CHAPTER

12

Noninvasive Skin Tightening and Body Contouring

Andrew A Nelson, Mathew M Avram

INTRODUCTION

Mankind has long been obsessed with achieving the so-called "perfect body"; in differing times and different circumstances, the ideal body has evolved. Currently, in our image-obsessed culture, many people possess a strong desire to lose weight to achieve their perfect body. Unfortunately, obesity is an epidemic in our culture and weight loss is a challenging goal for many. While traditional dieting and exercise remain the best way to lose weight and maintain the weight loss, this may not work for all patients. Even patients who have achieved weight loss may continue to have small "problem areas". As a result, patients are increasingly turning to their physicians desiring new technologies to help achieve body contouring and the ideal body.

Historically, liposuction was the only means to achieve body contouring. And while liposuction remains the gold standard, it is an invasive procedure with associated pain, bruising, and downtime. Modern medicine has witnessed a dramatic movement towards minimal or no downtime procedures, as patients have become increasingly unwilling to tolerate prolonged healing or recovery times. The field of body contouring has rapidly evolved in the last several years with the introduction of numerous new technologies including lasers, radiofrequency devices, ultrasound devices and cryolipolysis. These noninvasive devices have been reported to have multiple beneficial effects including: improving the appearance of excess adipose tissue, reducing the overall volume of fat, reducing waist and thigh circumference, improving the appearance of cellulite and skin tightening. While these technologies are relatively new, and their potential utility must ultimately be determined by well done randomized scientific studies, the initial results and possibilities are incredibly exciting.

DETERMINING YOUR PATIENT'S CURRENT STATUS AND TREATMENT GOALS

The first step in determining which treatment option is best for your patient is to first assess your patient and discuss their therapeutic goal. Depending on your patient's status, as well as their "problem areas" and goals, certain devices may be a better option.

The classic definition for obesity is based on a patient's body mass index (BMI) (It is calculated as a person's weight in kilograms divided by the square of his/her height in meters). This is a quick and easy calculation for patients and physicians. Obese patients are defined as those patients having a BMI greater than 30. Typically, obese patients (BMI > 30) are not good candidates for noninvasive body contouring and likely would benefit more from bariatric or other surgical interventions to help achieve meaningful weight loss. Thus, the simple BMI calculation may help to determine those patients who are not ideal candidates for noninvasive body contouring. Unfortunately, the BMI is also an oversimplification, as it does not necessarily take into account the patient's mixture of muscle and adipose tissue, or their overall body type. Many

patients who present for noninvasive body sculpting may be in very good shape overall with a normal BMI, but feel plagued by only a few small problem areas, such as the thighs or flanks. Therefore for these patients, the authors utilize measurements such as thigh circumference, waist circumference, skin fold thickness, visual assessment, and photographic comparisons pre- and post procedure in our practice; these assessments more typically reflect the patient's ultimate clinical presentation and outcome.

It is also important to differentiate between fat and cellulite when assessing your patient. Excess fat and obesity are due to an overabundance of structurally normal adipocytes. In contrast, cellulite is best considered as a structural abnormality of adipocytes. How then does normal fat become cellulite? This remains an area of ongoing research, but it is thought that cellulite may result from hormonal changes. Cellulite is rare in prepubertal females and males of any age, but is so common in postpubertal females that some researchers classify cellulite as a female secondary sexual characteristic. Estrogens are thought to stimulate lipogenesis while inhibiting lipolysis, thereby contributing to cellulite formation. Furthermore, it is believed that certain body areas have less effective lymphatic and vascular circulation, thereby contributing to the development of cellulite in these "high-risk areas". Ultrasound and magnetic resonance imaging (MRI) studies have documented the significant structural alterations between normal adipose tissue and abnormal cellulite structure. In normal adipose tissue, the fibrous septae between the lobules of adipose tissue are arranged in an overlapping criss-cross pattern, creating greater strength of the tissue. Cellulite, on the other hand, has fibrous septae that are arranged parallel to each other, and perpendicular to the skin surface. This weaker structure allows for the focal herniation of adipose tissue, which ultimately contributes to the classic undulating, lumpy, "cottage cheese" appearance of cellulite. It remains unclear whether the presence of excess adipose tissue increases the risk of the development of cellulite. As a result of the differences between excess normal adipose tissue and structurally abnormal cellulite, the authors believe that excess fat and cellulite should be considered distinct entities and treated as such. Certain devices that may be effective for treating cellulite may not treat excess adipose tissue, and vice versa.

