Evaluation of the Efficacy of Non-Invasive Body Contouring Devices

PRELIMINARY RESULTS

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Non-Invasive Body Contouring Devices

Disclosures

• Dr Robert J Troell
  No direct disclosures

• Syneron
  placed *Velashape II* device in office for 6 week trial

• Zeltiq
  placed *Cryolipolysis* device for one day trial

• Sound Surgical Technologies
  placed *Touch View* diagnostic ultrasound device for cumulative trial time less than 4 weeks

• LPG
  No donation of equipment or training
Non-Invasive Body Contouring Devices

- Mechanical massage (Endermologie/LPG)
- Low-level Diode laser therapy (Zerona)
- Cryolipolysis (Cool sculpting/Zeltiq)
- Ultrasound diathermy (VaserShape/Sound Surgical Technologies)

- Monopolar Radiofrequency (Thermacool/Solta, Accent/Alma, Venus Freeze/Venus Concepts, Excilis)
- Bipolar radiofrequency, infrared light, massage (Velashape II/Syneron)
- Focused ultrasound (Liposonic, Ultrashape)
Non-Invasive Body Contouring
IRB Evaluated Devices

- Mechanical massage/ Endermologie (LPG)
- Cryolipolysis/ cool sculpting (Zeltiq)
- Bipolar radiofrequency, infrared light, massage, vacuum (Velashape II)
- Ultrasound diathermy, Massage (VaserShape)
Non-Invasive Body Contouring Devices

Manufacturer Advertised Treatment Outcomes:

- Tighten skin
- Decrease body circumference
- Decrease localized excess fatty tissue
- Cellulite improvement
- Stria improvement
- Increased lymphatic drainage
- Increased blood supply
- Improve muscle discomfort
- Improve muscle spasm
Non-Invasive Body Contouring Devices
Clinical Study

• IRB approved scientific study through “Liberty IRB”

• Three limbs to randomized clinical study:
  Vasershape v. Cryolipolysis
  Vasershape v. Velashape II
  Vasershape v. Endermologie

• Treatment anatomical area: flank/hip
  (side randomized for specific treatment)

• Crossover study: treat one side with half of manufacturers recommended treatment levels and then crossover to the opposite side with the other modality with the same protocol after healing time.
Non-Invasive Body Contouring Devices
Clinical Study Treatment Protocols:

• Treatment protocols per “manufacturers” recommendations
  a. duration of each treatment
  b. frequency (treatments/week)
  c. energy level/treatment session

• Treatment protocol healing time between treatments based on “manufacturers” recommendations before another treatment
  - Vasershape- 2 weeks
  - Velashape II- 2 weeks
  - Endermologie- 2 weeks
  - Cryolipolysis- 16 weeks (4 months)
Non-Invasive Body Contouring Devices
Clinical Study Treatment Protocols:

• **Vasershape** -
  1 Rx/wk, 6 total Rxs
  Modulated ultrasound - 15 minute duration
  Continuous ultrasound - 6 minutes duration
  Zonal massage - 2 minutes initially, 4 minutes at end of Rx

• **Cryolipolysis** -
  Duration of treatment - 60 minutes
  Vacuum cooling device measured to size of flank
  Cooling standardized
Non-Invasive Body Contouring Devices
Clinical Study Treatment Protocols:

- **Velashape II-**
  1 Rx/wk, 6 total treatments
  (initial Setting: (2-3-2), lowered if discomfort)
  Infrared light- level 2 out of 3
  Radiofrequency- level 3 out of 3
  Vaccum- level 2 out of 3

- **Endermologie-**
  2 Rx/wk, 12 total treatments
  start level 3, go higher to level 5 if tolerated
  35 mins total body, calculated for one hip to 5 mins
  Wear body suit during treatment session
Non-Invasive Body Contouring Devices
Clinical Study Material & Methods:

• **Patients**-
  18 total, 18 – 60 y/o, 3 men, 15 women
  All subjects healthy with no medical problems
  6 subjects in each limb: 1 male, 5 female

