 5-point Likert scale questionnaire consisting of 19 questions regarding patients satisfaction. Results show that on average more than:
 - **97%** of patients **would recommend** the treatment to family and friends
 - **97%** were **satisfied** with the treatment results
 - **91%** of patients reported **better posture and stronger core**
 - **100%** of the patients reported **being able to perform their daily activities** without any issues after the treatments
 - **100%** of patients **could spend quality time with their children** after the treatments



CONCLUSION

- This data analysis showed that the **combined use of the abdominal HIFEM+RF and standalone HIFEM pelvic** procedures improves the quality of life of female patients after childbirth
- The average core strength increased by **25.2%** (+26.6 mm Hg)
- The average waist circumference was reduced by -1.82 inch (**-4.6 cm**)
- Satisfaction was high, particularly:
 - **94% of subjects were satisfied** after the last treatment
 - **91%** of patients reported **better posture and stronger core**
 - **100%** of subjects were able to **perform their daily activities** and **spend quality time with their children**
- No adverse events or side effects were observed



XVIII) CONSECUTIVE APPLICATION OF STANDALONE HIFEM PROCEDURE WITH SIMULTANEOUS APPLICATION OF HIFEM AND SYNCHRONIZED RADIOFREQUENCY FOR SARCOPENIA TREATMENT

Diane Duncan, M.D., FACS¹

¹Plastic Surgery Associates, Fort Collins CO, USA

Presented at the 5th Annual Global Aesthetics Conference, 2022



MORE FOR LESS

EMSCULPT[®]
neo

STUDY DESIGN

- **30 Subjects** (26-75 years, 19.7-33.5 kg/m²)
 - 27 women, 3 men
- All were scheduled for **7 treatments sessions**:

Study Devices	Study Treatment Visit						
	1	2	3	4	5	6	7
HIFEM+RF Treatment on Abdomen	X		X		X		X
Standalone HIFEM Treatment on Pelvic Floor	X	X	X	X	X	X	



STUDY DESIGN

- **The primary outcomes included** the evaluation of:
 - Maximum and comfortable gait speed (m/s)
 - Timed up and go test (TUG, s)
 - Balance test (s)
 - Number of steps in 2 minutes (N)
- **The secondary outcomes** measured:
 - InBody measurement of visceral adipose tissue (VAT) and skeletal muscle mass (SMM)
 - Dual-energy x-ray absorptiometry (DEXA) of bone mineral density (BMD)
- The data were collected at baseline, after the last treatment, at 1-month and 3-month follow-up visit



MORE FOR LESS

EMSCULPT^{neo}

RESULTS - PRIMARY OUTCOMES – ALL PATIENTS

3 months after the last treatment **ALL PATIENTS** (N=30) showed on average:

