Energy Based Devices for Body Contouring

Sharon McQuillan, MD

Body Shaping Market

• Overall body shaping market will expand by 11.7% per year to reach $494.7 million.
• In 2008, more than 8 million body shaping procedures were performed for fees in excess of $2.8 billion.
• It is predicted that this number will expand to more than 14 million treatments in 2013 at fees of over $60 billion.

Skin Tightening Market

• In 2008, sales of skin tightening devices are estimated at $56.9 million.
• Through 2013, sales are expected to increase 10.3% per year to $93 million.
• Procedure volume is predicted to rise from 668,100 treatments in 2008 to almost 2 million treatments in 2013.
• Fees predicted to rise from $968.7 million to almost $2.4 billion.
Projected Market Growth

• Greatest impact on body contouring market will be development of laser and light technology systems
  – Increase in procedure volume 52.2% annually to more than 7.4 million by 2010
  – Increase in procedure revenue 43.7% per year from $181.3 million to $1.1 billion by 2010

Non-Invasive Body Contouring Treatments

• Lymphatic Drainage
• Dermoelectroporation
• No Needle Mesotherapy
• Radiofrequency-Infrared device
• Infrared
• Diode-Rhythmic Massage device
• Broad Band Light
• Ultrasound
• Cryolipolysis

Lymphatic Drainage

• Lymph fluids contain nutritive substances such as minerals and vitamins supporting cellular nourishment, as well as the waste products of cellular metabolism and various pollutants
• The lymph nodes eliminate the waste and toxins
• Used to re-shape and contour the appearance of the arms and legs that age prematurely when engorgement of the lymph causes fluid and waste retention
• With regular lymphatic drainage massage, the lymph capillary system gets expanded and attracts intercellular fluid better and faster, to quickly bring the lymph fluids to the lymph nodes for cleansing.
**Lymphatic Massage Drainage/Suction**

- Acts on skin, subcutaneous tissue, connective tissue, fatty tissue and the arteriolar, venous, and lymphatic microcirculation
- Stimulation of the metabolism, vascularization with lymphatic drainage and purification

**Mechanism of Action**

- Mobilization of tissues, activating arteriolar microcirculation
- Connective tissue traction to exercise skin
- Activation of reflected arcs and fibrous banding stimulation
- Neurometabolic regulation with metabolic activation
- Rhythmic compression of tissues with lymph drainage

**Mechanism of Action**

- Mechanical stimulation acts on the following mechanoreceptors
  - Corpuscles of Meissner
  - Corpuscles of Water-Pacini
  - Corpuscles of Golgi
  - Corpuscles of Merkel
  - Golgi Complex
Treatment Phases

• Vascularization phase (reactivate cutaneous microcirculation)
• Drainage phase (drain lymphatic stagnation)
• Stimulation phase (stimulate fibroblasts and interstitial neurophysiologic systems)
• Invigorating phase (stimulate skin)
• Exercise phase (produce tissue and muscle tone)
• Visceral phase (stimulate abdominal visceral activity)

Indications

• Phlebolymphology
• Post liposculpture
• Cellulite
• Localized adiposity

Lymphatic Drainage Massage Devices

• Synergie (Dynatronics)
• Endermologie (LPG Systems)
Dermoelectroporation

• Treatment method enabling absorption of ionic drug solutions using equipment that generates electric pulses allowing the opening of cellular gates and promoting passage of substances through the epidermis
• Procedure normally preceded by microdermabrasion
• Indicated for treatment of fibrous cellulite
No-Needle Mesotherapy

- Laser is used as a pre-treatment to provide biostimulative effects to treated tissue:
  - Increase in blood flow
  - Microcirculation
  - Increase in metabolic rate
  - Increase in cell permeability
- Threshold electroporation proceeds in a domino-effect manner with dilation of microconduits in one region giving rise to the same effect in another

No-Needle Mesotherapy Laser

Laser Specifications
- Diode Cluster Array
- 685nm & 830nm wavelengths
- 4x50mW 685nm laser diodes
- 4x200mW 830 laser diodes
- Fluence 3-5 joules/cm²

First Phase

685nm Laser (limited to epidermis & SCT)
- Absorbed by cells
  - Light energy transformed to cellular energy in mitochondria which are stimulated and consume fat faster
  - Cell membrane permeability increased
  - Activates macrophages
  - Increases fibroblast proliferation
First Phase

