

Special Topic

The Evidence Behind Noninvasive Body Contouring Devices

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Aesthetic Surgery Journal
2015, Vol 35(3) 279–293
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DOI: 10.1093/asj/sju063
www.aestheticsurgeryjournal.com

OXFORD
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Abstract

The demand for body contouring is rapidly increasing, and interest in noninvasive approaches has also grown. The author reviewed the evidence base behind the currently available devices and methods for nonsurgical body contouring. There is little high-level evidence in the present literature to support the effectiveness of any of these devices.

Accepted for publication October 2, 2014.

Liposuction has become one of the leading cosmetic surgical procedures worldwide. In 2013, the International Society for Aesthetic Plastic Surgery reported that more than 1.6 million liposuction procedures had been performed globally, making it the second most common cosmetic procedure after breast augmentation.¹ According to the 2013 American Society for Aesthetic Plastic Surgery statistics,² liposuction was the most commonly performed cosmetic surgical procedure in the United States in 2013.

The demand for body contouring is rapidly increasing, and interest in noninvasive approaches has also grown. According to the statistics from the American Society for Aesthetic Plastic Surgery, 9.5 million nonsurgical procedures were performed in 2013, compared with only 1.8 million surgical procedures. In 2013, almost 95,000 nonsurgical fat reduction procedures and 294,000 nonsurgical skin-tightening procedures were performed in the United States.² There are numerous noninvasive body-contouring devices currently available on the market. These devices broadly deliver an external form of energy that causes changes in the underlying adipocytes. The devices can be classified according to the type of energy used (Table 1).³ The aim of the present study was to review some of these devices and the evidence supporting their use and effectiveness.

METHODS

A search for relevant studies was undertaken using Medline. The medical subject heading terms used for the search

included body contouring, mechanical suction, SmoothShape, Endermologie, TriActive, VelaSmooth, external radiofrequency, VelaShape, Thermage, Accent, TiteFX, high-frequency focused ultrasound, UltraShape, Liposonix, cryolipolysis, Coolsculpt, low-level light laser, Zerona, Exilis, Venus Freeze, Vanquish, and VASERShape. Combinations of these terms were also used to maximize the return of results. The identified studies were then classified according to the level of evidence for key clinical recommendations using the American Society of Plastic Surgeons Levels of Evidence Rating Scale for Therapeutic Studies (Table 2).⁴ Some of the levels of evidence were reported by the journal in which the articles were published, but when a level was not provided, the rating scale from the American Society of Plastic Surgeons was used to determine the appropriate level for that article.

MECHANICAL SUCTION

Endermologie

Endermologie (LPG Systems, Valence, France) was developed in France by Louis Paul Guitay in the 1970s

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Table 1. Classification of Noninvasive Body-Contouring Devices According to Energy Used³

Energy	Device (Company)
Mechanical suction	Endermologie (LPG Systems)
Mechanical suction and thermal	TriActive (Cynosure)
	SmoothShapes (Cynosure)
Radiofrequency	VelaShape (Syneron Candela)
	VelaSmooth (Syneron Candela)
	Thermage (Solta Medical)
	Accent (Alma Lasers)
	TiteFX (Invasix)
	Vanquish (BTL Industries, Inc)
	Exilis (BTL Industries, Inc)
Ultrasound	Ultrashape (Ultrashape)
	Liposonix (Solta Medical)
	VASERShape (Solta Medical)
Cryolipolysis	Coolsculpting (Zeltiq)
Low-level light laser	Zerona (Erchonia Medical, Inc)

Table 2. The American Society of Plastic Surgeons Levels of Evidence Rating Scale for Therapeutic Studies⁴

Level of Evidence	Qualifying Studies
I	High-quality, multicentered or single-centered, randomized controlled trials with adequate power or systematic reviews of these studies
II	Lesser-quality, randomized controlled trials, prospective cohort studies, or systematic reviews of these studies
III	Retrospective comparative study; case-control study; or systematic review of these studies
IV	Case series
V	Expert opinions, case reports or clinical examples, or evidence-based studies on physiology, bench research, or "first principles"

(Figure 1). He suffered soft tissue injuries in a road traffic accident, and the resultant scars were treated with manual massage. Louis Paul Guitay developed a device that mimicked this manual massaging. The device was originally used for scars that resulted from trauma and burns; however, users noted that it also improved the appearance of cellulite and altered fat distribution. The most recent versions of this device are the Integral and Endermolab devices (LPG Systems) (Figure 1). The mechanism of action comprises negative pressure suction and a roller

**Figure 1.** Endermologie integral device. Image courtesy of LPG Systems.

applicator that is passed over areas of fatty deposits.⁵ Tests in a porcine model revealed some disruption of adipocyte membranes after use of Endermologie. The investigators found no evidence of mobilization of fatty tissue or of fat breakdown products or metabolites in urine or blood samples from the porcine specimens.⁶

Chang et al⁷ reported the effects of Endermologie in a series of 85 patients, 46 of whom had 7 weeks of treatment and 39 of whom had 14 weeks. After 7 weeks, the average reduction in body circumference was 2.17%. In 15.2% of patients, there was an increase in the mean body circumference. The mean reduction of weight after treatment was 0.99 kg, which is equivalent to a 1.5% reduction. More than a quarter of patients (28.8%) reported weight gain. After 14 weeks, there was an average overall reduction of 2.65% in body circumference and a 1.84% weight loss. In addition, 32.4% of subjects gained weight, and 12.8% had increased body circumference (Level IV Evidence).⁷

In a more recent study with 118 patients, Kutlubay et al⁸ reported that 99% of subjects had reductions in body circumference measurements, with a mean reduction of 2.9 cm. During the study period 87% of patients had a recorded reduction in weight, with a mean reduction of 2.71 kg (Level IV Evidence). It is unclear whether the patients with weight loss subsequently noticed significant reductions in body circumference measurements accounting for the positive result in this paper.