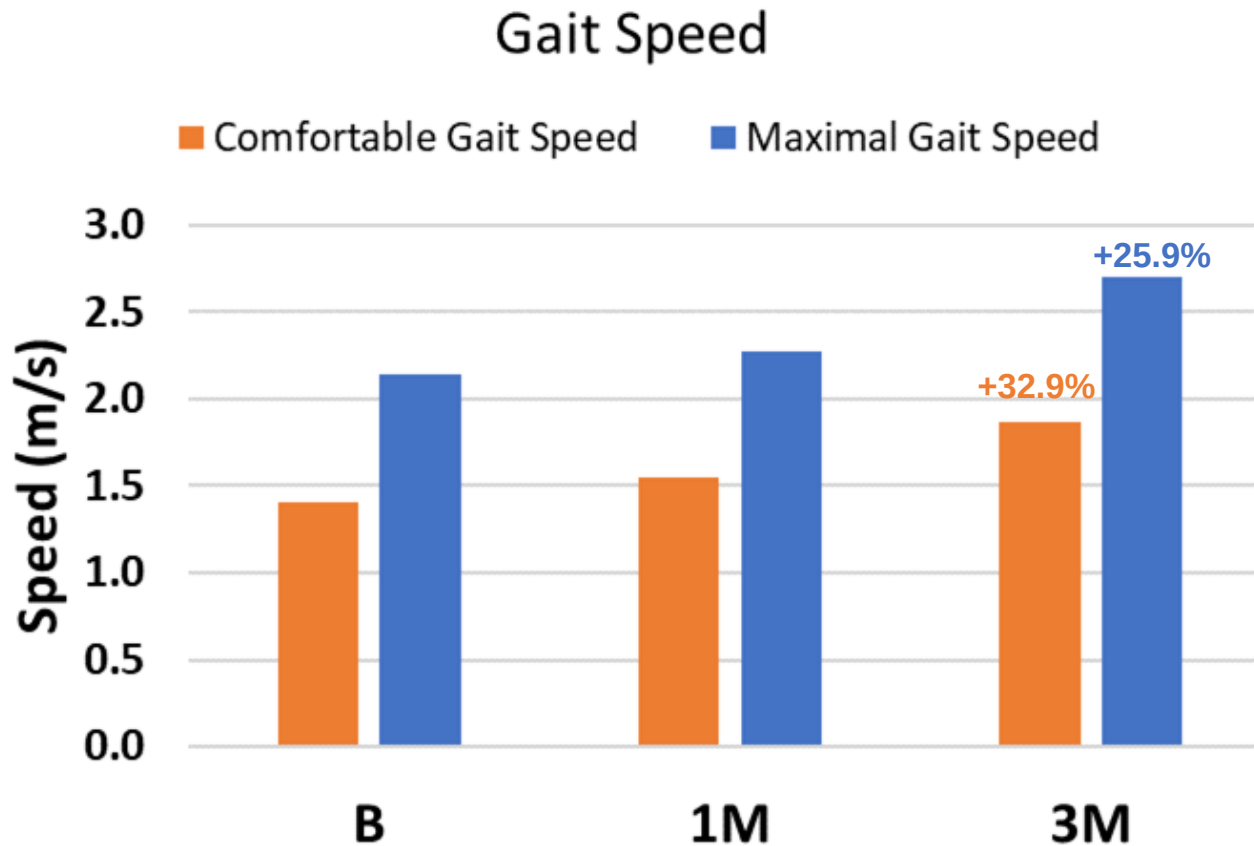
- Comfortable gait speed increase by **32.9%** (p-value=0.001)
- Maximal gait speed increase by **25.9%** (p-value<0.001)
- The TUG test showed a **-21.1%** decrease in the time (p-value<0.001)
- Balance improved by **11.6%** (p-value=0.04)
- Number of steps done in 2 minutes increased by **18.4%** (p-value < 0.001)



MORE FOR LESS

EMSCULPT^{neo}

RESULTS - PRIMARY OUTCOMES – ALL PATIENTS



The bar chart is showing the gradual improvement in both comfortable and maximal gait speed peaking at 3 months.



MORE FOR LESS

EMSCULPT^{neo}

RESULTS - PRIMARY OUTCOMES – ELDERLY PATIENTS

3 months after the last treatments, **PATIENTS OVER 60 YEARS** (n=16) showed on average

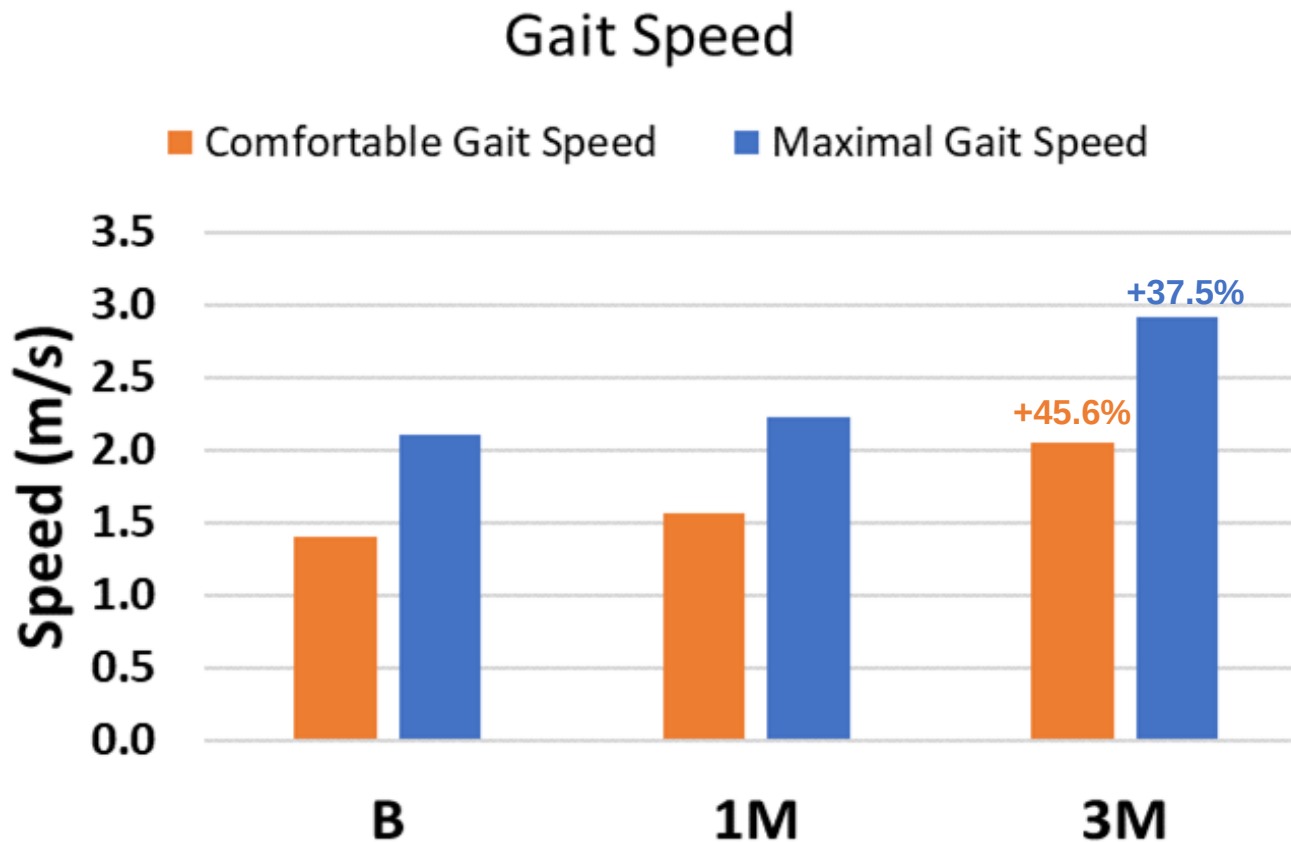
- Comfortable gait speed increase by **45.6%** (p-value=0.007)
- Maximal gait speed increase by **37.5%** (p-value=0.015)
- The TUG test showed a **-20.6%** decrease in the time (p-value<0.001)
- Balance improved by **30.3%** (p-value=0.04)
- Number of steps done in 2 minutes increased by **20.9%** (p-value<0.001)



