Tissue Restructuring by Energy-Based Surgical Tools

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KEYWORDS

• Tissue restructuring • Energy devices • Noninvasive cosmetic surgery • Radiofrequency • Ultrasound

KEY POINTS

- Advancements in surgical techniques have to the development of many noninvasive concepts or incorporation of existing concepts into plastic surgery armamentarium; stem cells-based therapies, mesotherapy, and energy-based surgical tools such as ultrasonic, radiofrequencies, lasers, cryogenic, hydromechanical, microwave technologies are among the newest developments.
- Clinical outcomes following noninvasive procedures with energy-based devices tend to be much more subtle than those following invasive surgical procedures.
- As with any medical procedure, noninvasive procedures carry some degree of risk of adverse effects as those resulting from non-uniform healing after application of ultrasonic energy, lasers or radiofrequencies in addition to trivial problems such as transient edema, skin erythema, bruises.

OVERVIEW

Various oils, creams, and lotions have been used for skin-quality maintenance and beautification over the centuries. However, the quest for the preservation of youth and beauty has evolved with the introduction of invasive cosmetic plastic surgery procedures, which have been developed and popularized since the beginning of the last century. During the last 2 decades, advancements in surgical techniques have paralleled advancements in dermatologic sciences, leading to the development of many noninvasive concepts (eg, stem cells–based therapies, mesotherapy) and modalities (eg, lasers) and providing new tools for cosmetic surgery and medicine. Energy-based surgical tools, including ultrasonic, radiofrequency (RF), cryogenic, hydromechanical, and microwave technologies with the capability of tissue cutting, sealing, or restructuring, complement these medical concepts well by allowing noninvasive, non–open-access interventions. Energy-based noninvasive surgical tools can be used for ablative bio-stimulation (eg, collagen production) or tissue restructuring functions (eg, tightening or lifting) and they are the subject of this review. Experience with a laser-therapy device for body contouring (1440 nm wavelength laser for soft tissue sculpting), as an example of laser-based technology applied to body contouring, is reviewed in another article of this issue. Additionally, because the focus of this article is tissue restructuring and its applications in aesthetic surgery, hydromechanical tools (eg, water-jet technology used to cut and emulsify soft tissue) are not featured.

THERAPEUTIC OPTIONS

In general, the application of noninvasive energy-based devices for tissue restructuring can lead to results that are less dramatic than those from surgical procedures.[1–4] However, patients find value in the reduced amount of downtime needed to

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recover from noninvasive procedures by energy-based devices. For this reason, the noninvasive energy-based technologies have become popular, even when treatments must be repeated to achieve an optimal result or when approximating the result of an invasive procedure.

The typical 2 tissue-restructuring objectives for currently available energy-based devices are

1. Two-dimensional tissue shrinkage resulting in tissue lifting and/or firming
2. Volume-reducing and body-contouring techniques

Both objectives have energy-based technologies with modalities that are based on controlled thermal damage to the tissue. Therapeutic options for the most common conditions are depicted in **Table 1**. Ultrasound (US), RF, cryolipolysis, laser-assisted therapies, and even soft radiation have found an application in these objectives.

US-BASED DEVICES

US-based devices generate a US beam, which can be focused to a predetermined depth of penetration and placement of energy. After passing innocuously through the skin (or superficial skin layers), focused US waves reach a focal point where alternating waves of compression and rarefaction rapidly heat tissue (ie, thermal coagulation) or mechanically disrupt the target tissue via cavitation. Depending on which tissues are targeted and the degree of tissue disruption, focused US can be used for different purposes. These purposes include the lifting and tightening of the skin and skin-adjacent tissues (ie, microfocused US [MFUS]) or body contouring (ie, high-intensity focused US [HIFUS]).[2–4]

