Combination of Synchronized Radiofrequency and HIFEM Procedure for Effective Body Contouring

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DISCLOSURES

BTL - advisory board, PI research, consultant

Endo – advisory board, trainer

Galderma – PI research, consultant, trainer

Abbvie - speaker

Revance – trainer, stockholder

PCA – advisory board, consultant, speaker, PI research

Pulse Biosciences – PI research, consultant

Soliton - research
Background

- Subcutaneous fat and muscle tissue significantly contribute to abdominal body contour.
- For complete body contouring, it is important to address both tissues.
- Recently introduced device achieves that by combining RF+HIFEM = Benefit from RF’s additional effect on fat and HIFEM’s superiority for muscle toning.

**RADIOFREQUENCY**
- Heating of subcutaneous fat
- Effective fat cell elimination

**HIFEM**
- Selectively targets muscle tissue
- Induces muscle growth

RF+HIFEM = Benefit from RF’s additional effect on fat and HIFEM’s superiority for muscle toning.

Evaluate the efficacy of a novel device simultaneously delivering HIFEM and RF for subcutaneous fat reduction and muscle toning.
Research Design

• Documenting changes in fat and muscle tissue in a response to the HIFEM+RF treatment was searched and summarized.

• Quantitative and objectively assessed values obtained by medical imaging modalities were extracted.

• Secondary outcomes, including but not limited to, patient comfort and satisfaction were reviewed.
Identified Research

Abdomen


• 3 treatments (30-minutes, Qweek), 1 or 2 applicators based on the subject’s abdominal width. HIFEM set to maximum tolerable level (0-100%) and RF energy set to 100%.
Identified Research

Interim data on Outer Thighs and Inner Thighs


- 4 bilateral treatments (30-minutes, Qweek), 2 applicators, one over each thigh (one study lateral/one inner). Treatment intensities (0-100%) were set according to tolerance.
INITIAL ULTRASOUND STUDY- ABDOMEN

Effect of the BTL-899 Therapy for Non-invasive Lipolysis and Circumference Reduction of Abdomen.
Denkova R. 2018.

N = 42 patients (29 women, 13 men)
3 treatments (30 min each; 1 per week)

Fat reduction

Patient satisfaction

Fat reduction over time

https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192224.pdf
SECOND ULTRASOUND STUDY


RESULTS AT 3 MONTHS

- 28.3% Average fat reduction
- 24.2% Average increase in muscle
- 93.9% Patient satisfaction

Before: 2.73 cm
1 month after: 1.85 cm

Before: 0.75 cm
1 month after: 0.91 cm

Second ultrasound study.
Abdominal toning and reduction of subcutaneous fat with combination of HIFEM procedure and radiofrequency treatment. Carolyn Jacob MD, David Kent MD. N = 41 patients

**RESULTS AT 3 MONTHS POST-TREATMENT**

- **30.8%** Average fat reduction
- **26.1%** Average increase in muscle
- **18.8%** Average reduction in abdominal separation
- **5.9cm** Average circumferential reduction
## Abdominal Contouring - Subcutaneous Fat

HIFEM+RF treatments were found to significantly reduce the thickness of abdominal fat layer.

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Imaging</th>
<th>Subjects</th>
<th>Fat reduction (%)</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N</td>
<td>Age</td>
<td>BMI</td>
<td>Post treatment</td>
<td>1 month</td>
<td>3 months</td>
</tr>
<tr>
<td>Denkova R. (2018)</td>
<td>USN</td>
<td>42</td>
<td>24-59</td>
<td>20.9-36.9</td>
<td>17.0±2.7%</td>
<td>26.0±1.7%</td>
<td>29.8±3.4%</td>
</tr>
<tr>
<td>Samuels J. et al (2020)</td>
<td>USN</td>
<td>48</td>
<td>21-73</td>
<td>20.5-34.3</td>
<td>-</td>
<td>20.5±8.6%</td>
<td>28.3±5.4%</td>
</tr>
<tr>
<td>Jacob C. et al (2020)</td>
<td>MRI</td>
<td>41</td>
<td>22-62</td>
<td>21.2-34.3</td>
<td>-</td>
<td>24.4%</td>
<td>30.8%</td>
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</table>