Once the patient has been evaluated and their treatment goals discussed, the patient and the treating physician can begin to effectively discuss the noninvasive body contouring options. Determining the best treatment option for your patient is dependent on clinical presentation, treatment goals, and most importantly—the patient's preferences.

PHYSICAL TREATMENT OF FAT AND CELLULITE

Noninvasive Devices

Endermologie (LPG Systems, Valence, France) is an FDA (United States Food and Drug Administration) cleared device, which improves the appearance of cellulite through massage and kneading of the affected skin. The device combines positive and negative pressure created between two rollers to physically manipulate the patient's skin. The technique is thought to stimulate blood and lymphatic flow, thereby altering the architecture of the fat and improving the appearance of cellulite. It is less clear if Endermologie has any effect on reducing unwanted excess adipose tissue. Modest clinical improvements in cellulite have been documented in clinical studies. A study by Güleç of 33 women who were treated with Endermologie for 15 sessions, demonstrated a statistically significant improvement in the appearance of cellulite as assessed by a visual scale; however, few of the patients (5 of the 33 patients) actually demonstrated clinical improvement.[1] A recent study by Collis et al. compared twice weekly treatment with Endermologie to a combination treatment of aminophylline cream and Endermologie; the authors concluded that Endermologie is not an effective treatment of cellulite, although 10 out of 35 patients with Endermologie-treated legs reported that their cellulite appearance clinically improved.[2] In summary, Endermologie may result in modest improvements in the clinical appearance of fat and cellulite; however, it is likely that ongoing treatments would be necessary to maintain the improvement.

Radiofrequency Devices

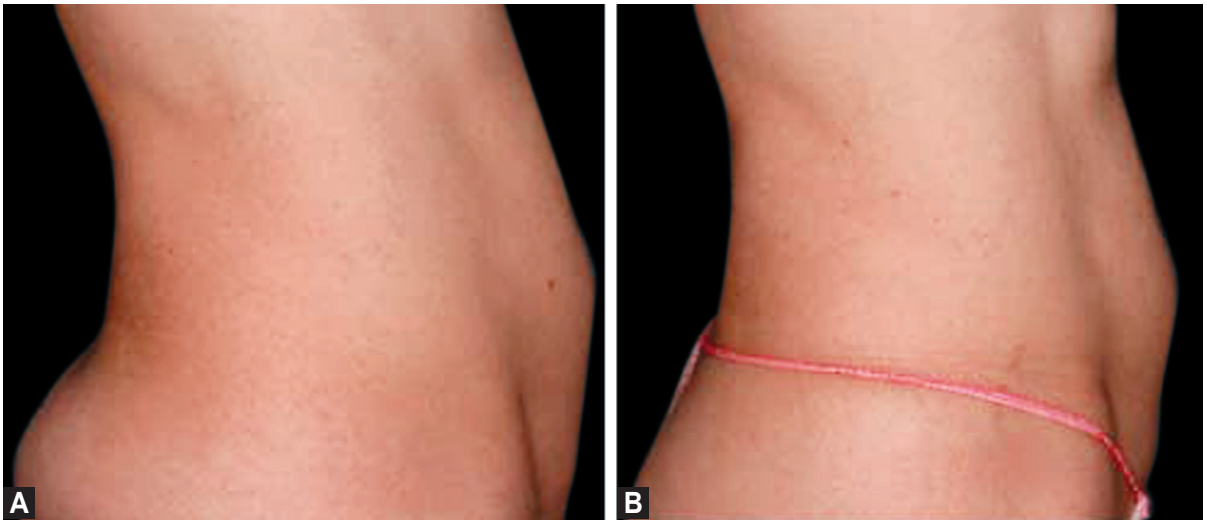
Radiofrequency (RF) devices pass sinusoidal, alternating current (AC) through tissue thereby causing ionic flow and ultimately heat from molecular friction. In essence, the tissue itself is the source of the heat, instead of the actual device. Radiofrequency is therefore thought to create localized heat in the targeted tissue mass, while limiting the collateral

spread of energy, neuromuscular reactions, or electrolysis. Adipocytes have high tissue resistance and relatively low heat transfer coefficients; as a result, adipose tissue can be readily heated by RF technologies and the heat will be relatively localized to the adipocytes. Recently, many RF devices have been advertised to improve the appearance of fat and cellulite.

