NONINVASIVE BODY CONTOURING

Just as liposuction is the number one cosmetic plastic surgery procedure performed worldwide, noninvasive body-contouring technology is the fastest growing segment of the aesthetic capital equipment space. The annual growth in noninvasive body-contouring procedures is estimated to expand by 21% per year.

The noninvasive body contouring technologies can be classified on the basis of the type of energy delivered by a particular technology in modifying the adipocyte.

Classification: (In order of Evolving Technology / from primitive to advanced)

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Device</th>
<th>Brands</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Suction:Massage Devices</td>
<td>Endermologie</td>
</tr>
<tr>
<td>2</td>
<td>Suction-Massage: Thermal Device</td>
<td>Triactive, Smoothshapes.</td>
</tr>
<tr>
<td>3</td>
<td>Radiofrequency Energy Devices</td>
<td>VelaSmooth, VelaShape,Thermage™,Accent,TiteFX.</td>
</tr>
<tr>
<td>4</td>
<td>High-Frequency Focused Ultrasound Energy Devices</td>
<td>Ultrashape, Liposonix</td>
</tr>
<tr>
<td>5</td>
<td>Cryolipolysis Energy Devices</td>
<td>Zeltiq</td>
</tr>
<tr>
<td>6</td>
<td>Low-Level Light Laser Therapy Devices</td>
<td>Zerona</td>
</tr>
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</table>

Basic Science:

The basic science of non invasive body contouring is really the basic science of the adipocytes, its storage of triglycerides, and the aggregate number of adipocytes as they relate to the focal and generalized excess of adipose tissue, the convex distension that forms the focal “bulges”, and more superficially, clinical cellulite topographically.

The adipocyte is a very important cell involved in energy storage, hormonal regulation, and a host of other endocrinologic functions. The adipocyte has a large amount of cytoplasm that serves as a storage depot for triglycerides, which are composed of glycerol and free fatty acids. The adipose cells are our intermediate and long term energy storage depot. When caloric intake exceeds caloric output, adipocytes then swell with Triglycerides. As adipocytes continue to enlarge within their intralobular and interlobular fascial compartments, they create “bulges” or convex distensions of soft tissue that then modify our contours.

Typical convex distensions that one sees in the female topography are “out-pouching”, “bulges”, or convex distensions of the hips, lower abdomen, outer thighs, inner knees, arms, bra line.

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For men, the typical android distribution of subcutaneous adipose–derived convex distensions commonly include the flanks (love handles), lower abdomen, “spare tire”, male fatty breast tissue and the submentum.

The basic science of the noninvasive modulation and modification of the adipocyte involves one of the several mechanisms. In one mechanism, the adipocyte experiences a periadipocyte thermal environment induced by transepidermal delivery of some energy and this heat increases the localized metabolic rate of the fat, evacuating, enhancing, and augmenting the natural egress of triglycerides out of the fat cell, resulting in diminishment of the convex distension.

Some technologies deploy energy, either a pulse of high voltage RF current, or a focused high–frequency ultra-sound energy experience that disables or destroys the adipocyte by permanently damaging the cell membrane, or coagulating or disrupting and releasing the adipocyte cell contents.

The other technology, such as low-level light laser therapy (Zerona), create temporary disruptions in the cell membrane of the adipocyte allowing egress of the triglyceride from the cytoplasm, and then the cell membrane rights itself. This is adipocyte deflation and not the destruction and hence preserves the physiological and endocrinologic roles of the adipocytes.

Through all these mechanisms the final result is that the sizes of adipocytes are reduced and/or the number of adipocytes are reduced, which when translated over hundreds of thousands or millions of fat cells, will result in a measurable reduction of fat and a circumferential reduction of the body contour area in the treated area.

The contraindications of all the noninvasive body-contouring procedures include pregnancy, pacemaker, medically unwell, and high unrealistic expectations.

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Comparative narration of all the classes of noninvasive body-contouring procedures:

A) **Suction/Massage Devices (Endermologie):**
   1. Mechanical suction and roller applicator.
   2. Touch/contact with the patient.
   3. Limited indications.
   4. More than 16 treatments are required, which lasts longer than 30 minutes.
   5. Popular in day spa environment.
   6. Very mild clinical effects.

B) **Suction-Massage: Thermal Devices (Triactive, Smoothshapes):**
   1. Suction roller in combination with transepidermal thermal energy.
   3. Touch/Contact with the patient.
   4. Limited indications.
   5. Mild to modest clinical results.