830nm Laser
Non thermal laser cluster
• Stimulates blood vessels in dermis and SCT and increases blood flow
• Enhances cell permeability
• Contributes to elimination of waste products – fat, sugars and proteins

Second Phase

Active Transport
• Utilizes appendages and exploits micro-conduits
• Interacts with Aquaporin water channels on cell membrane (opens gate)
• Enhances metabolism & microcirculation

Third Phase

Muscle Tone Phase
• Stimulates/tones muscle fibers
• Accelerates microcirculation
• Increases metabolic rate
• Increases blood flow
Fourth Phase
Lymphatic Circulation Phase
- Increases lymphatic drainage
- Increases metabolic rate
- Increases blood flow
- Reduces edema
- Enhances discharge of waste products

No-Needle Mesotherapy
- Treatment times with the technique vary according to the size and location of skin area treated, and are typically in the 20-25 minute range.
- Treatment time is standardized to achieve results in 8-10 sessions, but benefits typically seen in 4-5 sessions
Treatment Results

Before

After Seven Treatments

Radiofrequency-Infrared Devices

• Re-contouring of skin surface by the increase of controlled metabolism in adipose tissue
• Increase the rate of metabolic reaction and substance diffusion

Mechanism of Increasing Blood Supply

• 90% of blood vessels are closed at normal atmospheric pressure.
• Decreasing the atmospheric pressure increases vessel dilation and blood flow.

Hyperthermia Effect on Metabolism

- Increases substance exchange between fat cells and blood vessels
- Increases rate of fat metabolic reaction in mitochondrion

Treatment Philosophy

- Temporary improved surface contour
- Not “removing” fat
- Redistributing the water and glycerides by activating the metabolism of adipose tissue

Treatment Schedule

- Number of treatments – 8-12
- Treatment frequency - twice a week
- Supporting treatment - Once a quarter
- Treatment duration 30-45min (depending on size of area)
Available RF/IR Devices

• VelaShape/VelaSmooth-Syneron
  – Bi-polar and infrared device with negative pressure and tissue manipulation
  – FDA approved for cellulite reduction and reduction of thigh circumference
• Accent XL- Alma
  – Bi-polar and unipolar radiofrequency
  – FDA approved for skin laxity

Available RF/IR Devices

• Aluma- Lumenis
  – Bi-polar radiofrequency with vacuum suction
  – FDA approved for wrinkles and skin laxity
• Body by Thermage
  – Monopolar radiofrequency
  – FDA approved for wrinkles and cellulite in body areas

Clinical Studies:
Radiofrequency Devices

• 12 subjects underwent ThermaCool TC treatments
• Waist circumference, standardized photographs, skin laxity scores, global aesthetic improvement score, and patient satisfaction surveys assessed at baseline and several follow-up visits post treatment
• Average waist circumference an skin laxity scores decreased at visits 1, 2, 4, and 6 month post treatment
• Global aesthetic improvement score and patient satisfaction surveys reflected clinical improvements

Clinical Studies: Radiofrequency Devices

- 19 subjects skin types I-V underwent 5 weekly treatments to the upper arms using VelaShape
- Circumference measurements, photographs, and weight were recorded prior to treatment and at 1 and 3 month follow-up
- Change in arm circumference at 5th treatment with mean loss of inches of 0.625
  - At one month post treatment: mean loss=0.71 inches
  - At three months post treatment: mean loss=0.597 inches

Cellulite Reduction

Photos courtesy of Gerald Boey, MD, Canada
Post 4 treatments

Circumferential Reduction

Photos courtesy of Gerald Boey, MD, Canada
Post 5 treatments

After 8 elōs
Velasmooth Treatments

Courtesy of Dr. Mauricio

Powered by
1. Lasers for stimulation of microcirculation and neovascularization (Physical Mechanism)
2. Localized cooling for reduction of edema (Thermal Mechanism)
3. Rhythmic massage for lymphatic drainage (Mechanical Mechanism)

Incorporates three technologies:

- Series of 15 bi-weekly treatments
  - Sessions last approximately 30-45 minutes
- Monthly maintenance treatments
Sarah Boyce, MD Et Al.