MECHANICAL SUCTION AND THERMAL ENERGY

TriActive

These devices were based on the earlier endermology devices and incorporated an additional thermal energy component into the treatment. The TriActive device (Cynosure, Westford, MA) uses a low-energy diode laser with contact cooling, suction, and massage. The main indication for this device has been in the management of cellulite. A prospective, randomized, comparative study was performed in 20 patients to determine the efficacy of the TriActive and VelaSmooth (Syneron Candela, Irvine, CA) devices in the management of cellulite.⁹ The TriActive treatment regimen involved a twice-weekly session for 6 weeks. A reported improvement of 30% in upper thigh circumference and 37% in the lower thigh circumference was noted in that study. Patients reported a mean 20% improvement in appearance after TriActive treatment (Level II Evidence).⁹

SmoothShapes

Kulick¹⁰ evaluated the SmoothShapes device (Cynosure), which is dual-wavelength laser-suction and massage device (Figure 2). The series included 20 patients who underwent 2 treatment sessions on the lateral thigh area per week for 4 weeks. The investigators used 3-dimensional imaging technology to evaluate improvements in skin contour, such as cellulite, and volume reduction. Patients were evaluated 1, 3, and 6 months after treatment. Three-dimensional image analyses showed a 76% improvement in cellulite and an average volume reduction of 84 cc at 6 months (Level IV Evidence).¹⁰

MECHANICAL SUCTION SUMMARY

Treatment with Endermologie alone resulted in only modest improvements in a proportion of patients. The treatment requires a number of regular sessions to achieve this marginal improvement. The device with mechanical suction and thermal energy, commercially known as TriActive, has been shown to somewhat improve the appearance of cellulite and to reduce thigh circumference.⁹ However, these results were



Figure 2. SmoothShapes device. Image courtesy of Cynosure.

seen in a small number of patients, and there have been no large comparative studies to show the long-term results of that device.

EXTERNAL RADIOFREQUENCY

Radiofrequency devices are currently the most popular noninvasive body contouring devices used in practice. These devices apply volumetric bulk heat to the epidermis and dermis. There are both immediate and delayed sequelae of this volumetric heating. The immediate change is denaturation of the collagen fibrils with shortening of the fibril lengths. Later consequences involve neocollagenesis and subsequent skin tightening.¹¹

VelaSmooth and VelaShape

The VelaSmooth and VelaShape devices (Syneron) combine infrared light, mechanical suction, and bipolar radiofrequency (Figures 3 and 4). The VelaShape is a more powerful device (50 W) than is the VelaSmooth (25 W). The devices consist of 2 electrodes between which skin is

mechanically suctioned that deliver the bipolar radiofrequency. The infrared component of the device targets dermal water and the radiofrequency targets deeper layers of the skin, resulting in increased adipocyte metabolism and accelerated triglyceride egress from the cell. The thermal energy results in dermal tightening and stimulation of neocollagenesis.^{3,12}

Clinical studies have been undertaken to explore the efficacy of the VelaSmooth and VelaShape devices in the treatment of cellulite and body contouring. Sadick and Mulholland¹² reported a 40% improvement in cellulite and a 100% reduction in thigh circumference measurements in 35 patients who underwent VelaSmooth treatment (Level IV Evidence). Alster and Tanzi¹³ reported a 90% improvement in thigh and buttock cellulite in 20 women who had twice-weekly treatments for 3 weeks (Level IV Evidence). In a separate study, 16 patients who underwent long-term treatment had a 62% improvement in cellulite at 3 months

and a 50% improvement at 6 months when assessed by blinded evaluators. In that study, the complications noted were bruising in 5 patients and a superficial burn in 1 patient (Level IV Evidence).¹⁴

The use of the VelaSmooth and VelaShape devices in body contouring has also been reported in the literature. In a series of 16 patients who underwent treatment of the abdomen and thighs, the mean circumferential reductions were 4.64% (standard deviation, 1.15) and 5.50% (standard deviation, 6.12), respectively, at the 1-year follow-up (Level IV Evidence).¹⁵ Sadick and Magro¹⁶ showed a reduction in thigh circumference in 71.9% of treated patients after 4 weeks of using VelaSmooth. However, the study failed to show any improvement at the 8-week follow-up (Level IV Evidence). Another study of 20 patients treated with the VelaShape device showed significant improvements in mean circumferential reduction and skin laxity (Level IV Evidence).¹⁷ In their series of 29 postpartum



Figure 3. VelaSmooth device. Image courtesy of Syneron Candela.

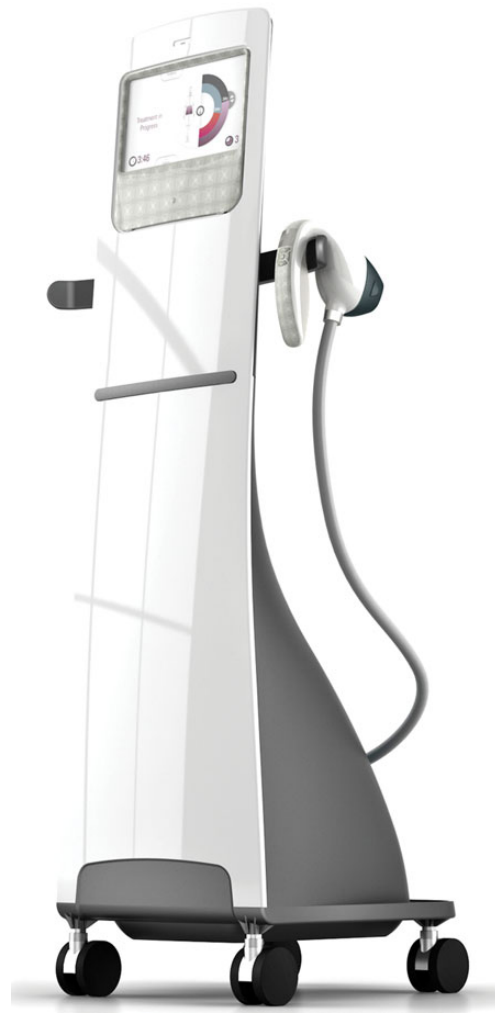


Figure 4. VelaShape device. Image courtesy of Syneron Candela.

