NON-INVASIVE BODY CONTOURING

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CONFLICTS OF INTEREST

RESEARCH GRANTS FROM BTL, SOFWAVE AND CUTERA

- FAT AND SKIN
- CELLULITE
- Muscle



LASER ASSISTED LIPOSUCTION

- LOCALIZED THERMAL AND MICROMECHANICAL LIPOLYSIS OF TARGETED TISSUES, AFFORDS REMOVAL OF LARGE VOLUMES OF FAT DEPOSITS FROM BOTH SUPERFICIAL AND DEEP LAYERS
- Photothermolytic effect is mediated by subcutaneous chromophores receptive to specific
 Laser Wavelengths, which subsequently dictate the penetration depth and scatter profile, with
 HIGH ABSORPTION LASERS PROVIDING A LOCALIZED EFFECTS, WHILE LOW-ABSORPTION LASERS ELICIT MORE
 DIFFUSE RESPONSES

Heller L, Menashe S, Plonski L, Ofek A, Pozner JN. 1470-nm Radial fiber-assisted liposuction for body contouring and facial fat grafting. Journal of cosmetic dermatology.

CRYOLIPOLYSIS

- THE FIRST CRYOLIPOLYSIS SYSTEM APPROVED FOR USE BY NATIONAL AND INTERNATIONAL REGULATORY BODIES WAS COOLSCULPTING
- LIPID-RICH ADIPOCYTES ARE MORE SUSCEPTIBLE TO THE EFFECTS OF COLD THAN OTHER CELL TYPES,
 CRYOLIPOLYSIS LEADS TO APOPTOSIS OF ADIPOCYTES.
- The procedure uses a surface vacuum applicator with no use of instruments that penetrate the dermis, and is therefore entirely noninvasive

AS EXPECTED, PUBLISHED DATA HAVE TYPICALLY
DEMONSTRATED MODEST EFFICACY COMPARED WITH
TRADITIONAL SURGICAL INTERVENTIONS SUCH AS
LIPOSUCTION — BUT NON-INVASIVE

TABLE 1 CoolSculpting applicators

Applicator	Body areas	Standard cycle duration
CoolAdvantage	Upper arms (large), upper back (large), upper flanks (large), lower flanks, inner thighs, banana roll (large), upper abdomen, lower abdomen	35 min
CoolAdvantage Plus	Upper abdomen (large), lower abdomen (large), lower flanks (large)	45 min
CoolAdvantage Petite	Upper arms, upper back, upper flanks, lower flanks, inner thigh, banana roll, upper abdomen, lower abdomen, medial knee	35 min
CoolMini	Submental, axillary puff, distal thigh, medial knee (small)	45 min
CoolSmooth Pro	Upper abdomen (flat), outer thigh	75 min

McKeown DJ, Payne J. Significant improvement in body contour with multiple cycles of CoolSculpting: Results of a prospective study. Dermatol Ther. 2021 Mar;34(2):e14850. doi: 10.1111/dth.14850.

MULTIPLE CYCLES PER SESSION = NEW TREND

- PROSPECTIVE ANALYSIS OF CONSECUTIVE, HEALTHY, ADULT PATIENTS UNDERGOING COOLSCULPTING IN
 ROUTINE PRACTICE ASSESSED WHETHER AN INTENSIVE REGIMEN OF COOLSCULPTING BASED ON MULTIPLE
 CYCLES/SESSIONS ON THE SAME BODY AREA(S) COULD YIELD GREATER (MORE CLINICALLY SIGNIFICANT)
 IMPROVEMENTS IN BODY CONTOUR
- 28 PATIENTS ENROLLED
- Patients underwent ≤4 cycles of CoolSculpting per body area during an initial treatment session, and ≤4 further cycles 4 weeks later (if required) and were followed up for ≥12 weeks

McKeown DJ, Payne J. Significant improvement in body contour with multiple cycles of CoolSculpting: Results of a prospective study. Dermatol Ther. 2021 Mar;34(2):e14850. doi: 10.1111/dth.14850.

- The Mean number of cycles per area was 2.8 ± 1.5
- Mean skinfold thickness decreased from 35.4 ± 9.9 mm pretreatment to 22.2 ± 7.6 mm at 12 weeks (mean change: -40%; P < .001)
- MEAN CHANGE IN SKINFOLD THICKNESS WAS GREATER WITH ≥3 VS 1 TO 2 CYCLES OF COOLSCULPTING (P = .01).
- MOST COMMON TREATED PARTS OF THE BODY WERE THE LOWER ABDOMEN (19%), THE UPPER ABDOMEN (14%), THE SUBMENTAL AREA (14%), THE UPPER ARMS (12%) AND THE LOWER FLANKS (12%).