MFUS

MFUS therapy uses US energy (in a low megahertz range) to noninvasively firm, tighten, and shrink the dermis and subdermal tissues producing a lift of soft tissues. There is currently only one commercially available MFUS device approved by the Food and Drug Administration (FDA) (the Ulthera System; Ulthera, Inc, Mesa, Arizona), with another recently available in the Korean market (Doublo System; Hironic Co LTD, Korea), which integrate real-time US imaging with focused US energy. This integration allows the clinician to target the desired treatment depth for the precise delivery of energy below the surface of the skin without affecting the intervening tissues. Multiple removable transducers offer a choice of depths for MFUS penetration (**Fig. 1**). In general, higher-frequency transducers are used for a more superficial tissue effect compared with lower-frequency transducers. For example, a 4-MHz transducer is characterized by a 4.5-mm depth (appropriate for deep dermis or SMAS treatment in facial areas) and a 7-MHz transducer is characterized by a 3.0-mm depth.[3,4] Unlike in focused US ablation therapies (eg, for tumors), which interlace coagulative sonication zones to ensure complete tumor ablation, cosmetic MFUS applications involve

Table 1
Energy-based devices for tissue restructuring: therapeutic options

Technology	Source of Energy	Wavelength or Other Physical Parameter	Tissue Target	Indication
Low-level laser therapy	Red light or near infrared	600–1000 nm	Subcutaneous fat, within a few millimeters range	Desire for focal, noninvasive fat reduction
MFUS	Ultrasound	4–10 MHz	Dermis, SMAS, frontalis, platysma muscles	Excessive skin laxity, need for skin tightening, forehead, brow ptosis
RF	Electromagnetic waves	300 MHz to 3 KHz	Dermis	Excessive skin laxity, mild skin wrinkling
Cryolipolysis	Thermoelectric cooling systems, cold air, contact cold gel panels	−3°C to 7°C	Subcutaneous fat, probably within a few millimeters range	Superficial subcutaneous fat collections, mild tissue ptosis (eg, jowls)
HIFUS	Ultrasound	2 MHz	Subcutaneous fat, up to 30-mm range	Superficial and intermediate fat deposits

Abbreviations: HIFUS, high-intensity focused ultrasound; MFUS, microfocused ultrasound.

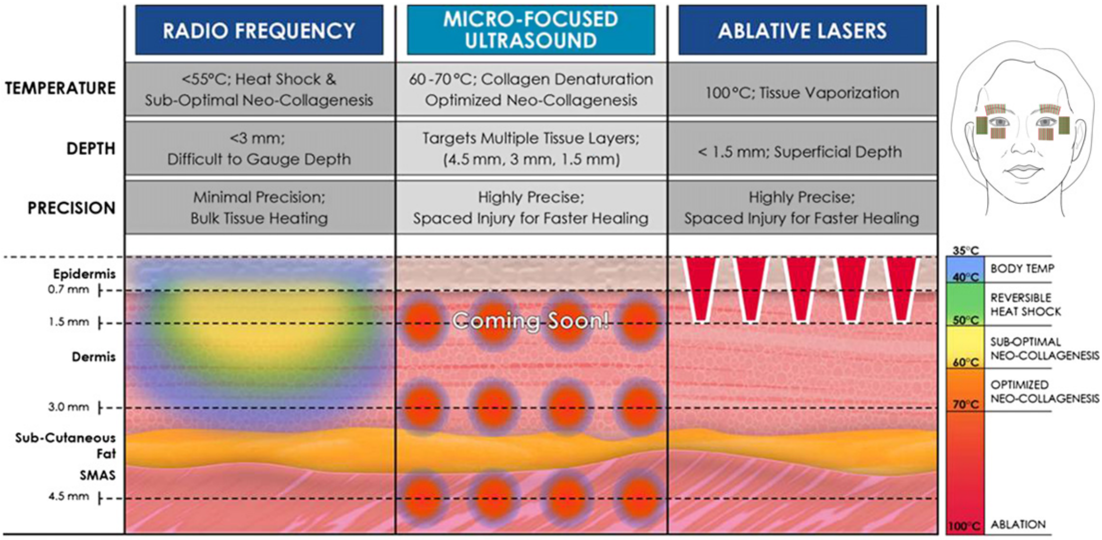

Fig. 1. General characteristics and differences between energy-based modalities for tissue restructuring. (*Courtesy of* Ulthera, Inc, Mesa, Arizona; with permission.)

treatments delivered in lines of small precisely spaced zones of tissue coagulation in the targeted tissues.[3,5] To help track the placement and quantity of the treatment lines delivered, the treatment area is marked using a standardized facial grid (**Fig. 2**). Zones of coagulation placed in the target tissues (eg, SMAS) undergo the wound healing process to produce subcutaneous microscars that contract, resulting in treated tissue firming or an aesthetic unit lift as the result of cumulative linear or gridlike field contracture (**Fig. 3**).