MORE FOR LESS

EMSCULPT[®] Neo

RESULTS - PRIMARY OUTCOMES – ELDERLY PATIENTS



The bar chart is showing the gradual improvement in both comfortable and maximal gait speed in elderly subjects peaking at 3 months.



MORE FOR LESS

EMSCULPT^{neo}

RESULTS - ALL SUBJECTS VS. ELDERLY SUBJECTS

The table shows an increase in all primary outcomes, with more profound results in the group over 60 years old

	ALL PATIENTS (n=30)	Elderly group (n=16) (60 Years +)
Comfortable gait speed	+32.9%	+45.6%
Maximal gait speed	+25.9%	+37.5%
The TUG test	-21.1%	-20.6%
Balance	+11.6%	+30.3%
Number of steps	+18.4%	+20.9%



MORE FOR LESS

EMSCULPT^{neo}

INBODY AND DEXA MEASUREMENTS - VAT (VISCERAL ADIPOSE TISSUE)

High VAT (above 100 cm²) = **High health risks** such as Type 2 diabetes, high blood pressure, heart disease, heart attacks, and breast or colorectal cancer.

- **25% of patients with Extremely High VAT** (above 160 cm²) were at the **High VAT** values (100 - 160 cm²) at 3 months follow-up visit.
- **18.2% of patients with High VAT** (above 100 cm²) were at the **Normal VAT** values at 3 months follow-up visit = **Lower Health Risks**.



MORE FOR LESS

EMSCULPT^{neo}

INBODY AND DEXA MEASUREMENTS - VAT (VISCERAL ADIPOSE TISSUE)

- **Patients over 60 years** showed an increase of **+1.4 lbs. in SMM** (Skeletal Muscle Mass) – after the treatments
NOTE – Only Abdomen & Pelvic muscles were treated
- Bone Mineral Density showed no significant changes, which indicates the safe use of the HIFEM+RF technology for the elderly as it does not contribute to osteoporosis or affect bone metabolism.



MORE FOR LESS

EMSCULPT[®] neo

EXAMPLE OF PATIENT RESULTS

A 65-year-old female (BMI of 21.1 kg/m²). At 3 months patient showed on average 26.1% improvement in the measured parameters, with **73% increase in balance**.

With improved abdominal contour, the patient's posture bettered as well.