• Clinical Evaluation of A Device for the Treatment of Cellulite: “Tri-Active”
  - Presented at American Academy of Cosmetic Surgery Annual Meeting 2004

  • 16 female subjects
  • 12 bi-weekly treatments
  • Photos and circumference measurements
  • Follow-up to 1 month

Results
  • Average of 21% improvement
  • No change BMI through study

Conclusion
  • Modest and temporary improvement using a pleasant device for treatment of cellulite

Tri-Active Before and After

After 19 Tri-Active Treatments:

Courtesy of A. Pelosi – Physiotherapist

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Diode with Mechanical Massage & Vacuum

- SmoothShapes by Elemé Medical
- Combines 650 nm and 915 nm laser and light energy with mechanical massage and vacuum
- Impacts appearance of cellulite-engorged cells and sclerotic cellular septae

Diode with Mechanical Massage & Vacuum

- 915 wavelength targets fat
- 650 wavelength increases cell membrane permeability so liquified fat can be transported out of cell
- Normal treatment session: twice weekly for 4 weeks
- FDA approved

What Is Photomology®?

An exclusive technology that treats cellulite and subcutaneous fat by combining dynamic laser and light energy with mechanical methods

- 915nm Laser to Liquefy Fat
- 650nm Light
- Contoured Rollers to move liquids from the interstitial fluid into the lymphatic system
- Vacuum enables consistent light penetration to tissue
Clinically Proven

- 915 nm wavelength: preferential absorption in lipids


Clinically Proven

Neira, et al. have demonstrated that 650 nm wavelength “facilitates the releasing of the fat panicles, allowing the fat to go from inside to outside the cell and placing it in the interstitial space.”


Ultrasound Validation of Pt.
Grade 2 cellulite

Before

After TX 8

• 20% decrease in superficial fat layer:
  5.52 ± 0.23 (Before) vs. 4.41 ± 0.17 (After)

• Relaxation of the fibrous septae resulting in improved smooth appearance of the dermis/hypodermal junction (circled)

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Clinical Studies

- 20 women with mild to moderate cellulite of lateral thighs
- Assessment tools: weight, BMI, % body fat, digital photography, VECTRA three-dimensional imaging, patient questionnaire
- Patients received 2 treatments/week for 4 weeks at 15 minutes per treatment
- Patients evaluated at 1, 3, and 6 months post treatment
- VECTRA analysis showed 82% improvement at one month
  - 76% improvement at 3 months
  - 73% improvement at 6 months


SmoothShapes Before & After

Photos Courtesy of Kenneth Beer, MD, FA

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Multiple Diode Laser System

- 635 nm diode multiple emitters on flexible arms that can be positioned around treatment area
- Mechanism of action: believed that light stimulates fat cells to create transitory pore in cell membrane, causing fat to be expressed into interstitial space and removed using normal metabolic pathways
- Treatment plan: 6 20 minute treatments scheduled every other two week time period
- FDA approval August 2010 for circumferential reduction of waist, hips, thighs

ZERONA BODY SLIMMING

PHASE 1 MEDICAL DEVICE CLINICAL TRIAL

Mean change in total combined circumference from the waist, hips, and thighs.

<table>
<thead>
<tr>
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<th>Test Group (n=35)</th>
<th>Placebo Group (n=32)</th>
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<tbody>
<tr>
<td>Mean reduction in total circumference (in.)</td>
<td>-3.521</td>
<td>-0.684</td>
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This outcome exceeded the pre-established target of 20% difference between treatment groups by 22%.

The odds are 1 in 100,000 that these results were due to random chance. (statistically significant, p = 0.0001)
REAL SCIENCE BEHIND ZERONA BODY SLIMMING

0 Minute
Filled Adipose Cell
Emulsified Fatty Debris Outside Cell
Empty & Collapsed Adipose Cell

1 Minute
12 Minutes
18 Minutes

ZERONA BODY SLIMMING

Transitory Pore Forming
Emulsified Fatty Debris leaking out of Cell
Empty & Collapsed Adipose Cell

ZERONA BODY SLIMMING

When 1,000's of Adipose cells are emptied of their fatty debris the slimming effect occurs.