women, Brightman et al¹⁸ also showed significant reductions in upper arm and abdominal circumferences at 1-month and 3-month follow-ups. The mean reduction in arm circumference at 3 months was 0.597 cm. The average abdominal circumferential reduction at 3 months compared with baseline was 1.82 cm. In that series, the complications that were reported were bruising and superficial crusting of the abdomen in 1 patient (Level IV Evidence). Nootheti et al⁹ compared the VelaSmooth device with the TriActive device in the management of cellulite. The VelaSmooth device improved upper thigh circumference by 28% and lower thigh circumference by 56%. There was no statistically significant difference between the VelaSmooth and TriActive devices in terms of overall outcomes (Level II Evidence).

Thermage

Thermage (Solta Medical, Hayward, CA) is a monopolar radiofrequency device that has applications for not only body contouring but also facial and periocular skin tightening (Figure 5). The device has primarily gained popularity for the treatment of the face and periocular regions. The system comprises a base unit with a coolant compartment that constantly cools the tip, thus reducing surface skin temperature. The hand piece has specific tips for the different parts of the body to be treated, and the latest comfort pulse technology device incorporates vibration within the hand piece to reduce pain. A return plate must be applied to the patient because it is a monopolar device. There have been a number of studies exploring the use of Thermage or the ThermoCool procedure in body contouring.^{3,11}

Anolik et al¹¹ used the ThermoCool TC device (Solta Medical) in 12 patients in blinded, multicenter study. That study was undertaken to assess the Thermage Multiplex tip for treatment of mild-to-moderate abdominal skin laxity. The average decreases in waist circumferences were 1.4, 1.7, 0.2, and 0.9 cm at 1, 2, 4, and 6 months after treatment, respectively. Patient satisfaction rates, as indicated by patients reporting being either very satisfied or somewhat satisfied, were 89%, 80%, and 78% at 2, 4, and 6 months after treatment, respectively. Reported complications were transient edema and erythema that were short-lived with no other significant long-term sequelae. However, the number of patients who attended their follow-up appointments was poor, with only 75% returning for the 6-month follow-up visit. The authors concluded that patient selection was paramount for determining successful treatment. They recommended the use of the device in patients with some skin laxity and mild adiposity. Obese patients with substantial redundant skin laxity would be unlikely to benefit significantly from the treatment (Level IV Evidence).¹¹ Wu¹⁹ described the abdominal applications of Thermage in his practice as being predominately for the crumpled skin around the



Figure 5. Thermage device. Image courtesy of Solta Medical.

umbilicus that results in a puckered-appearing umbilicus; stretch marks; skin laxity with hanging folds; and fine folds or crepey skin. That report did not, however, provide any results in terms of patient or clinician satisfaction or objective measures (Level V Evidence).¹⁹

Suh et al conducted a study to explore the use of the Thermage combined with a pulsed-dye laser (PDL) for the treatment of striae distensae in 37 Asian patients with Fitzpatrick skin types III-VI. Patients underwent 3 treatment sessions; the first consisted of both PDL and Thermage, whereas the subsequent sessions only used the PDL. These sessions were 4 weeks apart. Patients were reviewed 12 weeks after the initial first session and assessed clinically and histopathologically. Clinically, 59.4% and 89.2% of patients reported improvements in elasticity and overall appearance of the striae, respectively. Histopathological analysis was performed in 9 patients before and after treatment. In all 9 subjects, there was an increase in collagen,

and 6 subjects (66.7%) showed an increase in elastic fibers (Level IV Evidence).²⁰

Accent

Accent (Alma Lasers, Buffalo Grove, IL) is another monopolar radiofrequency device that delivers radiofrequency at 40 MHz. Emilia del Pino et al²¹ conducted a study of 26 patients who underwent 2 treatment sessions with the Accent device that were 15 days apart. Ultrasound assessment of the thighs and buttocks at baseline and 15 days after the second session revealed that 68% of patients had a volume contraction of 20% (Level IV Evidence). Goldberg et al² performed fortnightly treatment sessions with the Accent radiofrequency device for a total of 6 treatments. In that study, 27 of the 30 patients showed improvement, and the mean reduction in thigh circumference was 2.45 cm. The authors also performed biopsies, blood lipid analysis, and magnetic resonance imaging. No significant changes in blood lipid levels or magnetic resonance images were noted. Skin biopsies after treatment revealed dermal fibrosis (Level IV Evidence).²²

TiteFX

TiteFX (Invasix, Irvine, CA) is a newer device that utilizes suction-coupled radiofrequency to achieve a high desired skin temperature before deploying a high-voltage electroporation pulse that results in adipocyte apoptosis. A study of 25 patients was undertaken to assess the effects of TiteFX on cellulite and body contouring. TiteFX was administered once per week for a 6-week period. The patients were observed for 3 months after their last treatment. In that series, there was an average circumferential reduction of 3.58 cm (range, 1.5-4.4 cm), and 90% of patients reported improvement in the appearance of cellulite. The authors reported no significant complications associated with the treatment (Level IV Evidence).²³

Vanquish

The Vanquish (BTL Industries, Inc, Framingham, MA) is a contactless high-frequency field radiofrequency device in which the applicator is placed approximately 1 cm above the skin (Figure 6). The system delivers energy specifically into the adipose tissue layer while minimizing risk of overheating in the skin and deeper structures.²⁴ Using this technology in a porcine model, Weiss et al²⁴ showed a 70% reduction in fat layer by using ultrasound measurement after 4 treatment sessions. Histological analysis confirmed the safety of this device; the epidermis, dermis, and adnexal structures were unaffected by the treatment.