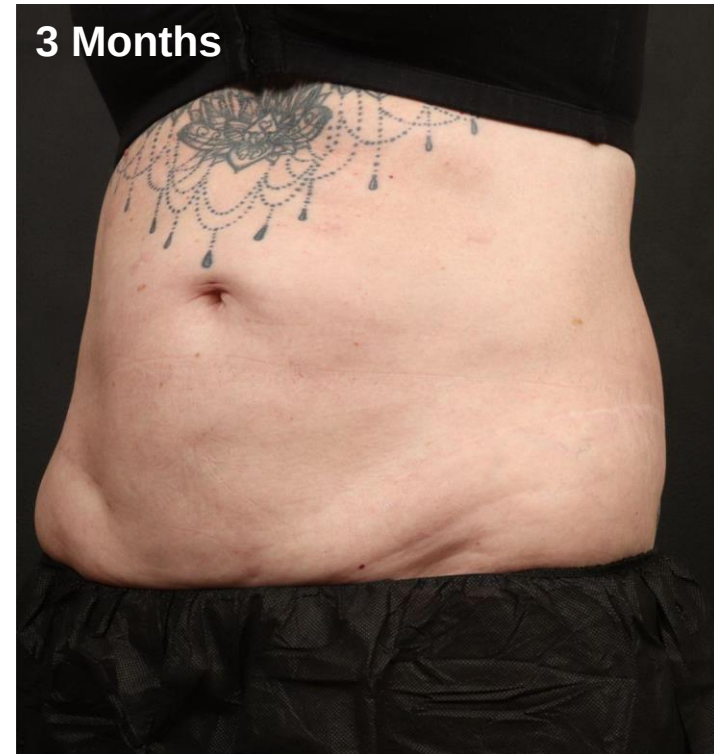
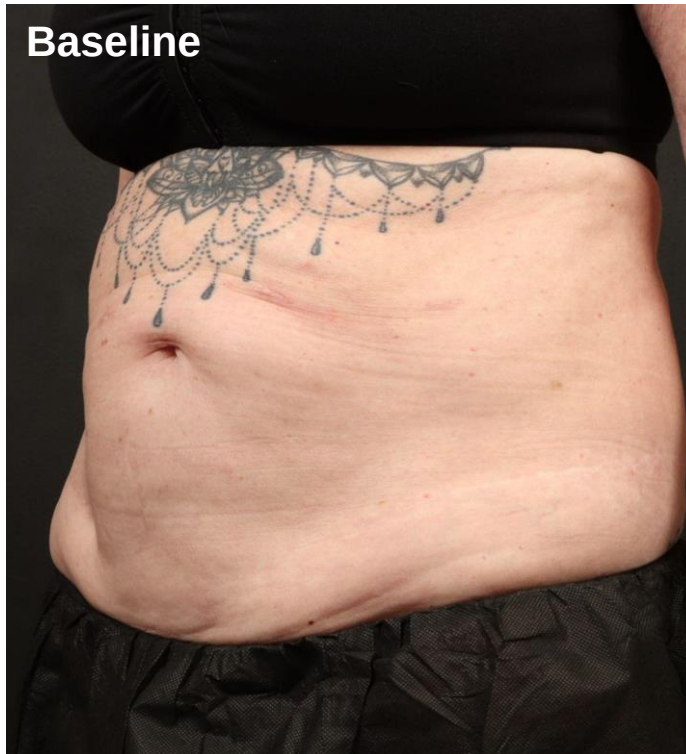


MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS

A 70-year-old female (BMI of 26.6 kg/m²). At 3 months patient showed **on average 59% improvement in the measured parameters**, with 55.5% increase maximal gait speed. The photographs show improved abdominal contour.



MORE FOR LESS

EMSCULPT®

CONCLUSION

- The evaluation of standard tests used for sarcopenia assessment indicated the possible use of the standalone **HIFEM** procedure (Pelvis) with simultaneous application of **HIFEM+RF** (Abdomen) for **improving mobility, balance, and health benefits** as all patients showed significant improvement in the measured parameters.
- Ancillary to functional benefits the patients also demonstrated aesthetic improvement.
- The patients **above 60 years** showed even **more profound improvements** when compared to the other group.



MORE FOR LESS

EMSCULPT[®] Neo

XIX) THE SIMULTANEOUS APPLICATION OF HIFEM PROCEDURE WITH SYNCHRONIZED RADIOFREQUENCY ON LATERAL ABDOMEN FOR FAT REDUCTION AND MUSCLE STRENGTHENING: INTERIM DATA

Carolyn Jacob, M.D.¹, Joel Cohen, M.D.², Barry DiBernardo, M.D.³, Stanley A. Okoro, M.D., MBA, FACS⁴, Young Cho, M.D., PhD⁵, Suzanne L. Kilmer, M.D.⁶

