REDUCTIONS IN THIGH AND INFRAUMBILICAL CIRCUMFERENCE FOLLOWING TREATMENT WITH A NOVEL DEVICE COMBINING ULTRASOUND, SUCTION, AND MASSAGE

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Abstract
Liposuction is the gold standard of body contouring procedures. Many patients, however, will not tolerate the invasiveness and subsequent recovery time associated with this procedure, despite the likelihood of superior results. Consequently, patients opt for minimally invasive forms of body contouring that require several treatments, have fewer associated side effects, and afford more modest improvements. The MedSculpt™ device is one such modality that combines computerized massage, vacuum suction, and ultrasound with a continuous sinusoidal pulse delivered at a frequency of 3 Hz. The efficacy of this device was assessed in the reduction of thigh and abdominal circumferences. Five patients were included in this pilot study. A total of 12 treatments were performed on a semiweekly basis to 2 abdomens and 3 pairs of thighs. Photographs and circumferential measurements of each area were obtained prior to, and at the conclusion of, the treatment course. The treatments were well tolerated and without side effects. The mean reduction in thigh circumference was 2.25 cm or 4%, with a 5 cm reduction in 1 subject. Although limited improvement was seen in supraumbilical circumference, the mean reduction in infrathigh circumference was 6.5 cm or 7.3%, with a 10 cm reduction in 1 subject. Mild improvement in skin tone, texture, and the appearance of cellulite was observed in all study participants. The results observed after 12 treatments were similar to or better than those seen with other minimally invasive, body contouring devices.

Introduction
Liposuction is the most frequently performed cosmetic surgical procedure in the United States and is a gold standard to which other forms of body contouring are compared.1 However, the procedure is not without risk, discomfort, and inconvenience, since patients may have pain and bruising and are required to wear compression garments in the postoperative period. Some patients will not tolerate the intraoperative and postoperative constraints of liposuction in spite of the potential for remarkable improvement. Consequently, new minimally invasive technologies employing vacuum suction, massage, ultrasound, radiofrequency, light-based therapies, or combinations of these modalities have arisen to fill this niche; these generally require multiple treatments, afford more modest improvements, and can improve skin surface texture and cellulite—outcomes that are not seen with traditional tumescent liposuction.

A number of noninvasive body contouring devices are approved by the Food and Drug Administration (FDA) and presently available. The TriActive® (Cynosure, Westford, MA) delivers a combination of low-energy diode laser, contact cooling, suction, and massage. The VelaSmooth® (Syneron Medical Ltd, Israel) is a combination device that delivers 2 different ranges of electromagnetic energy, infrared light, and radiofrequency, combined with massage. The Dermasonic® (Symedex, Minneapolis, MN) and MedSculpt® (Alderme, Irvine, CA) are externally applied ultrasound devices combined with vacuum suction and massage. The Cellu M6® (LPG Systems, Cedex, France) employs a mechanized system of rollers that delivers a computerized suction/massage regimen to the affected areas.

While no previously published studies assessing the MedSculpt are available at this time, it has been used following liposuction as an adjunctive therapy for cellulitis, myalgia, joint contracture, and muscle spasms, and is touted to improve the appearance of cellulite. The MedSculpt has 3 handpieces: a standard handpiece that provides massage only, a handpiece that provides both massage and ultrasound therapy, and a zonal handpiece that provides vacuum-assisted massage. The vacuum rendered by this device is ~850 mbar, and the ultrasound waves are emitted over a 4.9 cm² surface area with a continuous sinusoidal pulse and frequency ranging from 2.7 MHz to 3.3 MHz. The massage head is covered with a hypoallergenic rubber material and is softer than prototype Endermologie® devices with hard rollers. The manufacturer recommends semiweekly treatments over a 6- to 8-week period. To assess the efficacy of this device as a therapeutic modality for body contouring and reduction of cellulite, a small prospective pilot study of 5 subjects that received treatment to the thighs or abdomen was conducted.

Patients and Methods
This study included 5 female participants over 21 years of age. All subjects were in good health and were either previously
surgically sterilized, postmenopausal, or using a medically acceptable form of birth control. Subjects had no known anticoagulative or thromboembolic conditions, and maintained their normal lifestyle, weight, and diet. A total of 12 semi-weekly treatments were delivered to each area. Photographs and measurements were obtained prior to, and upon completion of, treatments. Each thigh or abdomen was treated with a combination of 10 minutes of ultrasound and 10 minutes of massage using the "localized adiposity" setting. Supraumbilical and infraumbilical measurements of the horizontal abdominal circumference were obtained at a distance of 5 cm above or below the umbilicus, respectively. Measurements of the horizontal thigh circumference were obtained at a distance of 20 cm below the left and right iliac crest. Skin tone, texture, and the appearance of cellulite were assessed before and after treatment, and improvement was scored as "minimal," "mild," "moderate," or "robust."