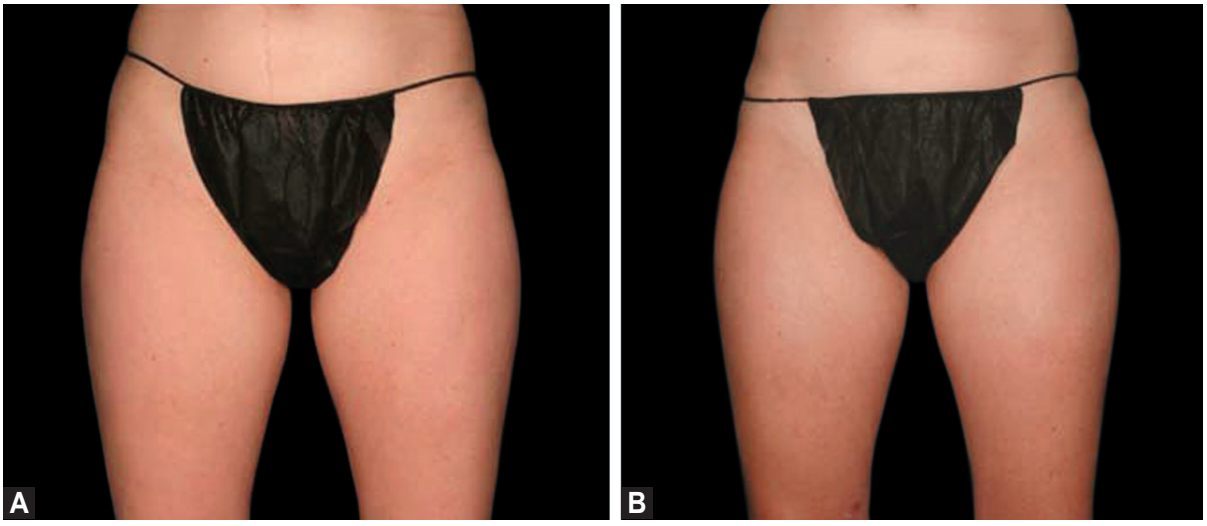
The VelaSmooth and VelaShape (Syneron Medical Ltd, Irvine, CA) devices combine physical manipulation similar to Endermologie (massage and suction), with bipolar RF energy and broadband infrared light (700–2000 nm) to treat excess fat and cellulite. It has been proposed that these devices heat subcutaneous tissue and fat, resulting in increased blood flow and lipolysis in the treatment areas, thereby improving the appearance of fat and cellulite. In a randomized clinical study by Nootheti et al., patients were treated twice weekly for 6 weeks with either the VelaSmooth device or another laser device for cellulite (TriActive, Cynosure Inc, Westford, MA).[3] Seventy-five percent of patients were observed to have an improvement, when comparing pre- and post-treatment photographs, but the results were modest. Patients were also observed to have a decrease in the upper and lower thigh circumference, as well as an improvement in the appearance of cellulite (Figs 12.1 and 12.2). However, no statistically significant differences in the efficacies of the two devices were observed and no placebo group was included in the study. Bruising is a common side-effect following treatment with the VelaSmooth device, likely related to the vacuum pressure and physical manipulation of the tissue rather than the RF technology itself .