• **Treatment protocol**-
  Randomized to three limbs (1, 2 or 3)
  Side of body randomized for treatment (coin toss)
  Subjects completed half of recommended Rx on one hip
  Wait (healing) period after initial treatment completed
  Crossover to opposite hip from randomized other therapy
Non-Invasive Body Contouring Devices

Clinical Study Material & Methods:
Non-Invasive Body Contouring Devices
Clinical Study Material & Methods:

Vasershape Day of Treatment
Non-Invasive Body Contouring Devices

Clinical Study Material & Methods:

Touch View Diagnostic Ultrasound

before

after
Clinical Study Material & Methods:

- **Measurements**-
  1. Half body circumference (measuring tape in cm’s)
  2. Ultrasound (Touch View) depth (thickness in mm’s)
     a. skin
     b. skin through subdermal fat
     c. skin to Scarpa’s fascia
     d. Scarpa’s fascia disruption (1 – 5)
     e. Scarpa’s fascia to muscle fascia
     f. skin to muscle fascia
  3. Equilateral triangle marked on flank to evaluate skin tightening
     (ultraviolet tattoo in corners with 50 mm limb length from prefabricated firm paper triangle)
Non-Invasive Body Contouring Devices
Clinical Study Material & Methods:
Non-Invasive Body Contouring Devices
Clinical Study Material & Methods:

- **Photodocumentation** - AP, Lateral (L, R), PA views

- **Patient survey** - completed after each treatment session discomfort, temperature perception, physical observed changes, patient satisfaction

- **Operated observation survey** - completed after each treatment session physical observed changes
Non-Invasive Body Contouring

Results

• Skin Tightening Assessment
  (Mean mm triangle reduction in limbs length)

  Vasershape: 13.3 mm reduction
  Cryolipolysis: 0.33
  Velashape: 0
  Endermologie: 0
Non-Invasive Body Contouring

Results

• **Circumferential Reduction** (Mean cm length difference between before & after)

  - **Vasershape:** 2.8 cms
  - **Cryolipolysis:** 1.7 cms
  - **Velashape:** 1 cm
  - **Endermologie:** 0
Non-Invasive Body Contouring

Results

• Overall Patient Experience

(Visual Analog scale 0 – 10, Result & treatment experience)

Vasershape: 7

Cryolipolysis: 4

Velashape: 3

Endermologie: 2
## Non-Invasive Body Contouring

### Results

- **Pain Patient Experience**

  (Visual Analog scale 0 – 10)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>During Rx</th>
<th>One Hour After Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vasershape</td>
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<td>0</td>
</tr>
<tr>
<td>Cryolipolysis</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Velashape</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Endermologie</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Non-Invasive Body Contouring
Results

• Pain Patient Duration (days)

  Vasershape: 0

  Cryolipolysis: 1 - 2 days

  Velashape: 1 days

  Endermologie: 0
Non-Invasive Body Contouring

Results

- **Touch View Diagnostic Ultrasound**
  (tissue depth reduction, Pre-treatment skin to muscle depth 3.1 – 5.8 cm)

  - **Vasershape:** 1 - 2 cms
  - **Cryolipolysis:** < 1 cm
  - **Velashape:** 0
  - **Endermologie:** 0
Non-Invasive Body Contouring
Device Mechanism of Action

• **Vasershape:**
  Lymphatics opened by manual or zonal massage
  Ultrasound delivered (modulated) for “cavitation” fat cell separation, then
  Ultrasound delivery (continuous) for skin tightening, followed by
  Vacuum of separated fat cells to the lymphatic system.
Non-Invasive Body Contouring
Vasershape Ultrasound Diathermy Effect
Non-Invasive Body Contouring
Vasershape Zonal Massage Effect

Increased flow of lymphatic fluid
Non-Invasive Body Contouring
Device Mechanism of Action

• **Cryolipolysis:**
  Selective fat cell death by selective crystallization of lipids in fat cells at temperatures near freezing.