HIFUS

HIFUS generates high-energy US waves (up to 10 000 W/cm^2) for lipolysis. The energy for HIFUS is typically more diffuse, and the focal points converge deeper than MFUS, delivered 10 to 30 mm below the skin level, targeting the subcutaneous adipose tissue. Like MFUS, HIFUS creates a temperature in the range of 56° to 65°C at its focal point, delivering the thermal energy to the targeted fat tissue layer without damaging intervening tissues (overlying and underlying fat). However, because the physical characteristics of HIFUS interaction with tissue predicated in a more diffuse and deeper way (than for skin-tightening devices) but still within a 3-cm reach, for the best possible result skin should contract over decreasing in volume of subcutaneous fat. Truly obese patients with poor skin tone are not good candidates for body contouring using this technology because the skin may not contract or re-drape deeper layers of tissue uniformly (**Fig. 4**).[6,7] Devices that deliver focused US energy on a 2-MHz wavelength have received much attention recently because they seem to be effective in disrupting adipocyte cell membrane, releasing intracellular content, and initiating triglycerides absorption. The cumulative goals of these treatments are ultimately in tissue volume reduction and contour change for the treated body part (see **Fig. 4**).[6,7]

RF DEVICES

A common mechanism of action for tissue restructuring and body-shaping technologies is through heat generated by tissue impendence to the RF current, resulting in the denaturation of the tissue components and subsequently soft tissue matrix remodeling.[2,7–9] The depth of energy delivered by an RF device depends on several factors, including the configuration of electrodes (monopolar vs bipolar), the conduction medium (type of tissue), parameters, and the frequency of the electrical current applied.[8] The gradient of energy delivered by RF devices is shaped by the position of electrodes. The first device to use monopolar RF for skin tissue tightening was the ThermaCool system (Thermage Inc, Haywood, California). ThermaCool operated in the 6-MHz RF range.[2,7,8] The activation of RF (fixed number of firing in a defined time) produces heat and the homogenous zone of coagulation at the depth depending on RF penetration depending on tip design (see **Fig. 1**b). Heating of the dermal layer causes collagen restructuring; as the healing progresses, the contraction of the collagenous scaffold results in skin firming (**Fig. 5**).