Unipolar, volumetric RF devices with more diffuse, deep heating are also being studied for the treatment of fat and cellulite. Thirty patients were treated by Goldberg et al. with a unipolar RF device (Accent, Alma Lasers US, Buffalo Grove, IL) every other week for a total of 6 treatment sessions; a decrease in mean leg circumference of 2.45 cm was observed, although the study was limited due to a lack of placebo or untreated controls.[4]

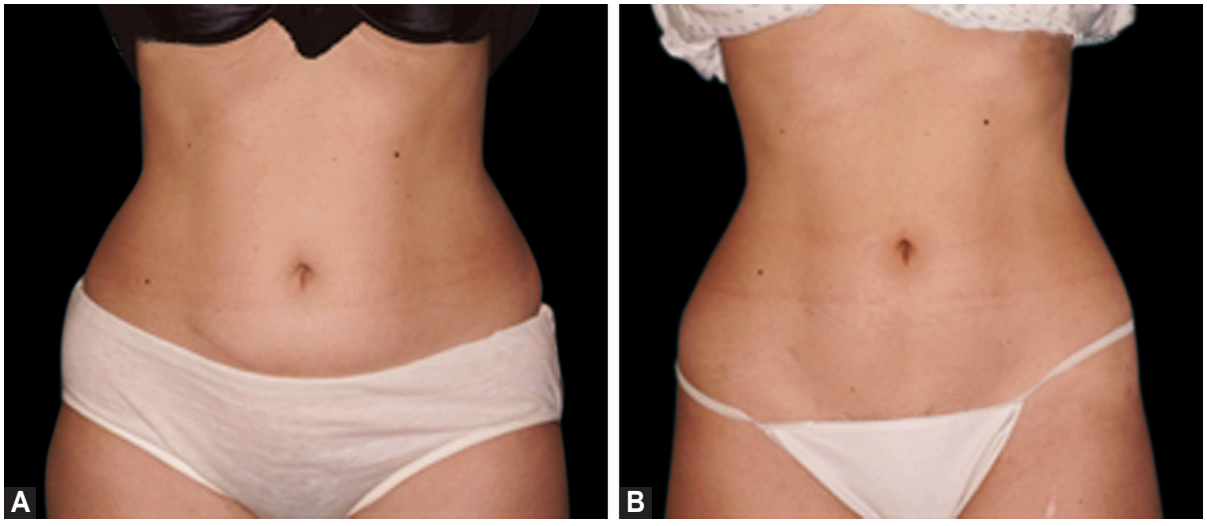
Recently, a novel RF device combining controlled radiofrequency heating and high voltage ultrashort electrical pulses has been developed to treat adipose tissue (BodyFX, InMode Inc, Richmond Hill, Canada). The BodyFX system utilizes a vacuum system and traditional RF heating to warm the tissue and adipocytes to the range of 43–45°C. This heats the triglyceride droplet within the adipocyte and begins thermal adipocyte apoptosis. The BodyFX device then delivers high voltage RF pulsing, which electroporates the cell membrane, basically poking a hole in the adipocyte membrane, leading to apoptosis of the adipocyte. These two mechanisms act synergistically to achieve greater levels of adipocyte apoptosis and greater clinical improvement. In initial studies, BodyFX has been shown to reduce circumferential measurements of treated areas, as well as improve



Figs 12.1A and B: Clinical improvement in the appearance of the abdomen of a 60-year-old woman before (A) and 3 months after (B) treatment with VelaShape. Baseline circumference: 87 cm; 3 month follow-up circumference: 84 cm
Source: Photos courtesy of Dr Lori Brightman. Reprinted with permission from: Kim J, Lask G, Nelson A (Eds). Comprehensive Aesthetic Rejuvenation: A Regional Approach. New York: Informa Healthcare; 2012



Figs 12.2A and B: Clinical improvement in the appearance of the thighs of a 41-year-old woman before (A) and 6 months after (B) treatments with VelaShape. Five treatments, radiofrequency level: 3, infrared level: 2. Vacuum level: 1, treatment duration: 3 minutes 53 seconds and 10 minutes 10 seconds. Mean baseline measurement: 58.5; mean 6-month follow-up measurement: 56.8 cm
Source: Photos courtesy of Dr Lori Brightman. Reprinted with permission from: Kim J, Lask G, and Nelson A (Eds). Comprehensive Aesthetic Rejuvenation: A Regional Approach. New York: Informa Healthcare; 2012