McKeown DJ, Payne J. Significant improvement in body contour with multiple cycles of CoolSculpting: Results of a prospective study. Dermatol Ther. 2021 Mar;34(2):e14850. doi:





flanks. A, A 42-year-old woman before treatment with 4 cycles (1 session) of CoolSculpting and B, at 12 weeks after treatment

FIGURE 5 CoolSculpting of the upper arms. A, A 58-year-old woman before treatment with 4 cycles (1 session) of CoolSculpting and B, at 12 weeks after treatment



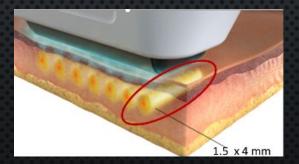


McKeown DJ, Payne J. Significant improvement in body contour with multiple cycles of CoolSculpting: Results of a prospective study. Dermatol Ther. 2021 Mar;34(2):e14850. doi: 10.1111/dth.14850.

ULTRASOUND

Parallel USB Technology

- Coagulation pattern elongated cylinders 1.5 x 4 mm are produced
 parallel to the skin surface and centered at a depth of 1.5mm
- High volume coverage along skin tension vectors
 - 28% 2 passes
 - 43% 3 passes
- No need for real time ultrasound visualization









Before

3m FU

6m FU





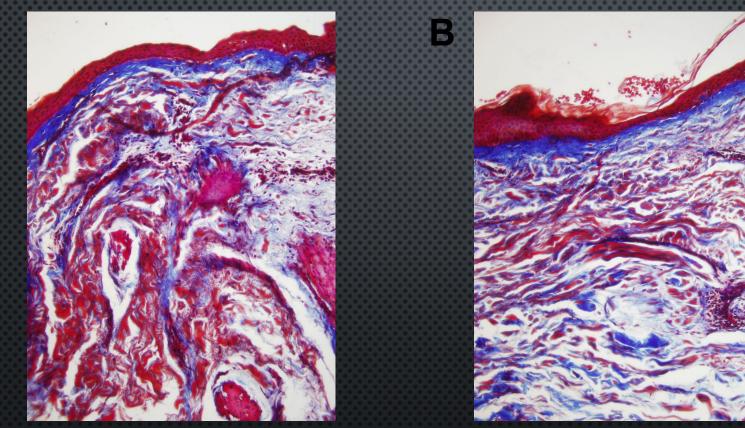
4 weeks after





4 weeks after

MASSON'S TRICHROME STAINING BEFORE AND 10 MONTHS AFTER ONE TREATMENT



Skin biopsy revealed a significant increase of dermal collagen in the reticular dermis after treatment (x20 magnification. A: taken before treatment, B: taken 10 months after treatment)

Alcian Blue staining

Before and 10 months after one treatment

Alcian blue (AB) staining, which stains all types of GAGs, showed strong stain in whole extracellular spaces in dermis and dermal cells including fibroblasts and endothelial cells. (x10 magnification. A: taken before treatment, B: taken 10 months after treatment). Note the significant increase in connective tissue HA with unique alignment of connective tissue fibers and overall increase in dermal thickness

Dr. Virginia Benitez Roig

RADIOFREQUENCY

- SKIN TIGHTENING
- FAT REDUCTION

• 12 weeks post treatment revealed mean reduction in fat thickness in the abdomen of 4.24 ± 2.3 mm and mean reduction in fat thickness in the flanks of 2.57 ± 0.8 mm



Figure 3 Digital photographs and ultrasound images of two subjects before and after treatment.
 (A) Thirty-five-year-old female before and at 12-week following treatment in the flank area.
 (B) Fifty-nine-year-old male before and at 12-week following treatment in the abdominal area.

Somenek MT, Ronan SJ, Pittman TA. A Multi-Site, Single-Blinded, Prospective Pilot Clinical Trial for Non-Invasive Fat Reduction of the Abdomen and Flanks Using a Monopolar 2 MHz Radiofrequency Device. *Lasers in surgery and medicine*. 2021;53(3):337-343.