Fajkosova et al²⁵ conducted a prospective case series of 40 patients to evaluate the Vanquish device. Patients

underwent weekly 30-minute treatment sessions over a 4-week period. Measurements were taken 1 month after the final treatment session. The 35 patients who completed the study had an average circumferential reduction of 4.93 cm in the abdominal zone. Three patients failed to show any significant reduction. Those patients were also noted to be the thinnest in the study, and a body mass index/circumferential reduction correlation graph revealed better results in subjects with higher body mass indices. No significant adverse events were noted related to the treatment other than transient erythema (Level IV Evidence).²⁵

RADIOFREQUENCY SUMMARY

Radiofrequency has been used in body contouring both internally and externally. The mechanism of action relies on volumetric heating of the skin and subcutaneous tissues. The devices can be classified as monopolar (Thermage and Accent) or bipolar (VelaSmooth and VelaShape). Bipolar devices generally require more frequent treatments, and a literature search reveals modest short-term improvements in cellulite and fat reduction. The monopolar devices tend to need fewer treatment sessions, and the evidence shows



Figure 6. Vanquish device. Image courtesy of BTL Industries, Inc.

circumference and fat reduction in approximately 60%-80% of subjects. The newer contactless device (Vanquish) has also shown some reductions in a small case series. There are other radiofrequency devices, such as Venus Freeze (Venus Concept, Toronto, Canada) and Exilis (BTL Industries, Inc); however, the literature search did not yield any publications in which these devices were used. The Venus Freeze uses multipolar radiofrequency and pulsed magnetic fields that generate heat, resulting in skin tightening and wrinkle and cellulite reduction. Exilis uses focused radiofrequency to produce the thermal effect. There are no high-level evidence studies in which the use of external radiofrequency in body contouring has been investigated.

EXTERNAL ULTRASOUND

The use of ultrasound for lipolysis was pioneered by Zocchi,²⁶ who used an invasive internal device. Noninvasive ultrasound can be broadly classified into 2 mechanisms: low-intensity/low-frequency nonthermal ultrasound and high-intensity focused ultrasound (HIFU). Low-intensity/low-frequency ultrasound devices are available; however, there is no evidence that they are effective in body contouring. There are currently 2 main commercially available HIFU devices used in body contouring, namely UltraShape (Syneron Candela) and Liposonix (Solta Medical). The UltraShape device is a focused, nonthermal machine that cavitates the adipose tissue (Figure 7). The Liposonix device uses a highly convergent energy that allows focused delivery of very high-intensity energy to a very specific focal zone (Figure 8).²⁷⁻²⁹

UltraShape

The UltraShape is an ultrasonic device used for noninvasive selective fat cell destruction. The device produces nonthermal pulsed ultrasonic waves at a controlled depth. Brown et al³⁰ demonstrated the safety of nonthermal focused ultrasound in animal models. The device was shown to result in fat cell lysis but not to induce injury to surrounding structures, such as nerves, skin, and vessels (Level I Evidence).

Moreno-Moraga et al³¹ conducted a study of 30 patients who underwent Ultrashape treatment to a variety of areas. All patients had 3 treatment sessions at 1-month intervals. The authors reported a 2.28-cm (standard deviation, 0.80) reduction in fat thickness and a 3.95-cm (standard deviation, 1.99) reduction in mean circumference. The greatest reductions were noted in the outer thighs and abdomen. The inner thigh showed the smallest reduction. No severe adverse reactions to treatment were noted. No increases in cholesterol levels were found, although triglyceride levels were mildly elevated but still within normal limits. Liver ultrasounds were also performed in patients, and these failed



Figure 7. Ultrashape device. Image courtesy of Syneron Candela.

to reveal any increased fat deposition in the liver (Level IV Evidence).³¹

A prospective, multicenter, comparative trial was conducted to assess the safety and efficacy of the UltraShape Contour I device.³² Investigators recruited 137 patients to the treatment group and 27 to the control or untreated group. Patients were assessed 12 weeks after a single treatment. At that follow-up, 82% of subjects reported some response, with a mean circumferential reduction of 1.9 cm. The control group showed no statistically significant reduction in mean circumference. The study also explored the effect of treatment on thigh circumference and compared the treated thigh to the contralateral untreated thigh that served as a control. These results confirmed a significant



Figure 8. Liposonix device. Image courtesy of Solta Medical.

reduction in mean thigh circumference. The authors also found a 2.9-mm reduction in mean fat thickness at 28 days. Complications included mild erythema (3 patients), blisters (2 patients), and transient sensory changes (1 patient). No significant increase in hepatic function was seen, and liver ultrasound did not show any increase in liver fat content (Level II Evidence).³²

Ascher³³ conducted a study of 25 patients who underwent 3 treatments with the UltraShape device that were 2 weeks apart. In that series, there was a significant reduction of abdominal circumference (mean, 3.58 cm) 12 weeks after the final treatment session. A positive change in body contour was reported by 63% of the study participants (Level IV Evidence).

Shek et al³⁴ used the UltraShape Contour I device in 53 Asian patients to treat the abdomen and flanks.