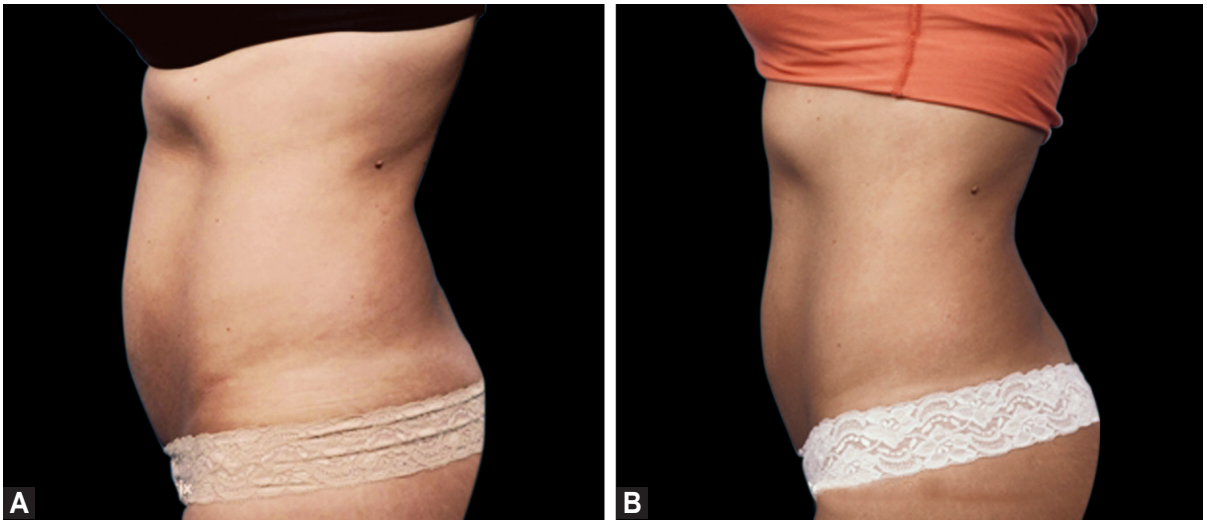
Figs 12.3A and B: Clinical improvement in abdominal circumference "muffin top" before (A) and 1 month after (B) 8 weekly treatments with the BodyFX device. Note that there is not only the reduction in subcutaneous adipose tissue, but there is tightening of the overlying skin as well
Source: Photos courtesy of Dr Steven Mulholland

the appearance of cellulite (Figs 12.3 and 12.4). At this time, the BodyFX device has not been cleared by the United States Food and Drug Administration, although it is approved in Canada, Europe, Australia, and parts of Asia. The BodyFX device represents a very exciting option for the treatment of excess fat, as it combines the added benefit of tightening the treatment area through traditional RF.

These RF technologies represent safe and efficacious therapeutic options for patients, although further clinical studies are necessary to establish their exact roles.

Ultrasound Devices

The diagnostic utility of ultrasound devices has long been established; more recently, high intensity



Figs 12.4A and B: Clinical improvement in abdominal circumference "muffin top", shown in profile view, before (A) and 1 month after (B) 8 weekly treatments with the BodyFX device. Note that there is not only the reduction in subcutaneous adipose tissue, but there is tightening of the overlying skin as well
Source: Photos courtesy of Dr Steven Mulholland

focused ultrasound (HIFU) devices have been developed to treat adipocytes and the subcutis. The LipoSonix device (Medicis Technologies Corp, Scottsdale, AZ) was recently FDA cleared for noninvasive waist circumference reduction. Other ultrasound devices are not yet FDA cleared or commercially available in the United States for the treatment of fat and cellulite.

A recent study by Jewell et al. of the LipoSonix high intensity focused ultrasound (HIFU) device documented significant improvement following a single treatment session.[5] One hundred and eighty patients were randomized to one of two different doses of HIFU or to a sham treatment. Twelve weeks following the single treatment, the patients treated with the higher HIFU dose had achieved a statistically significant improvement in waist circumference compared to the sham group (–2.44 cm versus –1.43 cm). Patients were observed to have "improved" or "much improved" outcomes as assessed by physicians, and patients were satisfied with their treatments. Common adverse events following the treatment included pain, bruising and edema. However, no significant laboratory abnormalities were observed following treatment, including: lipid profiles, markers of inflammation, coagulation, liver or renal function, hematologic assessments, or blood chemistry.