INJECTABLES: WIDELY USED "OFF LABEL USE" OF DEOXYCHOLIC ACID

- Anterior periaxillary fat (Shridharani SM. Injection of an adipocytolytic agent for reduction of excess periaxillary fat. Aesthet Surg J 2019;39:NP495-503.)
- POSTERIOR PERIAXILLARY FAT AKA "BRA BULGE" (VERMA KD, SOMENEK MT. DEOXYCHOLIC ACID INJECTION AS AN EFFECTIVE TREATMENT FOR REDUCTION OF POSTERIOR UPPER TORSO BRASSIERE STRAP ADIPOSITY. PLAST RECONSTR SURG 2018;141:200E-2E.)
- FOCAL AREAS OF LOCALIZED ADIPOSITY RESPOND THE BEST, BUT COST CAN BE PROHIBITIVE FOR LARGER AREAS

CELLULITE

TISSUE STABILIZED-GUIDED SUBCISION IN THE MANAGEMENT OF CELLULITE

- First long-lasting, minimally invasive device for improving the appearance of cellulite for at least 3
 YEARS VIA A SINGLE TREATMENT
- This allows for a more standardized approach in which fibrous bands are released and the treated skin becomes smoother
- TIME, PAIN, AND BRUISING ARE LANDMARK ISSUES WITH THIS TREATMENT

 Retrospective evaluation of 25 patients treated revealed 95.6% of patients were satisfied with treatment results. Physician evaluations revealed, on average a 1-point improvement in their cellulite grade-- 3 months post treatment

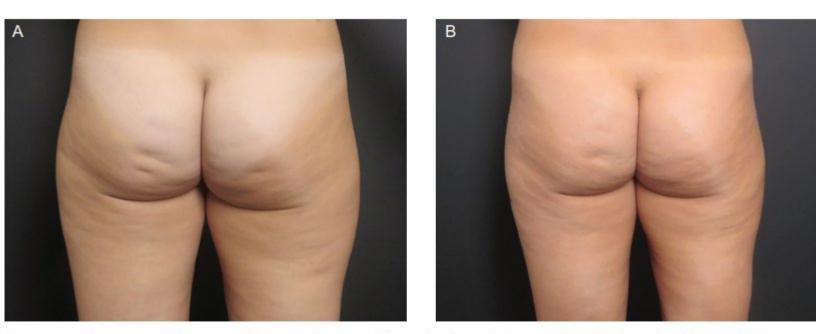


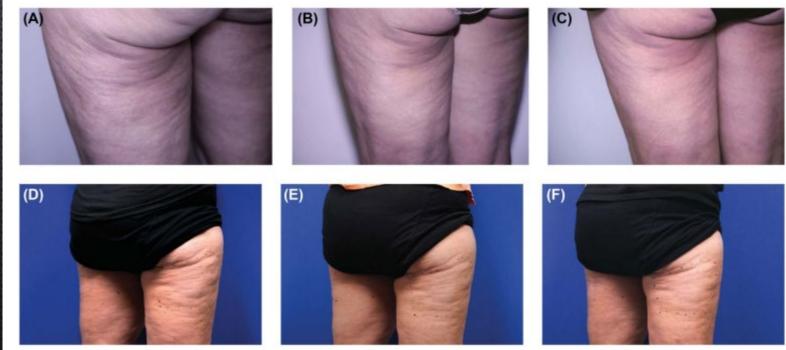
Figure 3. This 42-year-old woman with a Nürnberger-Müller rating for cellulite severity of (A) 3 at baseline and (B) 2 at 3 months post tissue stabilized-guided subcision treatment.

Nikolis A, Enright KM, Sapra S, Khanna J. A Multicenter, Retrospective Evaluation of Tissue Stabilized-Guided Subcision in the Management of Cellulite. Aesthetic Surgery Journal. 2019;39(8):884-892.

RADIOFREQUENCY MICRONEEDLING

• Temperature controlled bipolar RF energy delivery between the paired electrodes to create controlled, fractional treatment zones in reticular dermis and subcutis

- Multicenter Center Study treated patients (with grade II/III cellulitie) on b/l posterolateral upper thighs with a single treatment (treatment area defined by 15cmX 15cm)
- Overall success rate on both treated thighs as assessed by blinded physicians was 88% and 86% at 3- and 6-month follow-up



Microneedle Fractional Bipolar Radiofrequency
System for the Treatment of Cellulite. Dermatologic
surgery. 2018;44(10):1262-1271.

Figure 1. Typical results from 2 patients. Left (A, D): baseline; center (B, E): 3 months; and right (C, F): 6 months. Both
patients had a decrease of 1 and 2 dimples at 3- and 6-month follow-up, respectively, from a baseline of 4 and an
improvement of severity of undulation irregularities of 1 unit at 6-month follow-up from a baseline of 3.