¹Chicago Cosmetic Surgery and Dermatology, Chicago, IL, USA

²AboutSkin Dermatology and AboutSkin Research, Greenwood Village, CO, USA

³New Jersey Plastic Surgery, New Jersey, NY, USA

⁴Georgia Plastic & Reconstructive Surgery, Marietta, GA, USA

⁵Integrated Aesthetics, Spring, TX, USA

⁶Laser & Skin Surgery Center of Northern California, Sacramento, CA, USA

Presented at ODAC Dermatology Conference, Orlando, FL, 2023



MORE FOR LESS

EMSCULPT[®]
neo

STUDY DESIGN

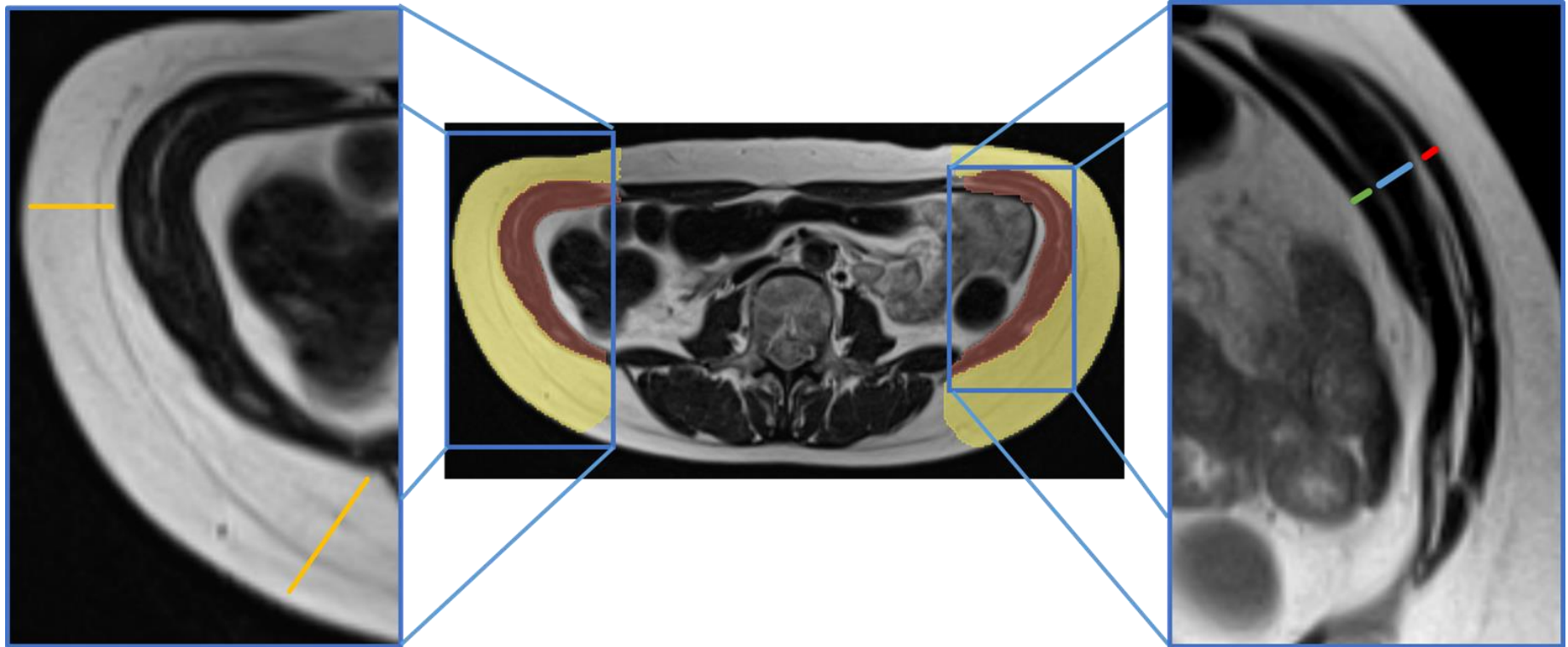
- **73 patients** were enrolled, with evaluated MRIs of 39 patients at 1-month follow-up
 - 22 - 63 years, 20.2 - 33.9 kg/m², skin type I-VI
- Patients were scheduled for four 30-minute treatments spaced once a week
- Evaluation included
 - The thickness and area measurements of oblique muscles and adjacent fat depots based on the magnetic resonance imaging (MRI) scans
 - Waist and hip circumference
 - Digital photographs of the treated area
 - 5-point Likert scale Satisfaction and Comfort (including 10-point pain scale) questionnaires
- Data were collected at baseline, after the last treatment and 1-month and 3-month follow-up visits