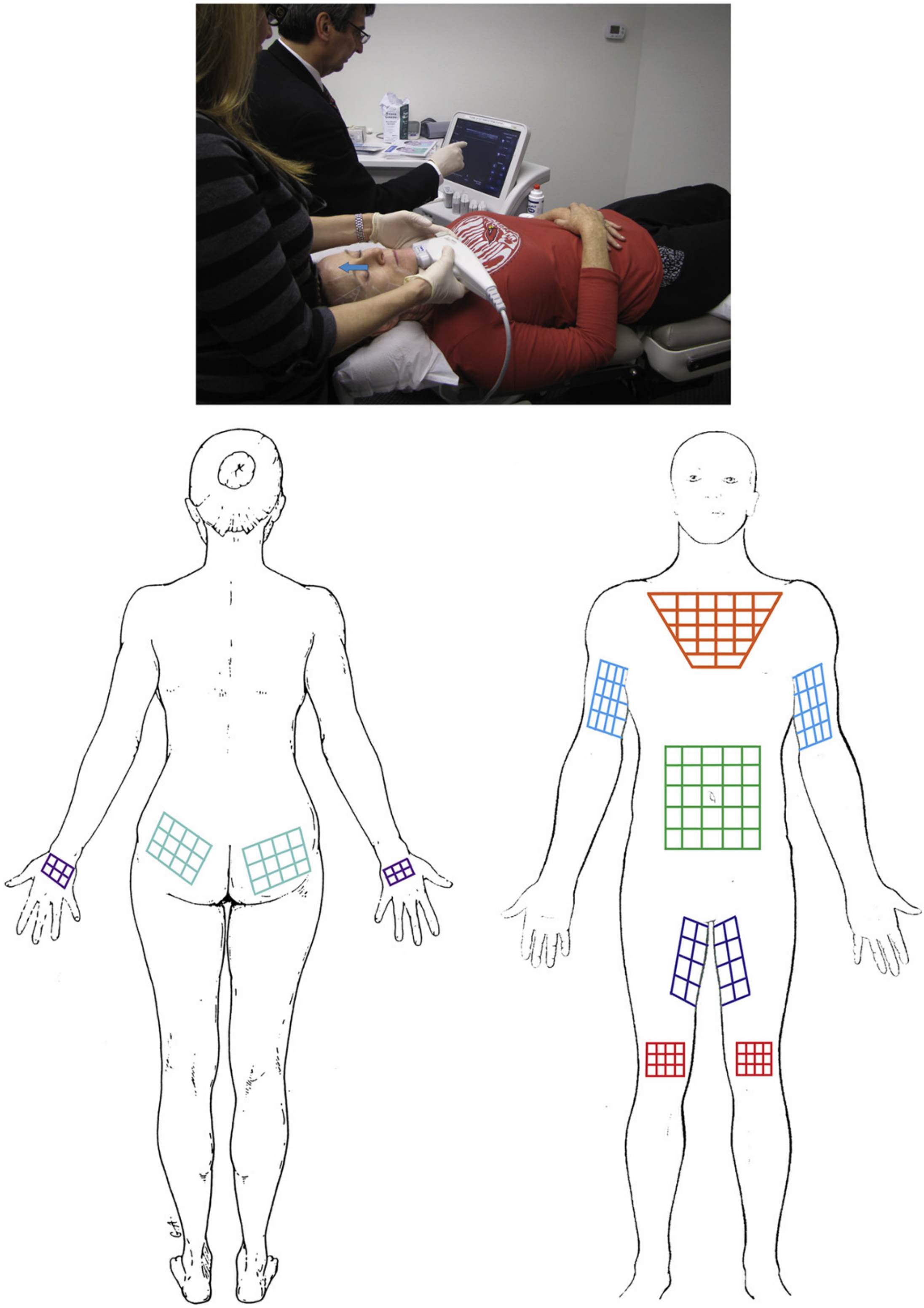

Fig. 2. Focused tissue coagulation is generated with precision of prescribed plane of treatment and healthy intervening tissue between zones of thermal coagulation. Grids and markings of lines of treatments help in positioning of energy delivery (*arrow*).