  Apoptotic fat cell death with inflammatory process resulting in fat layer reduction.
Non-Invasive Body Contouring
Cryolipolysis Mechanism of Action

• Cooling adipocytes sufficiently causes lysis
• Water of adipocytes crystallizes at a higher temperature than skin (preventing frost bite)
• Apoptosis - programmed cellular death
• Wound-healing process commences
• Dead adipocytes cleared by macrophages
• Uniform volumetric cooling of small fat amount
Non-Invasive Body Contouring
Cryolipolysis Mechanism of Action

- Lysis and apoptosis of adipocytes
- Gradual collapse of tissue matrix
- Fat layer thickness reduced
- However, Thickening of fibrous septae

Porcine tissue at 90 days
(Pig fat more sensitive to cold than human fat)
Non-Invasive Body Contouring
Device Mechanism of Action

• **Endermologie:** Has a profound physiological effect that can be easily measured, but its anatomic effects are more difficult to identify. It may exert its effects by altering the physiologic and metabolic activity of fat. Whether Endermologie® has a measurable anatomic effect of redistributing fat cells is yet to be proven.

• **Velashape:** Bipolar radiofrequency uses two small electrodes to deliver 1 MHz frequency energy. This low current density generates controlled tissue heating by “conductive coupling”, whereby, all current leaves the body in a small anatomical location. This is an unfocused, long wavelength with an inability to penetrate deeply (~2 mm maximum tissue depth). However, generates significant temperature in short time period, insensitive to skin color.
Non-Invasive Body Contouring
Velashape Mechanism of Action

• Causes tissue heating through absorption (resistive heating)
• Heating adipose tissue can cause adipocyte lysis
• Tissue impedance characteristics define absorption
  • Fat has poor electrical conductivity
  • Fibrous septae have higher conductivity
  • Most of the current flows through septae
  • Non-uniform heat distribution

Preferential RF heating of fibrous septae, Thermage 1.5 cm² tip, porcine model
Non-Invasive Body Contouring
Velashape Mechanism of Action

- 1 MHz “Conductive” RF generates high [current] at both electrodes
  - Advantage: High temperatures at superficial areas (ie. point of contact) can be reached
  - Time at optimal temperature limited, because cannot reach ~ 41°C without discomfort (Arrhenius Equation~ Time & Temperature)
  - Shallow penetration due to unfocused RF ~2 mm max tissue depth
- IR light (700-2000 nm) limited tissue depth penetration

Thermal camera image of porcine tissue
Absorption characteristics of human breast tissue
Non-Invasive Body Contouring

Endermologie Conclusions

• Effects of treatment: Minimal discomfort, some redness (< hour), rare bruising, minimal swelling (< 1 day), No Hypo-anesthesia

• Complications: none

• No circumferential reduction of flanks

• No skin tightening

• No decrease in depth of fat layer thickness

• No cellulite noted pre-treatment- no cellulite noted post Rx
Non-Invasive Body Contouring
Velashape Conclusions

• Effects of treatment:
  Mild to moderate discomfort at target temperature, some redness (hours), rare bruising, minimal swelling (day), No Hypo-anesthesia

• Complications: none

• Minimal circumferential reduction of flanks

• No skin tightening

• No decrease in depth of fat layer thickness

• No cellulite noted pre-treatment- no cellulite noted post Rx
Non-Invasive Body Contouring
Cryolipolysis Conclusions

• Effects of treatment: Painful, redness (hours), bruising (wks), swelling (days to wks), Hypo-anesthesia (wks to months) at treatment site

• Complications: rare (1/2000) subjects with severe prolonged pain, 2-4 weeks duration begins 3-7 days, Rx Neurontin

• Clinical Outcomes: Circumferential reduction abdomen & hips

• Limitations: Cannot treat thighs or arms, no cellulite treatment, Long treatment time (1 hr), No immediate results (effects seen after four months), Limited to tissue volume that can be clamped or suctioned into handpiece (no custom body shaping can be performed)
Non-Invasive Body Contouring
Vasershape Conclusions

• Treats bodies tissues more deeply than other alternatives
• Greater reduction in depth of the deep fat layer
• More significant Scarpa’s fascia dissemination
• Affects a larger volume of fatty tissue
• Skin tightening observed
• Has immediate results, no resurgence of fat once removed
• Circumferential reduction may be observed with one treatment
• All body areas, except the face and neck, can be treated
• May “custom” shape the body areas from treated to nontreated
• Most patient satisfaction and comfort of all devices studied
• No complications noted