MORE FOR LESS

EMSCULPT^{neo}

Methodology - MRI evaluation



The changes in the muscle and fat tissue were measured at mid-L3 vertebrae level. Cross sectional area of the **muscle tissue** and **fat tissue** was measured, together with thickness of fat layer and three lateral muscles of abdomen: **External oblique**, **Internal oblique**, and **Transverse abdominal muscle**

RESULTS - MRI

Preliminary evaluation of 15 patients at 3-month follow-up showed an average results of:

Muscles:

- +26.1% increase in cross sectional area and +24.6% increase in overall thickness

Fat:

- **-29.4% decrease** in measured cross sectional area
- **-29.2% in lateral flank fat** thickness
- **-28.2% in posterior flanks fat** thickness
- -28.7% decrease in overall fat layer thickness

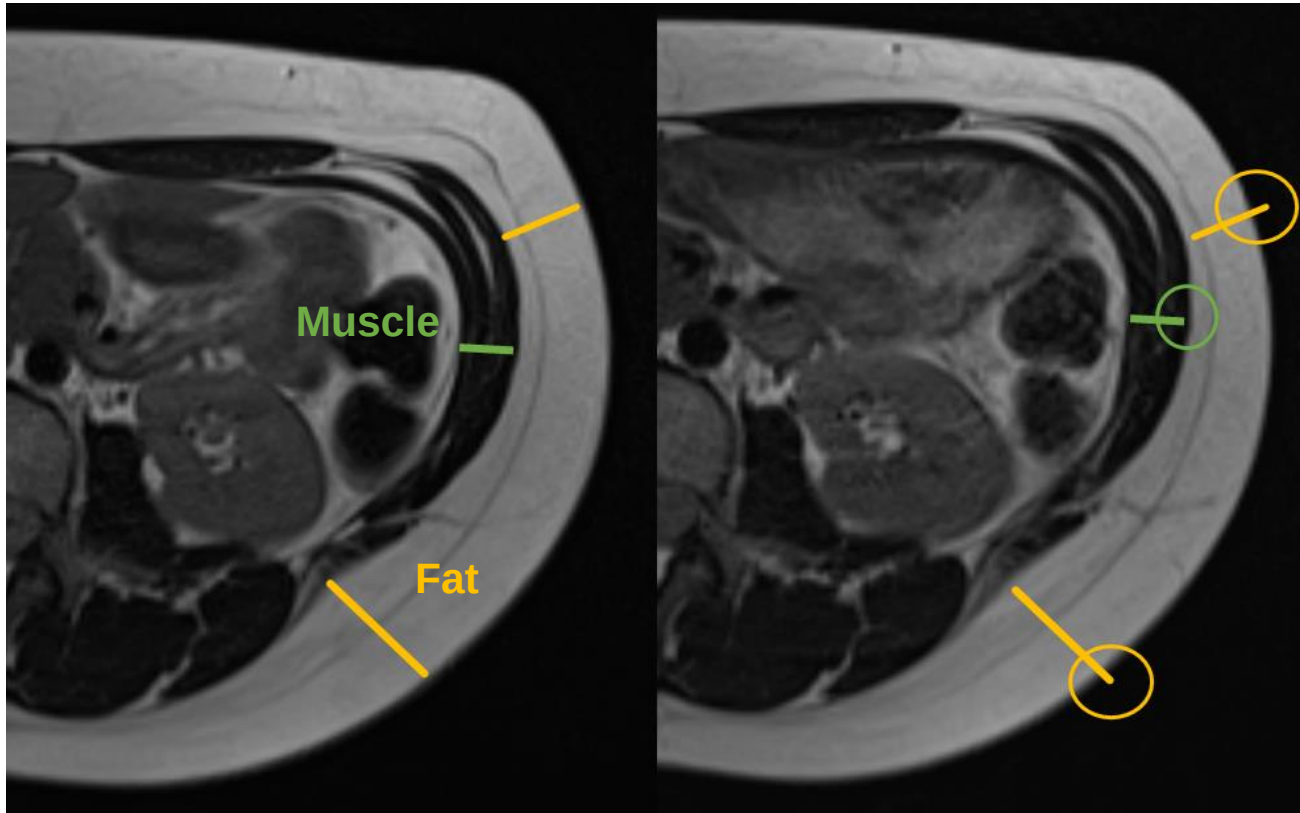


MORE FOR LESS

EMSCULPT[®] Neo

RESULTS - MRI

A 22-year-old female patient with a BMI of 27.3 kg/m². At the 3-month follow-up, the patient showed an average fat thickness reduction of -2.8 mm and an average increase in muscle thickness of +2.1 mm.