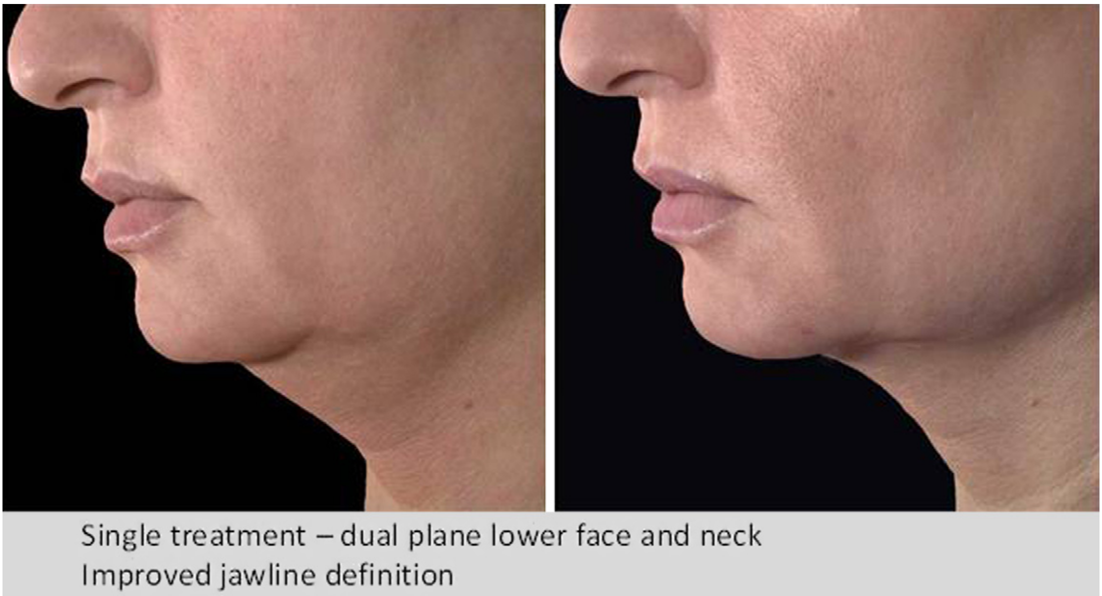

Fig. 3. Dual plane (dermis at the level 3 mm) and platysma or SMAS (at the level 4.5 mm) were subjected to focused ultrasound. For enhanced result, treatments are repeated 2 or 3 times in 2-month intervals. (*Courtesy of* Ulthera, Inc, Mesa, Arizona; with permission.)

CRYOLIPOLYSIS

Cryolipolysis energy systems (eg, Lipofreeze, Zeltiq, Pleasanton, California) expose soft tissues to external thermal devices in an attempt to lower temperatures to achieve selective tissue apoptosis. Body contouring by cryolipolysis relies on lowering the temperature of the skin and the underlying subcutaneous fat to the point whereby the lipids within the adipose tissue begin to crystalize

Fig. 4. HIFUS seems to be particularly effective in nonobese patients with good skin quality. In patients with good skin quality, skin retraction follows thermal ablation of subcutaneous fat producing pleasing aesthetic outcomes. (*Courtesy of* Solta Medical, Inc, Hayward, California; with permission; *Data from* Jewell M, Baxter RA, Cox SE, et al. Randomized sham controlled trial to evaluate the safety and effectiveness of a high intensity focused ultrasound for noninvasive body sculpting. Plast Reconstr Surg 2011;128(1):253–62; and Mulholland RS, Paul MD, Chalfoun C. Noninvasive body contouring with radiofrequency, ultrasound, cryolipolysis, and low-level laser therapy. Clin Plast Surg 2011;38(3):503–20.)

Fig. 5. Nonsurgical skin tightening secondary to radiofrequency treatment (Thermage). Recent modifications of Thermage technologies allow deeper penetration of RF, treatment of deep dermal layers inducing denaturation, and subsequent contraction of the tissue. (*Courtesy of* Solta Medical, Inc, Hayward, California; with permission; *Data from* Hodgkinson DJ. Clinical applications of radiofrequency: nonsurgical skin tightening (Thermage). Clin Plast Surg 2009;36(2):261–8.)

while remaining warm enough to prevent permanent damage to the overlying dermis. This temporary lowering of the surface temperature to approximately −3°C to 6°C does not cause permanent damage to the skin but triggers apoptosis of the adipose tissue and gradual resorption (over the period of weeks) of injured cell contents and lipid remnants, ultimately resulting in the desired loss of volume and skin retraction (**Figs. 6** and **7**). In cryolipolysis, the temperature lowers from the surface (there is no reversed gradient of temperature changes like in MFUS treatments) and the effect depends on the depth of freezing and the different susceptibility of different tissues to freezing.[7,10]

Fig. 6. Lipofreeze: the basis of this treatment is the notion that exposure to specific low temperatures (cold air delivered via hose behind the infrared thermometer) will selectively damage subcutaneous adipose tissue while leaving the skin undamaged. After the targeted freezing of the fat cells, apoptosis and gradual fat resorption begins resulting in a fat layer or deposit volume decrease and body recontouring. Blanching indicated by the arrow.

LASER-ASSISTED CONTOURING

Low-level laser therapy (eg, Zerona, Erchonia Medical, McKinney, Texas) has been shown to cause adipocyte content leakage when exposed to laser energy at 635 nm. Research continues to establish the most efficacious specific laser wavelength for this phenomenon. The lasers at this wavelength are thought to stimulate mitochondria to form transitory pores in the bilipid membrane of adipose cells. The pores then allow the cell contents (triglycerides and fatty acids) to leak into the interstitial space. Research has suggested that this is not damaging to the cell but allows for escape of the cell content and assists in the ease in which liposuction might be performed.[7,11,12] There are questions about whether laser-assisted lipolysis alone is sufficient for significant volume reduction. However, technologies that combine laser-assisted liposuction (using laser energy at 1064/1320 nm) may additionally demonstrate a selective capability to induce changes in dermal collagen scaffold and subsequently in dermal tightening, which may be a more promising approach.[11,12] A detailed discussion of laser-assisted tissue sculpting with 1440-nm wavelength devices is presented in another article of this issue.