Another novel ultrasound technology, the Ultrashape Contour I (Ultrashape Ltd, Tel Aviv, Israel) is being used in Europe and the United Kingdom for the treatment of excess adipose tissue. A recent prospective, nonrandomized, controlled trial of 164 patients was conducted by Teitelbaum et al., to determine the efficacy of the device.[6] A total of 137 patients underwent one Ultrashape treatment to the abdomen, thighs, or flanks. Twelve weeks after the treatment, circumference reductions of the abdomen (mean reduction: 2.3 cm), thighs (mean reduction: 1.8 cm), and flanks (mean reduction: 1.6 cm) were observed. The majority of the improvement in measured circumference was noted to occur within the first two weeks following treatment.

Ultrasound technologies represent a new and evolving area within the field of noninvasive fat treatment. Ultrasound technologies can also be incorporated into invasive liposuction procedures, known as ultrasound-assisted liposuction (UAL). While this is an effective treatment method, it requires an invasive liposuction procedure. More recently, novel noninvasive high intensity focused ultrasound technologies have been developed for improving the appearance of fat and cellulite. While these devices require further clinical study to determine their long-term efficacy and safety profile, they represent an exciting and promising opportunity within this field.

Lasers and Light Sources

Multiple novel light sources and laser technologies have been developed as therapeutic options for fat and cellulite. Historically, these laser devices were

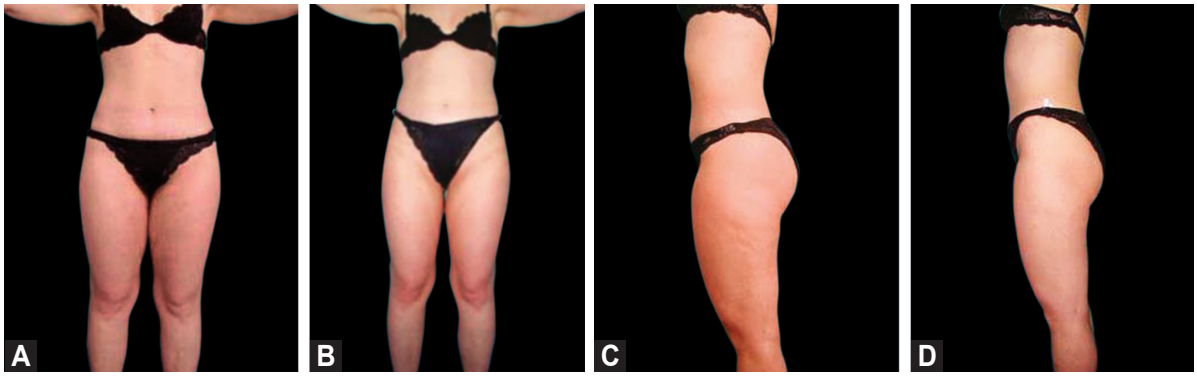
utilized as an adjunct with liposuction, known as laser-assisted liposuction (LAL). More recently, new noninvasive laser and light source devices have been marketed for the treatment of fat and cellulite. It is important to note that several devices which are advertised to improve fat and cellulite actually do not affect the adipocytes themselves, but rather, target the dermis in an attempt to stimulate collagen formation/remodeling. Devices with wavelengths in the near-infrared region, as well as intense pulsed light (IPL) sources, fall into this category. At the time of this writing, few laser devices are FDA cleared for the direct treatment of fat and cellulite.

The TriActive device (Cynosure Inc, Bedford, MA) combines deep tissue massage and suction (similar to Endermologie), with contact cooling and a low-intensity diode laser (808 nm). The TriActive device is thought to improve the appearance of cellulite by increasing lymphatic drainage, improving blood flow and tightening the skin in treated areas. Patients typically are treated with the device twice weekly, with progressive improvement following each treatment. In clinical studies, patients were noted to achieve objective reductions in hip and thigh circumference as well as subjective improvements in the appearance of cellulite, including a reduction in the appearance of skin dimpling, improvement in the overall contour of the limb, and improvement in overall skin texture (Figs 12.5A to D). TriActive treatments were generally well tolerated, although approximately 20% of patients developed mild bruising.