The patients in that series had up to 3 treatment sessions at monthly intervals. There was a high drop-out rate, with many patients lost to follow-up. The authors measured the abdominal circumference and fat thickness of subjects using calipers and ultrasound imaging. There was a slight decrease in abdominal circumference after the first treatment, but an increase was seen after subsequent treatments. However, only 18 of the original 53 patients came to the 3-month follow-up. Caliper measurements showed a mean increase of 0.13 cm in fat thickness 3 months after treatment. Ultrasound assessment of fat-layer thickness also showed a mean increase from 2.25 cm at baseline to 2.39 cm at 3 months. The authors concluded that these differences from previously published results might have been due ethnic variations in body shapes in the Asian population (Level IV Evidence).³⁴

Liposonix

HIFU has been used in medicine for some time, and applications include cardiac ablative procedures and the management of renal calculi and tumors. HIFU devices rely on delivery of focused thermal energy within subcutaneous tissue with no collateral damage to surrounding tissues. The mechanism of action is believed to be ultrasonic waves that cause rupture of adipocytes. The content of these ruptured adipocytes, which are primarily triglycerides, are dispersed into the interstitial tissues and then transported by the lymphatic system. The ultrasonic energy is also thought to cause cavitation. Temperatures of up to 56°C can be achieved at the focal point, resulting in coagulative necrosis and apoptosis within the targeted region. The disrupted adipocytes are resorbed 8 to 12 weeks after treatment, with 95% being resorbed after 18 weeks. The thermal effects of HIFU include disruption and denaturation of collagen fibers, which results in neocollagenesis.^{29,35}

Jewell et al³⁶ researched the use of a HIFU device in a porcine model. In that study, they demonstrated that temperatures of up to 70°C can be reached for short durations in the focal zone while the temperature in the surrounding tissues remained at a nondamaging level and the skin surface temperature remained unchanged. The authors noted that on gross pathology specimens, resolution of thermal lesions was almost complete 8 weeks after treatment. There was evidence that macrophages engulfed the debris from the focal adipocyte destruction and transported it away via the lymphatic system. They also noted no injury to any solid organs and no changes in serum lipid levels after treatment in an animal model (Level V Evidence).³⁶

The Liposonix system is a HIFU device. The frequency of the transducer that produces the HIFU energy is fixed at 2 MHz. Gadsden et al³⁷ conducted the initial safety studies of the Liposonix device in 152 human volunteers. Their study was in part performed in patients who were

undergoing abdominoplasties, which allowed tissue harvesting after HIFU treatment. The abdominoplasties were performed at various time periods after the HIFU treatment. In patients who had abdominoplasties within 2 hours of HIFU treatment, there was evidence of disrupted adipocytes. After 1 week, the treated focal areas were evident, with normal healing processes taking place. There was no evidence of extension of damage to the surrounding skin or fascia. Patients who had abdominoplasties up to 14 weeks after HIFU had macrophages engorged with lipid droplets. There was also evidence of thickened collagen as a consequence of the thermal effect of the HIFU treatment. After treatment, a number of adverse events were noted, including pain after treatment (76%), edema (72%), ecchymosis (68%), pain during treatment (64%), dysesthesia (59%), and erythema (45%). These were all temporary and resolved spontaneously. The authors concluded that the HIFU appears to be a safe treatment that causes no injury to the tissues outside of the focal zone and that has self-limited side effects (Level IV Evidence).³⁷

Fatemi and Kane³⁵ described the use of the Liposonix device in 85 patients who sought body contouring of the anterior trunk and flanks. A single treatment session comprising 2 passes was used as the treatment protocol for that study. The reported mean reduction in waist circumference was 4.6 cm (standard deviation, 2.4) 3 months after treatment. After 3 months, 70% of patients reported that they were satisfied with the treatment. Noted complications were prolonged tenderness, bruising, hard lumps, and edema. The investigators also performed serum analysis of cholesterol, triglyceride, high-density lipoprotein, low-density lipoprotein, and liver enzyme levels at regular intervals before and after treatment. The serum laboratory measures remained within normal limits after treatment (Level IV Evidence).³⁵

A multicenter, randomized, sham-controlled study was conducted to investigate the safety and tolerability of the HIFU device.³⁸ There were 180 patients recruited into the study who were then randomized to treatment with the HIFU at 1 of 3 energy levels (0, 47, or 59 J/cm²). The safety of the procedure was assessed at 24 weeks using blood tests and reports of adverse events. A total of 168 patients completed treatment and follow-up; the remainder were lost to follow-up or excluded from the study for a variety of reasons. There were no significant differences in serum levels of total cholesterol, triglycerides, fatty acids, high-density lipoprotein, low-density lipoprotein, or very-low-density lipoprotein between the 3 treatment groups. The main adverse events noted in the treatment group were procedural pain (90.2%), postprocedural pain (56.6%), mild ecchymosis (49%), moderate ecchymosis (16%), swelling (9%), and severe ecchymosis (<1%). No adverse events were reported after 12 weeks. The authors did not see any complications such as skin dimpling, burns, indurations, or increased laxity in their series (Level II Evidence).³⁸

EXTERNAL ULTRASOUND SUMMARY

There are 2 main external ultrasound devices used in body contouring. The UltraShape device relies on nonthermal ultrasonic waves to cause cavitation in the adipose tissues. There are a number of studies in which this device has been shown to be safe and effective in the reduction of fat layers. However, there was a study in which no benefit of using this device was found in an Asian population.³⁴ The Liposonix device relies on a highly focused delivery of high-intensity energy that results in focal zones of heating, which causes coagulative necrosis and cell death. The evidence has shown the safety of this device, and its mechanism of action has been demonstrated in both animal and human studies. The response to treatment has also been shown in a small number of studies. There are no studies with high levels of evidence in which positive responses to these devices have been shown in large numbers of patients. There are also no comparative studies or randomized controlled trials in which these devices were used. Jewell et al³⁸ reported a level II study of the safety of the Liposonix device, but the effectiveness of the treatment was not addressed. There are some other ultrasound devices, such as the VASERShape (Solta Medical), that also combine ultrasound with zonal massage. I did not identify any publications related to this device in my literature search. Although these devices are widely used, there is little significant evidence to support their effectiveness in body contouring.