Alexiades M, Munavalli G, Goldberg D, Berube D.

Prospective Multicenter Clinical Trial of a Temperature-Controlled Subcutaneous

POLY-L-LACTIC ACID

- BIOSTIMULATORY VOLUMIZER THAT INDUCES FOREIGN BODY REACTION UPON INJECTION TRIGGERING NEOCOLLAGENESIS
- Inflammatory reaction subsides by six months followed by production of dermal collagen for up to 2 yrs
- FDA APPROVED FOR FACIAL VOLUMIZATION, BUT HAS BEEN USED SUCCESSFULLY OFF THE FACE

FIGURE 1. Change in GAIS Scale at 1, 3, and 6-month post treatment as assessed by blinded investigator. Asterisk indicates *P*<0.05.

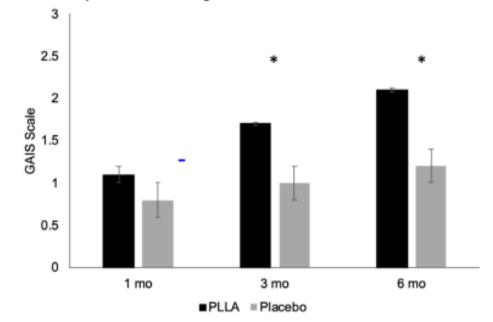
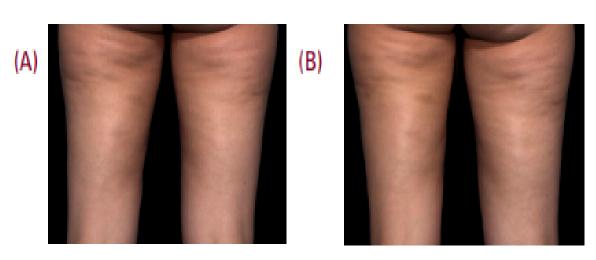


FIGURE 2. (A) Before and (B) after 3 treatments with Sculptra on left thigh and saline on right thigh in female patient (FST IV, 128.0 lbs, BMI: 20.0). No change in weight and BMI was recorded post treatment.



OVERALL PLLA OFFERS MILD IMPROVEMENT IN THE RIGHT PATIENT AND DILUTIONS MAY NEED TO BE
ADJUSTED TO ACHIEVE THE BEST OUTCOME BASED ON PATIENT'S SKIN TEXTURE, DEGREE OF LAXITY, AND
VOLUME

MUSCLE

MUSCLE STIMULATION

- THESE DEVICES HAVE BECOME HIGHLY SOUGHT AFTER DUE TO SOCIAL MEDIA
- VERY SUCCESSFUL IN CLINICAL PRACTICE WITH MINIMAL PROVIDER INVOLVEMENT.
- RESULTS DO DEPEND ON PATIENT SELECTION
- TOUCH UP TREATMENTS ARE NECESSARY TO MAINTAIN RESULTS.

- FIRST IN OFFICE DEVICE FOR MUSCLE BODY CONTOURING
- Relies on high focused electromagnetic stimulation (HIFEM) as opposed to electrical stimulation
- THE APPLICATOR HAS A CIRCULAR COIL. ELECTRICAL CURRENT PROPAGATES THROUGH THE
 COIL WHICH INDUCES RAPIDLY FLUCTUATING MAGNETIC WAVES. THESE WAVES PASS THROUGH
 TISSUE AND INDUCE AN ELECTRICAL CURRENT IN THE UNDERLYING MUSCULATURE INDUCING
 CONTRACTIONS

THE ABDOMEN

- 22 PATIENTS WITH AVERAGE BMIS THAT UNDERWENT FOUR TREATMENTS EVERY TWO WEEKS
- WEIGHT, WAIST MEASUREMENTS, AND PHOTOGRAPHS WERE ASSESSED AT BASELINE, AFTER THE LAST TREATMENT, AND THREE MONTHS POST-TREATMENT.