The SmoothShapes device (Eleme Medical, Merrimack, NH), combines two different wavelengths of laser with a physical massage system similar to Endermologie. The 915-nm diode wavelength liquefies fat, while the 650-nm wavelength improves fat membrane permeability, thereby allowing the adipocytes to be mobilized to the interstitium. A treatment session consists of multiple passes with the SmoothShapes device, and two to three treatment sessions are performed each week for best results. In clinical studies by Lach and Kulick, the SmoothShapes device results in reduction of the thickness of the subcutaneous fat pad, as assessed by MRI.[7,8] The device was well tolerated with no significant associated adverse events.

The VelaSmooth and VelaShape (Syneron Medical Ltd, Irvine, CA) devices, as discussed previously, combine physical manipulation, bipolar RF energy, and broadband infrared light (700–2000 nm) to facilitate a multimodality approach to fat and cellulite treatment. The efficacy of these devices was previously discussed in the section regarding radiofrequency. In the future, more devices may approach fat and cellulite treatment through this multimodality approach in an effort to achieve greater efficacy.

Recently, a low-level laser device (Zerona, Erchonia Inc, McKinney, TX) was FDA cleared for the noninvasive reduction of circumference of hips, waist and thighs. Zerona is a low-level diode laser (615 nm), which produces five independent beams. The center beam is fixed, while the four remaining beams can be individually adjusted allowing multiple body areas (abdomen, flank, thighs) to be treated simultaneously. The exact mechanism of action has not been fully elucidated, though it has been proposed that low-level laser therapy stimulates the



Figs 12.5A to D: Marked clinical improvement in appearance in thighs before (A and C) and after (B and D) 19 treatments with TriActive

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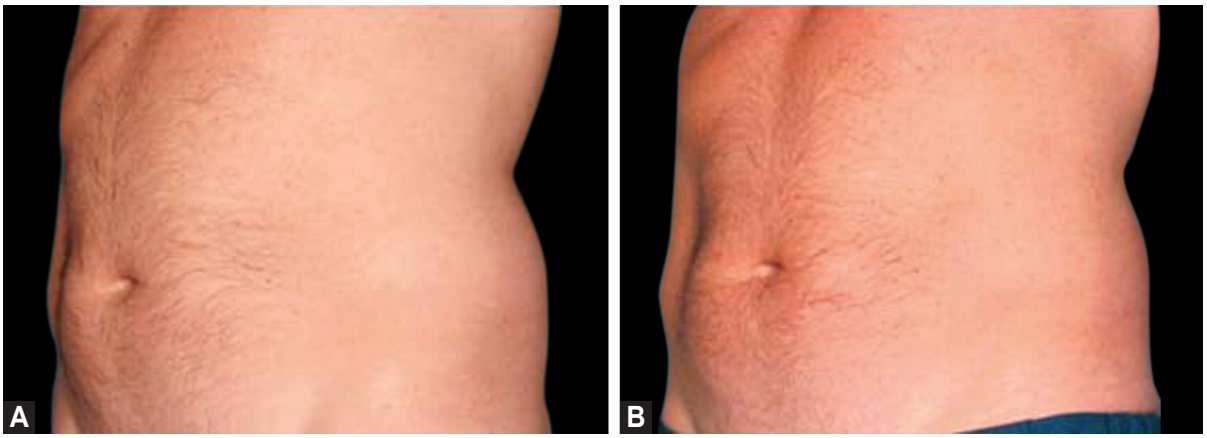
fat cell to emulsify; the liquefied fat is then mobilized via a temporary pore in the cell membrane from inside the cell to the interstitium, where the fat is ultimately absorbed into the lymphatic system. Typically, Zerona treatments are performed every other day for a total of six treatments, with each treatment lasting approximately 40 minutes. In a recent clinical trial, a total of 67 patients were randomized to either six treatments with the Zerona device or six "sham" treatments. At the completion of the study at 2 weeks, the "active" treatment group averaged a cumulative reduction of 3.54 inches compared to the "sham" group which averaged a cumulative reduction of just 0.68 inches. No significant adverse effects were observed in the study. Low-level laser therapies represent another potentially promising treatment option for excess adipose tissue.