Panel of Collapsed and emptied Adipose Cells
How Does the Fatty Debris Leave the Body?

1. The fat leaves the cell and enters into the interstitial space.
2. The fatty material is absorbed by the lymphatic system
   - Transported via efferent lymph vessels to lymph nodes
   - Triglycerides are broken down via lipases
     - Lysosomal Acid Lipase
3. Transported to the circulatory system where the debris can be processed by the liver (fatty acid oxidation).

Overall, the body has a natural system in place to transport and degrade triglycerides without inducing an adverse outcome.

Several studies were completed on Lipid panels to determine that triglyceride and cholesterol levels did not increase.

BODY SLIMMING PROTOCOL – Enhancing Results

PROVEN EFFECTIVE as a standalone device. However, by making simple lifestyle changes patients can enhance their results.

<table>
<thead>
<tr>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
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<tbody>
<tr>
<td>Curve+</td>
<td>Lymphatic Stimulation</td>
<td>Hydration</td>
<td>Low-Fat Diet &amp; no Alcohol</td>
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<td>★</td>
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Zerona By Erchonia Medical

Before & After
Non-Ablative Lasers

- Stimulate growth of new dermal collagen by subclinical injury that activates fibroblasts
- Uses near infrared wavelength which does not “see” melanin, unlikely to burn skin
- No downtime, “lunch hour” anti-wrinkle laser
- Topical only or no anesthesia required

Non-Ablative Lasers

Tightens Skin by two methods:
- Collagen Stimulation
- Collagen shrinkage

Collagen Remodeling

- Thermally insult a region in the skin
- Initiate an inflammatory response
- Stimulate fibroblast activity
- Exercise the skin’s wound healing ability to remodel or replace collagen
- Bulk heating causes collagen shrinkage
Targets Water in Tissue

- 800nm - 1800nm Broad Band Spectrum
  - Selected and tailored for ideal water absorption
  - Allows uniform, even heating of the dermis

Comparison of IR to RF Device

- Significant heating in the dermis
- Cooling of the epidermis

Types of Infrared Non-Ablative Devices

- Cutera Titan
- Palomar Lux Deep IR Fractional
- Sciton SkinTyte
Post-partum laxity

- 39 year old patient
- 3 children
- 1 treatment 37J/4 passes

Before

6 Months after

Dr. Lopez ST Photos

Immediately Post Tx

Ultrasound Combinations
Ultrasound/Elastomassage/LED

• Applications
  – Cellulite
  – Localized adiposity
  – Pre/post liposuction
• Handpiece produces undulatory motion improving lymphatic and venous circulation allowing for subcutaneous fat reduction

Ultrasound/Elastomassage/LED

• Ultrasound handpiece delivers thermal and cavitational effect to adipose cells
• Results in toned, smoother, appearance with reduced circumference of treated areas
• MedSculpt by General Project
• FDA approved

Med Sculpt Before & After
Focused Ultrasound Devices

- Focused ultrasound beam is directed toward a specific area within the fat layer
- Ultrasound wave causes fat cell lysis by breaking the adipose membranes without damaging neighboring structures like skin, blood vessels, and peripheral nerves
- Awaiting FDA approval
Focused Ultrasound

<table>
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<tr>
<th>Focused</th>
<th>Non-Focused</th>
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<tbody>
<tr>
<td>Ultrasonic energy is delivered only to the target tissue while surrounding tissues remain unharmed.</td>
<td>All tissues from the skin and down to an undetermined distance are exposed to ultrasonic energy.</td>
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“Natural” Mechanism for Fat Clearance

- Gradual clearance of TG over first two-three weeks when most circumferential reduction occurs
- Clearance of the cell debris through the “wound healing” process over first 3-4 weeks (like a bruise)

Clinical Studies

- Average waist circumference reduction of 2 cm using single treatment on 164 patients

- 3.95 cm average waist circumference reduction in 10 patients
UltraShape™ Single-Treatment Results
Abdomen

Pre-Treatment
4 weeks Post-Treatment
Reduction → 2.7 cm
Photos courtesy of ProBeauty Clinic, Macher, Belgium

UltraShape™ Three Treatment Results
Lower Abdomen

Pre-Treatment
1 month Post-Treatment
Reduction → 6.7 cm
Photos courtesy of Dr. Chris Ingellfield, London, UK