Average Changes in Abdominal Tissues in Treated Subjects

Measurement	Baseline	2-Month FU	Difference	<i>P</i> -value
Muscle thickness [mm]	11.1 ± 3.1	12.7 ± 3.3	1.6 ± 0.7	P < 0.001
Fat thickness [mm]	23.6 ± 8.2	19.3 ± 7.6	-4.3 ± 2.5	<i>P</i> < 0.001
Abdominal separation [mm]	16.6 ± 7.2	14.9 ± 6.7	-1.8 ± 1.5	<i>P</i> < 0.001
Waist circumference [cm]	95.3 ± 6.6	91.5 ± 7.4	-3.8 ± 2.1	<i>P</i> < 0.001
Weight [lb]	175.8 ± 24.8	175.2 ± 24.3	-0.5 ± 2.5	P>0.05

Jacob CI, Paskova K (2018) Safety and efficacy of a novel high-intensity focused electromagnetic technology device for noninvasive abdominal body shaping. Journal of cosmetic dermatology 17: 783-787.

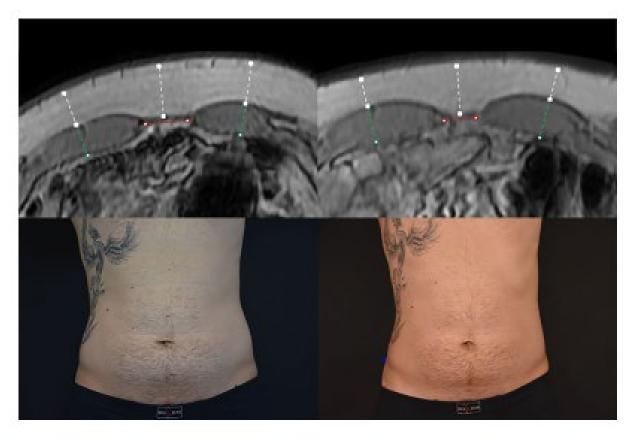


Fig. 5. Magnetic resonance and digital images of Subject ID2 before (left) and 2 months post-treatments (right). Male (30), BMI 24.8 kg/m² (before) and 24.5 kg/m² (2 months), weight −2.2 lb (−1.2 %), subcutaneous fat −30.3% (white markings), muscle thickness +13.7% (green markings), abdominal separation −24.9% (red markings), circumference −3 cm. Combination of the effects produced an overall visual improvement in patient's abdominal area.

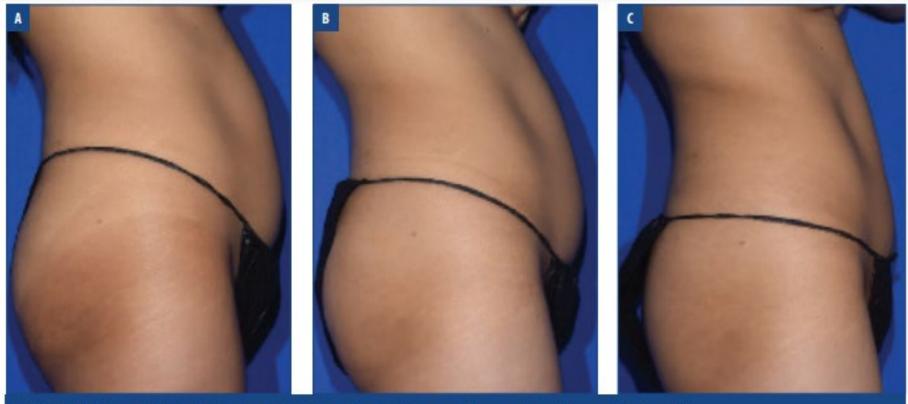


FIGURE 3. Digital images of subject ID 10 (female, age 37 years) taken at baseline (A), one-month follow-up (B), and three-month follow-up (C)

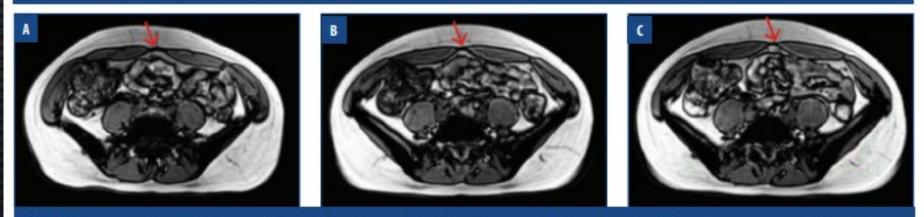


FIGURE 4. MRI images of subject ID 6 (below umbilicus), aged 38 years. Compared to baseline (A), the one-month (B) and three-month (C) images show correction in the abdominal separation, muscle thickening, and reduced fat thickness (red arrows).