Courtesy of Carolyn Jacob, M.D



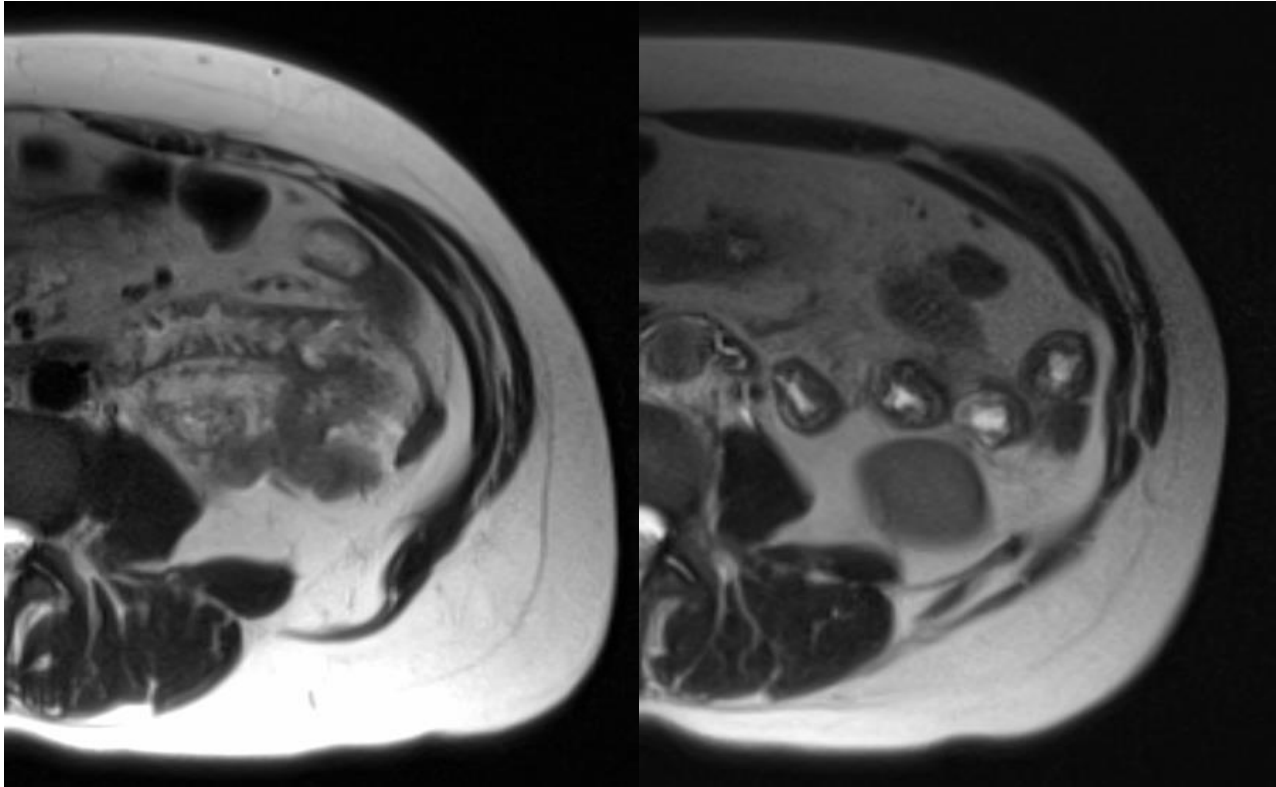
MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS MRI

At the 3-month follow-up, the patient showed an average **fat thickness reduction of -6.9 mm** and an average **increase in muscle thickness of +1.9 mm**.

The fat tissue is visibly reduced with a posterior flanks area showing -10.2 mm.



A 51-year-old female patient with a BMI of 27.8 kg/m².

Courtesy of Joel Cohen, M.D.



MORE FOR LESS

EMSCULPT[®] neo

SECONDARY RESULTS

- The average waist circumference reduction was -1.7 ± 2.5 cm, with **maximal reduction of -6.0 cm** at 3-month follow-up
- Questionnaires
 - Satisfaction at 3-month follow-up
 - **88.9%** of patients reported improved appearance of the treated area
 - **86.1%** of patients reported that the treatment area feels more toned
 - **86.1%** of patients reported improvement in the treated area
 - **86.1%** of patients reported more confidence in their clothes after the treatments
 - **88.9%** of patients were satisfied with the treatment results.
 - Comfort after the last treatment
 - **98.5%** of patients found the treatments comfortable
 - **84.9%** of patients reported none to mild pain during the treatments



EXAMPLE OF PATIENT RESULTS

A 45-year-old female patient with a BMI of 23.6 kg/m². Three months after the treatments, the patient showed a waist circumference **reduction of -3 cm** and improved abdominal contour.