CRYOLIPOLYSIS

The concept of cold-induced fat destruction comes from reports of infants that sustained “popsicle panniculitis.” This clinical entity arises when prolonged contact with a popsicle results in an area of focal lipoatrophy. However, the exact mechanism underlying the selective destruction of adipocytes by cooling is not fully understood. Fat or adipose tissue may be preferentially more sensitive to cold exposure. Cryotherapy has also been used in the destruction of superficial cutaneous lesions for some time. The aim of cryolipolysis, however, is to cause selective damage to the adipocytes without dermal damage. This concept was introduced in 2007, and in 2010 the US Food and Drug Administration approved the use of the first cryolipolysis device. This novel technique has become another noninvasive method of fat removal and body contouring.³

Manstein et al³⁹ undertook an animal study in which they investigated the effects of cold exposure on subcutaneous fat in Yucatan pigs. The initial exploratory study showed a reduction of fat in the superficial fat layer at 3.5 months. This reduction was approximately 80% of the superficial fat layer or a total reduction in fat-layer thickness of 40% from the procedure at the treated site. They also performed a dosimetry study to assess the degree of

fat damage at varying temperatures. They found that at lower temperatures (-7°C and -5°C), there was a greater likelihood of fat damage after 28 days. Histological analysis further demonstrated a marked reduction in the distance between fat septae. The authors reported that cryolipolysis was highly selective for targeting the subcutaneous fat layer and did not affect the epidermis, dermis, or underlying muscular tissue. Lipid analysis at regular intervals up to 3 months after treatment revealed no significant change in serum lipid levels. The authors also reported the appearance of numerous lipid-laden mononuclear cells after 2 weeks that might have been a consequence of adipocyte apoptosis and subsequent removal by phagocytosis. That could account for the observation of no significant increase in serum lipid levels (Level V Evidence).³⁹

A further animal study by Zelickson et al⁴⁰ confirmed the initial findings reported by Manstein et al. In that study, 2 pigs underwent ultrasound assessment to measure the thickness of the fat layer, which was reduced by 33% after treatment. Pathological gross measurement of the fat-layer reduction revealed a mean decrease of 51.5%. The authors also found no significant increase in serum lipid levels after treatment (Level V Evidence).⁴⁰

CoolSculpting treatments (Zeltiq, Pleasanton, CA) have been cleared by the Food and Drug Administration to reduce fat in the flanks (2010) and abdomen (2012). The device has an applicator that is applied externally to the area to be treated, and the tissue is vacuumed up between 2 cooling panels for 30 to 60 minutes. The amount of cooling is determined by thermistors that monitor the skin temperature.³

Dover et al⁴¹ conducted a multicenter, prospective, non-randomized study of 32 patients who underwent cryolipolysis for treatment of the flank and back. Patients were treated with 1 session and evaluated 4 months later. At the 4-month follow-up, 84% of subjects reported fat reduction and contour changes. In 10 patients, ultrasound measurements were taken that revealed a 22.4% reduction in the fat layer (Level IV Evidence).

Coleman et al⁴² performed a study in 10 patients in which a Zeltiq prototype device was used for the treatment of the flanks. The objectives of that study were to assess clinical efficacy and sensory changes after cryolipolysis. Patients underwent treatment on one side and the other side was used as a control. Nine patients had neurological sensory testing, and 6 of the 9 patients had ultrasound assessment of fat-layer thickness at 2 and 6 months. Weekly sensory assessment was performed, and it revealed that 66.7% of patients had some degree of reduction in sensation after treatment. The sensation was restored several weeks (mean, 3.6 weeks) after the procedure. These changes in sensation had all resolved by 2 months after the treatment. There was an average reduction in the thickness of the fat layer of 20.4% at 2 months and 25.5% at 6 months after a single treatment. One patient had histological biopsies performed

to assess the impact of cryolipolysis on neural tissues. The histological results showed no long-term changes to structure or functionality of either epidermal nerve fibers or nerve plexi in the dermis (Level IV Evidence).⁴²

Klein et al⁴³ conducted a multicenter study of 40 patients to identify the effects of cryolipolysis of the flanks on serum lipid levels. Serum lipid levels and liver enzymes were measured at day 1 and 1, 4, 8, and 12 weeks after treatment. The results showed no significant increase in triglyceride or lipid levels 12 weeks after cryolipolysis (Level IV Evidence).

In a Chinese study, Shek et al⁴⁴ explored the efficacy of cryolipolysis and the benefits of repeated treatment of the flanks and abdomen. They performed a single cryolipolysis session on 21 patients. These patients were reviewed 2 months later, and 81% reported improvement in the treated area. The authors used calipers to measure patients and found an average reduction of 14.67%. Twelve additional patients had 2 sessions performed approximately 3 months apart. In those patients, the average improvement after the first treatment was 14.0%. The average improvement after the second treatment was only 7.2% for the abdomen. There was no statistically significant improvement after the second session for the flanks, with an average overall improvement of only 4.3% (Level IV Evidence).⁴⁴

Dierickx et al⁴⁵ conducted a European multicenter study of 518 patients who underwent cryolipolysis. The vast majority of subjects had treatment of the flanks (59%) or the abdomen (28%). The reported side effects were erythema (100%), clay-like skin (52%), stiff skin (48%), bruising from the vacuum hand piece (9.8%), severe pain (4%), increased sensitivity (2.5%), nodular or diffuse infiltration in treatment area (2.5%), vasovagal reaction (2.1%), and decreased sensitivity (0.4%). The follow-up was poor; only 46.9% of patients were reviewed at 3 months, whereas the remaining 53.1% were lost to follow-up. In those patients who were seen at 3 months, 73% reported being either extremely satisfied or satisfied. Caliper measurements revealed that 94% of patients had some degree of reduction in fat thickness, with an average reduction of 23% (Level IV Evidence).⁴⁵