Indications for Specific Therapeutic Options

As with any procedure, patient selection is key. To ensure reasonable expectations, proper selection

Fig. 7. Before and after Lipofreeze treatments. Repeated treatments resulted in lateral hips tissue firming and reduction of saddlebag fat deposits. (*Courtesy of* Dr Simon Ourian.)

requires explaining to patients that results from noninvasive energy-based procedures will be less dramatic than with invasive methods of rejuvenation (see **Table 1**). Additionally, currently available tissue-tightening devices are not suited for patients with significant loss of tissue tone, with severe laxity, or with structural ptosis (frequently observed in patients with a history of a massive body weight loss). Therefore, unrealistic expectations are obviously a key contraindication for the application of all types of tissue-restructuring modalities. Other considerations involve the treatment of patients with existing medical conditions, which should be handled based on the patients' medical history, what is written of the subject in the medical literature, the practitioner's own clinical experience, and any other clinical information that may be available from the device company. An example of this is the treatment of patients with active inflammatory skin lesions (eg, acne). Such patients should not have affected areas treated with energy-based devices because the energy may lead to the exacerbation of existing problems (**Fig. 8**).

CLINICAL OUTCOMES

Clinical outcomes following noninvasive procedures with energy-based devices tend to be much more subtle than those following surgical procedures. As with any type of procedure, energy-based technologies do not offer guarantees of clinical efficacy, and outcomes will vary between patients depending on factors, such as age, gender, skin type, genetics, and lifestyle. Also, outcomes often vary between devices within each category, and clinical data for certain technologies can be sparse depending on the regulatory requirements. This situation can lead to uncertainty as to the clinical efficacy and safety of some techniques and devices within each category, especially the "me too"–type devices, which may rely on the clinical data of predecessor technologies for market acceptance and FDA approval. In such cases, clinical experience reports in the medical literature may serve to elucidate the utility of any devices in question.

Some newer modifications of RF- or US-based devices include programs allowing multiple-pass

Fig. 8. Patient with preexisting to MFUS forehead lift acne lesion developed eruption of cellulitis around the acne pustule, which subsided with days of topical and oral antibiotics treatments.

techniques for greater efficacy of applied energy.[2] As new energy-based surgical tools proliferated, many of them were modified to enhance their efficacy and additional performance-improving modalities were added (eg, surface cooling capability) to allow more energy to be delivered to the target tissues without safety concerns (eg, burning the superficial tissues). For example, many skin-tightening devices can work in tandem with other modalities in an effort to produce a complementary or even synergistic approach (**Table 2**).

Each of the energy-based technologies mentioned has been shown to produce some degree of clinical efficacy in published studies, which resulted in the FDA approval for at least one device in each category. Notable are the clinical outcomes as defined by the pivotal US studies for the first-in-class devices for each category.

- US
  - MFUS: In a rater-blinded prospective cohort study (n = 35), patients were evaluated after receiving MFUS (Ultherapy, Ulthera Inc, Mesa, Arizona) treatment on the forehead, temples, cheeks, submental region, and the side of the neck using probes targeting tissue at depths of 4.5 mm (both 4 MHz and 7 MHz) and 3.0 mm (7 MHz). Masked assessment of patient photographs before and 90 days after treatment showed clinically significant lifting of the brow (*P* = .00001), with a mean lift of 1.7 mm.[3,4,13,14]
  - HIFUS: In a multicenter, randomized, sham-controlled, single-blind study, adults with at least a 2.5-cm thick layer of subcutaneous fat were randomized to receive HIFUS treatment (Liposonix, Solta, Hayward, California) of the abdomen and flanks. Patients received treatment that consisted of 3 passes at 47 J/cm, 59 J/cm, or 0 J/cm (sham control). At week 12, change versus sham was shown to be significant for patients treated with 59-J/cm (-2.44; *P* = .01) but not with 47 J/cm (-2.06 cm; *P* = .13). Improvement over sham was also marked by investigator assessment by global aesthetic improvement and patient satisfaction.[6]
- RF: A reduction of facial skin surface in up to a 20% range, compared with the nontreated area and surface characteristics improvement in terms of the reduction of wrinkling, was noted using RF technology.[2] However, a study comparing monopolar RF (Thermage TC-3 System, Solta Medical, Hayward, California) and MFUS, using a split-face brow lift model, revealed no statistically different efficacy between devices.[15] Clinically, cooling systems minimizing patient discomfort are an advantage of modern RF systems. RF systems are contraindicated in patients with a pacemaker, defibrillator, or other implanted electronic devices that could be deprogrammed by RF.[9]
- Cryolipolysis energy devices: Despite the encouraging observations regarding cryolipolysis for body contouring, there are no published long-term safety and efficacy data on humans available in the medical literature to date. One device company has data on file that claims interim data from a multicenter, prospective, nonrandomized, bilateral study of 32 patients using cryolipolysis for subcutaneous fat reduction.[16] In this study, patients were given a single treatment on one flank with