C) **Radiofrequency Energy Devices (VelaSmooth, VelaShape, Thermage™, Accent, TiteFX):**
   1. US-FDA approved.
   2. Controlled 700-nm to 2000-nm Infrared (IR) light and suction couple-conducted bipolar RF energies with mechanical manipulation.
   3. Adipocyte destruction.
   4. Touch/Contact with the patient.
   5. Controlled Thermal Stress promoting neocollagenesis.
   6. Transient erythema is a side effect.
   7. A self controlled 20 women study (3 biweekly treatment) for thigh and buttock cellulite shows that 18 patients noticed overall clinical improvement.
   8. One long follow-up study conducted in an Asian population found average circumference reductions of the abdomen and thigh at 3.17 cm ± 2.75 cm and 3.50 cm ± 2.04 cm, respectively.

D) **High-Frequency Focused Ultrasound Energy Devices (Ultrashape, Liposonix):**
   1. Awaiting FDA clearance.
   3. Composed of the system console, the therapeutic ultrasound transducer, and a real–time video – tracking and guidance system.

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4. Touch/contact with the patient.
5. A prospective study conducted on 30 patients (underwent 3 treatments at 1-month interval) found a mean reduction in circumference at 3.95 ± 1.99 cm.
6. Importantly, there are many non-invasive, nonfocused ultrasound devices in the market such as Proslimet, Medcontour, Novashape etc., or the so-called “Ultracavitors”. That claim to have an effect on the fat cell, but there is no known published scientific, preclinical or clinical data to support such claims. The non focused ultrasound simply heats the underlying skin and tissue just as any standard physiotherapy ultrasound device. These devices do not meet the requirements to produce focused ultrasound; therefore, they can not increase maximal pressure deep without causing skin damage.

E) Cryolipolysis Energy Devices (Zeltiq):
   1. FDA Cleared for long reduction of subcutaneous fat (love handles)
   2. Cold-induced apoptotic adipocyte cell death.
   3. Touch/contact with the patient.
   4. A study conducted on 32 patients (underwent cryolipolysis with one side serving as the treatment side and the other as the control). At 4 months, 22 % fat reduction in the treated area was demonstrated in 10 patients undergoing ultrasound evaluation.
   5. Transient pain and dysesthesia.

F) Low-Level Laser Therapy Devices (Zerona):
   1. FDA aapproved for long reduction of subcutaneous fat in multiple areas and circumferential reduction.
   2. Adipocyte deflation (not destruction).
   3. The physiological and endocrinologic functions of adipocytes preserved.
   4. No touch, No pain.
   5. Low level laser device emitting a wavelength at 635 nm (Class III B laser).
   6. The histologic and basic science research behind LLLT is very solid, perhaps more so than most technologies in the noninvasive body-contouring market.
   7. In a study reported in the year 2002, the effect of low-level laser energy on adipose tissue demonstrated that 6-min exposure of 635-nm 10-Mw Laser diode energy created a 99% release of fat from adipose tissue taken from abdominoplasty samples. These samples were evaluated by transmission electron microscopy after irradiation, which revealed a transitory pore in the cell membrane opening, which thereby permitted the fat content to leak out of the cell into the interstitium.

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8. The laser does not destroy or lyse the adipocyte completely, which is a differentiation from the proposed mechanism for ultrasound-induced changes.

9. In a 35-patients double-blind, placebo-controlled trial, demonstrated a significant reduction in treatment area circumference after 2 weeks, at 3 sessions per week. Patients underwent treatment of their hips, thighs and waist. After completing all sessions, there was an overall reduction of 8.775 cm in all 3 sites collectively. Participants had 2.45 cm reduction at the waist, 2.625 cm reduction at hip and 2.125 cm reduction in the thighs.

10. One more study demonstrated a 5.375 cm reduction in waist circumference over a 4 weeks treatment course in 44 patients.

11. Another 67 subjects study demonstrated a loss of 7.5 cm.

12. A review of 110 consecutive, well selected patients shows that the minimum “guarantee” of 7.5 cm to 22.5 cm over 10 pinch locations occurred in 80% of patients.

13. Zerona truly occupies a unique position in the noninvasive body-contouring space, as it is the only generalized laser-slimming technology.

14. Further, the departure from adipocyte ablation positions, the Zerona is in unique and beneficial category as it exemplifies a truly noninvasive approach including slimming without cell death or upregulation of inflammation.