A large retrospective series from the United States of 528 patients who underwent cryolipolysis for treatment of a variety of areas has also been published.⁴⁶ In that study, the most popular treatment areas were the flanks (38%), lower abdomen (28%), and abdomen (11%). The investigators did not perform any objective measurements of fat-layer reduction in that study. They reported 3 cases of mild-to-moderate pain or neuralgia that resolved within 4 days. Commercially, the authors reported that the CoolSculpting device had been highly profitable in their practice (Level IV Evidence).⁴⁶

A further development has been a device that combines cryolipolysis and shock waves. The Proshockice device (PromoItalia, Milan, Italy) comprises a freezing probe and

shock probe. The freezing probe can produce temperatures from 5°C to -5°C. The shock probe emits frequencies between 1 to 16 Hz and between 50 to 500 bar. Ferraro et al⁴⁷ used this device in a series of 50 patients with localized fat and cellulite. The treatment strategy varied depending on the area being treated, but generally cryolipolysis was performed for 30 minutes and shock therapy was performed for 10-15 minutes. Patients had 1 session every 15 weeks (mean, 3.73 sessions). The main treatment areas were the abdomen, thighs, arms, buttocks, and ankles. The mean reductions in fat circumference were 6.86 cm for abdomens, 5.78 cm for thighs, 2.75 cm for arms, 5 cm for buttocks, and 2.25 cm for ankles. The authors noted mildly increased cholesterol and triglyceride levels after treatment, but these remained within normal limits. There were no adverse events, such as paresthesias, hematomas, or ecchymoses. Histological analysis revealed an alteration in adipocyte morphology in the treated areas but not the untreated areas, and subsequent analysis using staining techniques showed apoptosis. The authors reported no histological changes in the skin but observed shrinkage of collagen fibers in a parallel arrangement and neovascularization of the subcutaneous tissue (level IV Evidence).⁴⁷

CRYOLIPOLYSIS SUMMARY

The use of cold temperatures to selectively cause adipocyte apoptosis has been termed cryolipolysis. There have been a few new devices on the market that use cryolipolysis. In the initial animal studies, cold was shown to be effective in selectively destroying adipocytes with minimal collateral damage to surrounding structures.^{39,40} A small number of series have documented the use of cryolipolysis devices in a clinical setting. The main indications for cryolipolysis have been in patients with small deposits of adiposity on the flanks or abdomen. In published studies, the average reductions in the fat layer have ranged from from 14.0% to 25.5%.^{41,42,44} These studies all have level IV evidence, and there are currently no randomized controlled or comparative studies of cryolipolysis devices. The complications reported from the published series reveal relatively few long-term sequelae. The main reported side effects were erythema and sensory changes, although those were transient and resolved reasonably quickly. No significant elevations in serum lipid levels were seen after cryolipolysis treatment.

LOW-LEVEL LASER THERAPY

Low-level laser therapy (LLLT) is slightly different from the treatments discussed previously. LLLT has been defined as treatment with a dose rate that causes no immediate detectable rise in temperature in the tissue being treated and no macroscopically visible changes in tissue structure.⁴⁸ The

commercially available low-level lasers include the Zerona (Erchonia Medical, Inc, McKinney, TX) (Figure 9).

The mechanism behind the action of LLLT is not fully understood, although a few studies have been performed to elucidate it. Neira et al⁴⁹ performed LLLT in 12 patients who underwent abdominoplasty, and they then analyzed biopsied fatty tissue from the areas treated with lasers for 0, 2, 4, and 6 minutes with and without tumescent infiltration. These tissues were compared with untreated tissues to identify differences resulting from LLLT and the addition of tumescent infiltration. Electron microscopy revealed that in laser-treated areas, there was temporary membrane disruption that created pores that allowed liquefied fat to leak into the interstitial space. The effect of the laser appeared to be enhanced by the addition of tumescent infiltration. In untreated areas, the adipocytes remained intact and maintained their round shape. The authors showed that low-level laser exposure for 4 minutes using the 635-nm diode device resulted in an 80% release of adipose tissue into the interstitial space, and after 6 minutes, there was 99% release (Level V Evidence).⁴⁹ Brown et al⁵⁰ did not replicate these findings in their porcine and human study. They used a device similar to that used by Neira et al⁴⁹, but they used it for much longer periods and obtained scanning electron micrographs from both the porcine and human samples. They showed that there was no change in the round shape of the adipocytes and there was no evidence of pores in the adipocyte membrane, as previously described (Level IV Evidence).⁵⁰ In an additional



Figure 9. Zerona device. Image courtesy of Erchonia Medical, Inc.

human study, Caruso-Davis et al⁵¹ found no increase in glycerol or fatty acid levels after 10 minutes of LLLT, although there was an increase in triglyceride levels. These findings suggested that fat loss from the adipocytes was not due to lipolysis but might be due to pores in adipocytes resulting in increased triglyceride levels (Level IV Evidence).