Focused Ultrasound: Ulthera

- Two specialized ultrasound modalities
  - Imaging
  - Emitting/focusing acoustic energy to create a thermal effect
- Treats the collagen and elastin fibers of the superficial musculoaponeurotic system (SMAS)
Focused Ultrasound: Ulthera

• Allows unprecedented control over placement of thermal energy at precise depth
• Treatment energy emitted from concave transducer and focused at precise depth
• Passes through dermal barrier without disrupting it

Focused Ultrasound: Ulthera

• Treatment energy applied in linear rows into tissue at treatment site
• Causes thermal damage to lift and tighten fibromuscular layer
• Approval in Canada for tightening lax skin; trials are underway in US

Ulthera: Before & After
Focused Ultrasound: Liposonix

- High-Intensity Focused Ultrasound (HIFU)
- Pending FDA approval
- Disruption of adipocytes percutaneously
- Two-part mechanism of action
  - Mechanical effects that immediately disrupt cell membranes
  - Heat destroys additional fat cells

HIFU

- Result: coagulative necrosis and cell death within targeted treatment area
- Dead cells induce wound healing response and attract macrophages which engulf and transport lipids and cellular debris from treatment area
- Most adipocytes resorbed within 12 weeks of treatment; 95% resorbed after 18 weeks

Clinical Studies

- 282 patients underwent single HIFU treatment (45 minutes) of anterior abdomen and flanks
- Waist circumference decreased by average of 4.7 cm after one treatment with 2 different focal depths after 3 months

Acoustic Wave Therapy

- Utilization of high energy acoustic waves that are introduced to patient’s body in the form of high-frequency oscillation
- Acoustic waves are generated via planar and radial type applicators
- Currently marketing as D-Actor or Cellactor by Storz Medical
- FDA approved for the relief of minor muscle aches and pains and for temporary increase in blood circulation

Mechanism of Action

- Enlarged fat cells bulge upwards towards skin’s surface, giving skin “orange peel” appearance
- Inelastic vertical connective tissue fibers do not stretch with adipose tissue
- Local blood circulation reduced
Mechanism of Action

• Oscillating acoustic waves are introduced into the body
• Connective tissue relaxes
• Epidermal firmness increases
• Blood circulation enhanced
• Collagen production stimulated

Mechanism of Action

• Improved firmness, restored elasticity of skin and connective tissue
• Improvement in skin texture

Clinical Study

• In vivo measurements of 26 female patients with lipedema and cellulite taken before and after either complex physical decongestive therapy (manual lymphatic drainage and compression) or shock wave therapy
• Oxidative stress factors of blood serum and biomechanic skin properties were evaluated
Clinical Study

- Oxidative stress demonstrated by increased serum concentrations of malondialdehyde (MDA) and plasma protein carbonyls
- Both therapies caused MDA release
- Shock wave therapy patients experience significant smoothing of dermis and hypodermis surfaces


Before & After

Cyrolipolysis™

- Non-invasive cooling of adipose tissue to induce lipolysis
- Discovered by R. Rox Anderson and Dieter Manstein
- Demonstrated that subcutaneous fat cells are more vulnerable to effects of cold than surrounding tissue
**Cryolipolysis™ Mechanism of Action**

- Cooling applied through skin to fat layer
- Cooling maintained to damage fate cells
- Fat cells begin natural removal process lasting for several months
- Removal of cells over time results in gradual fat layer reduction

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**Cryolipolysis™ Study**

- Exposure to cooling via energy extraction results in apoptosis of fat cells
- Leads to release of cytokines and other inflammatory mediators that eliminate cells
- Inflammatory cells digest affected fat cells, reducing fat layer thickness
- Lipids released from fat are transported and released via normal metabolic pathways

Cryolipolysis Study Conclusions

- “Prolonged, controlled local tissue cooling can induce selective fat cell reduction and subsequent loss of subcutaneous fat, without damaging the overlying skin”
- Process referred to as selective cryolipolysis
- Technology behind Zeltiq system

Zeltiq Cryolipolysis

- Currently FDA cleared for various applications related to skin cooling during dermatologic treatment
- FDA approved for non-invasive fat layer reduction September 2010

4 months after one procedure
4 months after one procedure