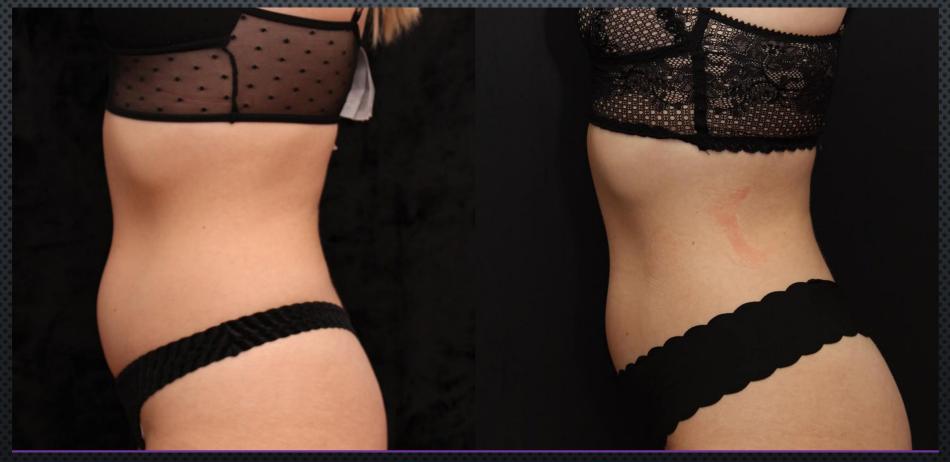
- FDA CLEARED DEVICE FOR IMPROVEMENT OF ABDOMINAL, BUTTOCK, AND THIGH TONE, STRENGTH, AND FIRMNESS
- DEVICE EMPLOYS BIO-ELECTRICAL MUSCLE STIMULATION THROUGH MULTIPLE ELECTRODES THAT STIMULATE SKELETAL MUSCLE TO CONTRACT THROUGH ELECTRICAL CURRENT AND NOT MAGNETIC OR ELECTROMAGNETIC ENERGY
- 16 ELECTRODES WHICH CAN TREAT UP TO EIGHT AREAS AT ONE GIVEN TIME



TruSculpt Flex







seline Affei

MUSCLE AND FAT



RF AND HIFEM BE APPLIED TOGETHER?

BEFORE AFTER





3 MONTHS AFTER THE LAST TREATMENT, COURTESY OF: BRUCE E. KATZ, M.D.

BEFORE AFTER





1 MONTH AFTER THE LAST TREATMENT, COURTESY OF: BRUCE E. KATZ, M.D.

BEFORE AFTER AFTER

3 MONTHS AFTER THE LAST TREATMENT, COURTESY OF: BRUCE E. KATZ, M.D.



1 MONTH AFTER THE LAST TREATMENT, COURTESY OF: DAVID KENT, M.D.

BEFORE AFTER AFTER





3 MONTHS AFTER THE LAST TREATMENT, COURTESY OF: RADINA DENKOVA, M.D.

BEFORE AFTER



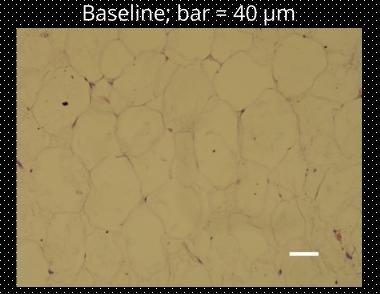


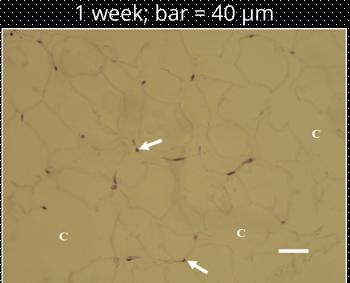
1 MONTH AFTER THE LAST TREATMENT, COURTESY OF: DAVID KENT, M.D.

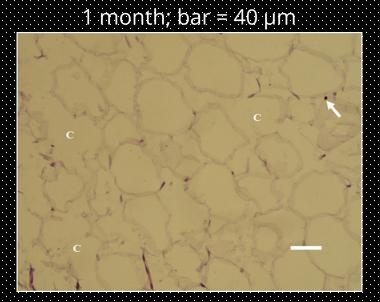
CURRENT EVIDENCE

Histology of fat tissue treated by HIFEM+RF has shown:

Disintegration of adipocyte membranes Apoptotic nuclear changes (pyknotic nuclei) with Caspase-3 stain Change in fat cell morphology - shrinkage







Samples at follow-up suggested elevated level of apoptosis manifested by pyknotic nuclei (arrows) and adipocyte elimination (C)

NON-INVASIVE BODY CONTOURING