A multicenter, double-blind, randomized, placebo-controlled trial was performed on 67 patients.⁵² Patients were randomized to active treatment using LLLT (35 patients) or inactive sham treatment (32 patients). Treatment in both groups was performed over 2 weeks, with 3 sessions that 2 days apart per week. Circumferential measurements of the waist, hips, and thighs were taken before treatment and 2 weeks afterward. The authors defined success as a combined circumferential reduction of at least 3 inches for the waist, hips, and thighs after treatment. Using this criterion, 62.9% of the active treatment group and 6.3% of the placebo group had a successful outcome from treatment. The active treatment group had an overall reduction in mean waist circumference of 0.98 inches at 2 weeks and 1.08 inches at 4 weeks. The placebo group had no significant reduction in waist circumference. Similarly, there was a significant reduction in hip circumference after active treatment, with a mean reduction of 0.7 inches at 4 weeks, whereas there was no change in the placebo group. The active treatment group also saw reductions in thigh circumference, whereas the placebo group did not.⁵²

Jackson et al⁵³ further reported a series of 689 patients who had undergone LLLT for body contouring. These patients underwent a 2-week regimen of 6 total sessions, as described in the previous study.⁵² The authors had complete data for 660 participants, and the mean overall reduction in waist, hip, and thigh circumference was 3.27 inches. This change was statistically significant. The mean changes for waists and hips were -3.16% and -2.34% , respectively. The authors also measured subjects' untreated areas, such as the neck, chest, arms, and knees. The results showed a significant reduction in untreated areas as well. The exact mechanism for this finding was not known, but the authors concluded that LLLT may be an effective method for body slimming (Level IV Evidence).⁵³

Nestor et al⁵⁴ conducted a randomized, double-blind study using either the Zerona device (20 patients) or a sham control (20 patients) for treatment of the upper arm. Patients were given 6 sessions over 2 weeks and had upper arm circumference measurements taken at 3 points 2 weeks after treatment. The results revealed a significant reduction in total upper arm circumference in the treatment group (mean, 3.7 cm) compared with the placebo group (mean, 0.2 cm) (Level II Evidence).

There have been a number of studies in which serum levels of lipids after LLLT have been investigated. The consensus among these studies is that LLLT causes a reduction

in serum cholesterol and triglyceride levels (Level IV Evidence).^{55,56}

LLLT SUMMARY

There has been interest in the use of LLLT as a noninvasive method of body contouring. The exact mechanism of how LLLT works remains unclear. However, there is some higher-level evidence that shows LLLT to be effective in body contouring. There have been randomized, double-blind, sham-controlled trials that have shown significant circumferential reductions after LLLT.⁵⁴ This evidence has also been supported by a large series of 660 patients in whom the benefits of LLLT were seen. Jackson et al⁵² found overall circumferential reductions in untreated areas as well. This coupled with the results of studies in which there were reductions in serum cholesterol and triglyceride levels have increased interest in LLLT as a method of body slimming.^{55,56}

DISCUSSION

There are currently a large number of devices available that are marketed as noninvasive body-contouring systems. The general mechanism of these devices relies on the use of an externally applied energy to cause adipocyte disruption or apoptosis. The mechanical energy-based devices have shown only little improvements in terms of circumferential reductions, and they require numerous repeated treatments. These devices are generally not used for body contouring.

The radiofrequency devices have become the most popular systems for body contouring at this time. There are a large number of these machines available, and they all have varying specifications. The most commonly used ones include the VelaShape or VelaSmooth devices, which are bipolar machines. These require more sessions than do their monopolar counterparts. There have been numerous case series in which the effectiveness of these devices has been shown, but few studies with high levels of quality and evidence exist.

External ultrasound devices are also very popular machines for noninvasive body contouring. There are a number of studies in which the safety of these devices has been illustrated in both animal and human models. The 2 most commonly used machines of this type are the UltraShape and Liposonix devices. The literature contains a number of case series that have shown modest improvements in circumference measurements after these treatments. There was a study with level II evidence that supported the use of the UltraShape device, but there has also been a case series in Asian subjects in which the device was not found to be effective.^{32,34} The Liposonix HIFU device has also been shown to be effective in a

number of series. In the only study on the Liposonix device with level II evidence, the authors did not make any comments about the clinical effectiveness of the machine; they only highlighted its safety profile.³⁸

The concept of cryolipolysis is relatively new to the body-contouring sector, and there is currently a lot of marketing promoting these devices. The mechanism of action for these devices and their safety profile have been demonstrated in animal studies.^{39,40} All clinical data for these devices are based on case series. There are no studies with high levels of evidence to support the use of these devices or to prove their effectiveness.

Finally, the role of LLLT in noninvasive body contouring has been elucidated. The underlying mechanism of action still remains under debate, but there is evidence in the literature to show that this device works. There was a small, randomized, controlled trial that demonstrated LLLT to be effective in circumferential reduction.⁵⁴ Some evidence has also emerged to support the use of these devices as generalized slimming machines and as devices that can improve serum cholesterol and triglyceride levels.

There is generally not much in the way of high-level evidence to support the use of any of the noninvasive body contouring devices. The research papers that have been published are often supported by the companies that manufacture the machines or are authored by investigators who have financial interests in the companies. There are no comparative trials to demonstrate the effectiveness of one technology over the other, with the exception of an article comparing the TriActive and VelaSmooth devices.⁹ The majority of studies also had very short-term follow-up periods with no long-term evaluation of the duration of the treatment results. The majority of studies failed to account for patient variables, such as generalized weight loss from lifestyle changes, that can contribute to reductions in measurements and affect outcomes.

A review article of this nature has some potential limitations. I used broad search terms, such as body contouring, to identify relevant studies for inclusion. Use of broad terms should help to avoid missing articles; however, there could be some relevant papers that were not included. I included more specific terms for individual devices to ensure that all relevant papers were found. The classification of levels of evidence for the studies was largely defined by the authors of the individual papers, which could introduce some bias.

CONCLUSION

The noninvasive device market needs further studies to evaluate these devices. Studies are also needed to compare and contrast devices to identify which technology provides the most benefit in terms of outcomes for patients.

Disclosures

The author declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding

The author received no financial support for the research, authorship, and publication of this article.

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