Cryolipolysis

CoolSculpting (Zeltiq Aesthetics, Pleasanton, CA) is a relatively novel FDA cleared device for noninvasive fat reduction. CoolSculpting utilizes cryolipolysis technology (controlled cold exposure) to selectively cool fat, thereby causing adipocyte apoptosis. The treatment cycle lasts approximately 60 minutes, at the conclusion of which, the skin appears cool, firm and erythematous. Following the treatment, the physician massages the area gently to break up any crystallized adipocytes. Over the next several weeks to months, the adipocytes undergo apoptosis, are mobilized and ultimately eliminated by the body. Typical treatment areas include the flank "love handle", the back "back fat pads" or the abdomen "muffin top" (Figs 12.6A and B). In a recent clinical study, a significant reduction in the thickness of the fat in the treatment area was observed following a single CoolSculpting treatment (mean fat pad thickness reduction of 22.4%, as measured on ultrasound). Of the 32 patients in the study, all had achieved a significant visible contour improvement following a single treatment. The best results were in patients with localized, discrete fat bulges. Treatments are typically well tolerated, although patients may develop bruising as well as transient altered sensation, numbness or even pain in the treatment area. CoolSculpting represents a safe, novel and efficacious, noninvasive treatment option for fat.

CONCLUSIONS

The last few years have witnessed profound changes in the field of body contouring with the development of safe, effective and noninvasive technologies. These noninvasive devices have been reported to have multiple beneficial effects including: improving the appearance of excess adipose tissue, reducing the overall volume of fat, reducing waist and thigh circumference, improving the appearance of cellulite, and skin tightening. While liposuction and surgical procedures remain the gold standard for patients seeking large volume fat removal, many patients prefer these novel noninvasive therapies as simple, no downtime procedures to improve the appearance of limited fat and cellulite.



Figs 12.6A and B: Clinical improvement in the appearance of the abdomen of a 56-year-old man at baseline (A) and 2 months after (B) a single treatment with the CoolSculpting Breeze device vacuum, massage 60 minutes each. Baseline: 88 cm; FU 2-month circumference: 86 cm

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Physical manipulation devices, radiofrequency devices, ultrasound devices, lasers and cryolipolysis have all been developed for the noninvasive treatment of fat and cellulite. Each technology has its own risks and benefits. Ultimately, rather than there being one single best technology for all patients, it is likely that different technologies will have specific patient types and situations in which they are best suited. As a result, it is important for physicians to assess each patient individually, discuss their current state and ultimate treatment goals, and choose a device accordingly. Ultimately, determining the best treatment option for your patient is dependent on clinical presentation, treatment goals, and most importantly, their patient's preferences. Following these principles, it is possible for patients to undergo safe, effective, noninvasive treatments to improve unwanted fat and cellulite.

SUMMARY

- Obesity is an epidemic; traditional exercise and dieting may not be effective for everyone. Many patients now turn to noninvasive technologies to achieve their ideal body.
- Noninvasive therapies represent safe, effective methods to treat limited areas of unwanted fat and cellulite. These technologies include: physical massage of the areas, radiofrequency, ultrasound, laser and cryolipolysis technologies.
- Physical massage of tissue is thought to improve the appearance of fat and cellulite by altering blood and lymphatic flow. Ongoing therapy may be necessary to maintain the improvement.
- Radiofrequency (RF) devices utilize alternating current to generate ionic flow and localized heat in adipocytes. Newer RF technologies also create holes in the adipocyte membrane (electroporation). These changes cause apoptosis of adipocytes, improving the appearance of fat and cellulite.
- High intensity focused ultrasound can also specifically target adipocytes, causing apoptosis, and thereby improving the appearance and thickness of the subcutaneous fat layer.
- Multiple laser devices, typically utilizing near-infrared wavelengths (in combination with physical manipulation), have been developed to improve the appearance of fat and cellulite by stimulating dermal collagen formation.
- Cryolipolysis is a technology which is thought to cause adipocyte apoptosis through controlled cold exposure (heat extraction), gradually improving the appearance and thickness of the fat layer over several months following the treatment.
- There are few head-to-head studies comparing these technologies, so it is not possible to determine an "ideal" device for all patients. It is likely that each technology may have a specific patient type or treatment area for which it is best suited.
- The best treatment option for your patient is best determined by discussing the options with the patient, their ultimate treatment goals and reaching an informed decision together.

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