15. It is possible to combine Zerona with other focal, ablative, fat-reduction technologies.

16. A significant reduction in blood Cholesterol level was observed in a 19 subjects study (underwent Zerona treatment).

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OTHER COMPARISONS:

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<th>I-Lipo</th>
<th>VASER</th>
<th>ZERONA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology</td>
<td>Ultrasound</td>
<td>Low level LASER</td>
<td>LASER assisted.</td>
<td>Low Intensity LASER</td>
</tr>
<tr>
<td>Invasiveness</td>
<td>Non Invasive</td>
<td>Non Invasive</td>
<td>Minimally Invasive</td>
<td>Non Invasive</td>
</tr>
<tr>
<td>Wave Length Used</td>
<td>640-650 nm</td>
<td></td>
<td></td>
<td>635 nm</td>
</tr>
<tr>
<td>Downtime</td>
<td>Zero</td>
<td>Zero</td>
<td>++</td>
<td>Zero</td>
</tr>
<tr>
<td>Pain</td>
<td>Zero</td>
<td>Zero</td>
<td>++</td>
<td>Zero</td>
</tr>
<tr>
<td>Sessions Required</td>
<td>Variable</td>
<td>Variable</td>
<td>Variable</td>
<td></td>
</tr>
<tr>
<td>Probes/Electrodes</td>
<td>Touch the patient</td>
<td>Touch the patient</td>
<td>Canula to be inserted.</td>
<td>NO TOUCH</td>
</tr>
<tr>
<td>Physician Comfort</td>
<td>Needs to move the probe over the areas.</td>
<td>Diodes need to be padded</td>
<td>Expertize required</td>
<td>Focus on the area and start the preprogrammed machine. Absolutely comfortable for both patient and the doctor.</td>
</tr>
<tr>
<td>Pre and post procedure protocols</td>
<td>Minimum</td>
<td>Minimum</td>
<td>More than the other three</td>
<td>Minimum</td>
</tr>
<tr>
<td>Area covered in one session</td>
<td>Limited as probe area is small and needs to be moved on the body segment.</td>
<td>More than ultralipo.</td>
<td>Depends on the degree of invasiveness and the expertise.</td>
<td>Whole abdomen front and back, hips, thighs can be covered at once. Similarly Chest, Face, Neck, Arms at once.</td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>Dealing with the areas around the private parts (genitalia/Pubis)</td>
<td>Difficult as the procedure is mechanical.</td>
<td>Difficult to strap the diodes there.</td>
<td>Depends on the expertise.</td>
<td>Very comfortable and easy.</td>
</tr>
<tr>
<td>Dealing with face</td>
<td>Difficult as the procedure is mechanical and the probe needs to be moved manually.</td>
<td>Difficult to strap diodes on the face.</td>
<td>Depends on the expertise</td>
<td>Very comfortable and easy.</td>
</tr>
<tr>
<td>Consumables</td>
<td>Less (Gel may be needed)</td>
<td>Less</td>
<td>++ (Needs setup)</td>
<td>Zero consumables</td>
</tr>
<tr>
<td>Side effects</td>
<td>Minimum</td>
<td>Minimum</td>
<td>Depends on the expertise</td>
<td>None</td>
</tr>
<tr>
<td>Chances of cross infection</td>
<td>Minimal ;( still can’t be ignored as the probe is in contact to the skin).</td>
<td>Minimal ;( still can’t be ignored as the diodes are contact to the skin).</td>
<td>Depends on the expertise</td>
<td>No chances of cross infections as this is completely no touch technique.</td>
</tr>
<tr>
<td>Cost to patient</td>
<td>Depends on the area covered and hence increases with the area covered.</td>
<td>Depends on the area covered and hence increases with the area covered.</td>
<td>Depends on area covered</td>
<td>As covering a wide area Chest/Arms/Face as one area and Whole abdomen/Hips/Thighs as one area and hence the effective cost to the patient is very less.</td>
</tr>
<tr>
<td>Results</td>
<td>Results of all the technologies are comparable.</td>
<td></td>
<td></td>
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</tbody>
</table>

- All the comparisons made are just for the understanding of the functioning of various technologies and not to grade any technology better than the other or vice-versa.

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- Body shaping and Cellulite reduction: technology proliferation driven by demand. Medical Insight Inc; 2009.


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