Courtesy of: Barry DiBernardo, M.D.

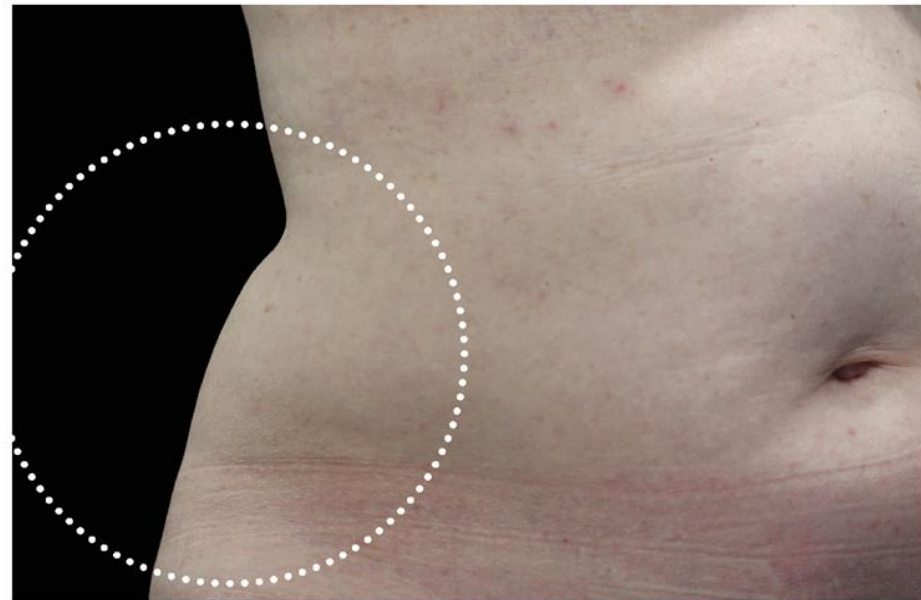


MORE FOR LESS

EMSCULPT®

EXAMPLE OF PATIENT RESULTS

A 54-year-old female patient with a BMI of 21.5 kg/m². One month after the treatments, the patient showed a **waist circumference reduction of -6 cm.**



Courtesy of Stanley A. Okoro, M.D.



MORE FOR LESS

EMSCULPT®
neo

EXAMPLE OF PATIENT RESULTS

A 55-year-old male patient with BMI of 29.1 kg/m². At 3-month follow-up, the patient showed a waist circumference **reduction of -4 cm.**



Courtesy of: Barry DiBernardo, M.D.



MORE FOR LESS

EMSCULPT®

CONCLUSION

- The evaluation of interim data show homogeneous **fat reduction of -29.4%** in cross-sectional area with **+26.1% increase in muscle** cross-sectional area.
- No serious adverse event or side effects were observed.
- The results described herein suggests that the simultaneous application of HIFEM+RF is safe and effective non-invasive alternative for the reduction of adipose tissue and muscle strengthening in the area of the lateral abdomen.



MORE FOR LESS

EMSCULPT^{neo}

EMSCULPT NEO®

EMSCULPT NEO® should only be used under the continued supervision of a physician or licensed practitioner. Patient should be continuously monitored and therapy discontinued immediately if the patient reports pain or excessive heat. Do not apply therapy over clothing or scar tissue, or if patient has electronic or metal implants. As with any heat-based therapy, burns may result. The Therapy Discomfort Button should always be accessible to the patient. Patient results and patient experience may vary. EMSCULPT NEO® is indicated for non-invasive lipolysis (breakdown of fat) of the abdomen and thighs and reduction in circumference of the abdomen and thighs with Skin Type I to Skin Type VI; and for non-invasive lipolysis (breakdown of fat) of the upper arms limited to skin types II and III and BMI 30 or under. EMSCULPT NEO® is also indicated for improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen; strengthening, toning, and firming of buttocks, thighs, and calves; and improvement of muscle tone and firmness, for strengthening muscles in arms. ©2023 BTL Industries, Inc. and affiliated companies. All rights reserved. BTL®, HIFEM®, EM®, EMSCULPT NEO®, and EMSCULPT® are registered trademarks in the United States of America, the European Union, or other countries. The products, the methods of manufacture or the use may be protected by one or more U.S. or foreign patents or pending applications, see www.btl.net.com/patents. Trademarks EMSCULPT, EMSCULPT NEO, EMSELLA, EMTONE, EMFEMME 360, EMFACE, and EMBODY are associated with the EM® family of products and services.



MORE FOR LESS

EMSCULPT NEO®