Results and Discussion
Treatments were well tolerated, and no untoward side effects, such as bruising, were observed. All patients showed improvement, and measurements of thigh circumference demonstrated a mean reduction of 2.25 cm, with a reduction of 5 cm in 1 subject (Table 1). Both patients showed improvements in the abdominal circumference, and although limited improvement was seen in supraumbilical circumference, the mean reduction in infraumbilical circumference was 6.5 cm, with a reduction of 10 cm in 1 subject (Table 2). All patients showed mild improvements in skin tone, texture, and the appearance of cellulite of treated areas.

Based on treatment parameters, 83% of treated thighs in this study had decreased circumference at the end of the 12 treatments, and the mean reduction in upper-thigh circumference was 2.25 cm (4%). In 2004, Sadick and Mulholland demonstrated a mean decrease of 0.8 inches (2 cm) in thigh circumference after 8 to 16 treatments of a noninvasive, body contouring device that employed a combination of infrared and bipolar radiofrequency energies and mechanical manipulation of the skin, and all patients in that study showed some improvement in skin texture and appearance of cellulite. Sadick and Magro assessed the efficacy of the same device in the treatment of thigh cellulite. Results found a decrease in the overall thigh circumference in 71.87% of the treated legs; however, modest reductions (0.44 cm-0.53 cm) were noted in the lower and upper thighs, respectively. In this pilot study, the MedSculpt produced reductions in thigh circumference and appearance and texture of cellulite that are equal to or better than that of existing noninvasive devices. Both patients in this study showed improvements in infraumbilical abdominal circumference after the treatment course, and the mean reduction in infraumbilical circumference was 6.5 cm (7.3%). Wannitchadee and Manuskiatti evaluated the combination of infrared and bipolar radiofrequency energies and mechanical manipulation in the treatment of abdominal cellulite. After 8 or 9 semi-weekly treatments, a mean reduction of abdominal circumference of 3.17 cm ± 2.75 cm (4.04% ± 3.69%) was observed. The reductions in infraumbilical abdominal circumference in the pilot study were similar to or better than those demonstrated with other devices.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Thigh</th>
<th>Pretreatment circumference (cm)</th>
<th>Posttreatment circumference (cm)</th>
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<tbody>
<tr>
<td>1</td>
<td>Left</td>
<td>56.0</td>
<td>51.0</td>
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<tr>
<td></td>
<td>Right</td>
<td>53.5</td>
<td>51.0</td>
</tr>
<tr>
<td>2</td>
<td>Left</td>
<td>59.0</td>
<td>57.0</td>
</tr>
<tr>
<td></td>
<td>Right</td>
<td>59.5</td>
<td>58.0</td>
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<tr>
<td>3</td>
<td>Left</td>
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<td>58.0</td>
</tr>
<tr>
<td></td>
<td>Right</td>
<td>62.5</td>
<td>63.0</td>
</tr>
</tbody>
</table>

Table 1. Summary of thigh circumference measurements.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Location</th>
<th>Pretreatment (cm)</th>
<th>Posttreatment (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Supraumbilical</td>
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<td>75.5</td>
</tr>
<tr>
<td></td>
<td>Infracumbilical</td>
<td>91.0</td>
<td>88.0</td>
</tr>
<tr>
<td>2</td>
<td>Supraumbilical</td>
<td>76.0</td>
<td>76.5</td>
</tr>
<tr>
<td></td>
<td>Infracumbilical</td>
<td>89.0</td>
<td>79.0</td>
</tr>
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</table>

Table 2. Summary of abdominal circumference measurements.
Limitations of this pilot study include a small sample size, the lack of a more objective assessment of the cellulite and skin texture, and a limited long-term follow-up period. The scoring of skin surface irregularities is a complex issue and cannot be done by photography alone; it requires patient evaluation. Three-dimensional ultrasound and magnetic resonance imaging, although expensive and cumbersome, may be useful to more objectively quantify skin surface irregularities.

In conclusion, the MedSculpt is a minimally invasive, body contouring device that reduces lower abdomen and thigh circumference and improves skin surface. While these findings are encouraging, a larger, blinded trial is required for future examination.

Disclosures
Dr. Moy has received investigational support in the form of grant funding for the study of this device.

References

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