• Improvement peaks 3 months after the last therapy
• Average **fat reduction** at 3 months was 29.6%
• Fat thickness reduction ranged from 7.6-8.3 mm at 3 months (Samuels et al, Jacob et al)
• No significant decline was seen at 6 months
Abdominal Contouring - Muscle Tissue

HIFEM+RF treatments were found to significantly enhance thickness of rectus abdominus while reducing the abdominal muscle separation

- Results peaked at 3 months with average increase of 25.2%
- Increase of muscle thickness at 3 months was consistent and measured 2.3 mm
- The results at 6 months were sustained
- Separation of abdominal muscles was reduced on average by 17.6% at 3 months, with maximum of 19.8% at 6 months (Jacob et al)

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Imaging</th>
<th>Subjects</th>
<th>Muscle increase (%)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Age</td>
<td>BMI</td>
</tr>
<tr>
<td>Samuels J. et al (2020)</td>
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</tr>
</tbody>
</table>
Abdominal Contouring - Other Data

HIFEM+RF body shaping effect coincided with considerable decrease in circumference

- Circumference reduction gradually improved up to -6.7 cm

**Overall Satisfaction with treatment results high:**
- 91% (Jacob et al); 94% of subjects reported *improved appearance of the abdomen*
- 94% (Samuels et al); 90% of subjects observed *improvement in both muscle and fat*
- 88% (Denkova R.) and the same amount of subjects *would recommend* the therapy

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Imaging</th>
<th>Subjects</th>
<th>Abdominal circumference decrease (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N</td>
<td>Age</td>
</tr>
<tr>
<td>Jacob C. et al (2020)</td>
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<td>22-62</td>
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</table>
Abdominal Contouring - Safety and Comfort

Therapy comfort measured by 10-point visual analogue scale (VAS; 0 - no pain, 10 - worst possible pain) was high:

- 1.0-1.2 points (Denkova R.)
- 2.9 points (Samuels et al)
- 2.3 points (Jacob et al)

-> no to minimal discomfort

No Serious Adverse Events were reported
Visualized changes in treated tissues

MRI slice above umbilicus, male 34 y/o, BMI 23.2 kg/m². Fat reduction 32.8%, muscle increase (yellow bar) 26.8%, separation of rectus reduction 14.1%
34 Year old male

BASELINE

3 MONTHS
Thigh Treatment
Methodology and Evaluation

Fat layer thickness
• Magnetic resonance images (MRI) in frontal plane

Hip & thigh circumference
• Widest part of the hip (red line)
• 0, 5 and 10 cm below the gluteal fold (green lines)

Satisfaction and comfort questionnaires
• 5-point Likert scale and 10-point VAS scale

Digital photographs and Adverse Events
HIFEM+RF for Treatment of Thighs - Interim Data

Lateral thighs (“Saddlebags“) MRI study

- 30 subjects (29-65 years, 19.0-34.5 kg/m²)
- Fat thickness decreased on avg by 1.40 ±0.34 cm at 1 month
- Hip circumference decreased by 3.0 cm
- 93% satisfaction
- Comfortable - VAS score of 2.45 points
HIFEM+RF for Treatment of Thighs - Interim Data

Inner thigh MRI study

• 16 subjects (24-69 years, 21.3-35.0 kg/m²)
• Fat thickness was significantly reduced by 0.84±0.15 cm (1 month) and 1.02±0.15 cm (3 months)
• Thigh circumference, measured at inner thigh bulge, decreased by 1.0 cm and 1.2 cm at 1 and 3 months, respectively
• 94% satisfaction
• Comfortable - VAS score of 1.45 points
Digital Photographs of Lateral/Inner thighs

Baseline vs. 1 month follow-up for lateral and inner thighs.
Conclusion

US and MRI documented the synergistic efficacy of HIFEM+RF for body contouring

- Avg 29.6% of abdominal fat reduction at 3 months
- 25.2% avg increase of abdominal muscle thickness at 3 months and 19.8% reduction in rectus muscle separation
- Abdominal circumference decreased (6+ cm)
- Interim thigh results show effectiveness in reducing fat layer and circumference
- High satisfaction and comfort levels

- Synchronized, simultaneous RF and HIFEM is effective for body contouring