Table 2
Examples of commercially available hybrid energy-based skin-tightening devices

Technology	Basic Modality	Performance Modifying Modality	Commercial Example
High-frequency RF	RF	Combination of unipolar and bipolar technology	Accent XL
RF	RF	Continuous cooling of the skin	Exilis
RF	Bipolar RF	Simultaneous vacuum suction	Reaction
RF	Bipolar RF	Infrared light, vacuum, mechanical massage	VelaShape II
Laser	Multiple wavelengths 1064, 1320, 1440 nm	Blend of multiple wavelengths allows simultaneous skin tightening and fat reduction	Smartlipo Triplex

a prototype cryolipolysis device (Zeltiq, Pleasanton, California). It is reported that patients were assessed 4 months following treatment, and 27 out of 32 (84%) showed visible improvement in the treated area, with a mean reduction in the subcutaneous fat (as measured by US) of 22.4%.

- Laser-assisted contouring: A double-blind, randomized, placebo-controlled trial of 67 patients was performed to evaluate the application of a 635-nm low-level laser for use as a noninvasive body-contouring treatment on the waist, hips, and thighs.[17] Study patients received either a low-level laser treatment or a sham treatment 3 times per week for 2 weeks. After 2 weeks, the treatment group saw 62.9% of patients with a circumference reduction of 3.0 in or greater over all body parts, whereas only 6.4% of the sham group showed a reduction of 3.0 in or greater. The mean reduction in circumference at the end of the treatments (week 2) was 3.52 in for the treatment group and 0.62 in for the sham group. However, 2 weeks after the final treatment, the mean circumference for the treatment group increased 0.31 in.

Other technologies using a 900-nm and 1064-nm range also seem efficient in disrupting fat, thus triggering fat deposits resorption. A combination of 1064 nm and 1320 nm seems to be useful for selective fat cell disruption, water vaporization, and demonstrated tissue-tightening potential at the same time.[12,18] Outcomes of clinically promising 1440-nm technology are presented in another article of this issue.

Overall, representative results of focused US, RF, and cryosculpting demonstrate very encouraging overall results (see **Figs. 3–5** and **7**). Further assessment of cryolipolysis and laser-assisted contouring must be made before any true effectiveness can be determined.

COMPLICATIONS AND CONCERNS WITH NONINVASIVE PROCEDURES

With any medical procedure, there is some degree of risk of adverse effects, and there is no exception with noninvasive procedures. Thermally (heat or cold) induced lipolysis raises a concern regarding the release of triglycerides into the lymph and blood. The relatively slow lipolysis process of these technologies probably explains that post-procedure spikes are not significant enough to pose a risk to the general health of patients.[6] In general, both the HIFUS and cryolipolysis procedures are safe, with no serious adverse effects registered. With many of the energy-based technologies, patients occasionally report transient edema, bruises, and skin erythema.[1,2,8] Arnica topically and orally should facilitate to resolve edema and bruises. Topical and systemic antibiotics may be indicated in case of activation of inflammatory skin conditions (see **Fig. 8**). A short course of steroids, such as oral prednisone, should be reserved for cases with more significant edema with or without signs of nerve impairment (eg, in situations when patients develop asymmetrical animation and presumably some transient neuritis) following RF, HIFUS, or MFUS. However, it should be noted that chronic use of antiinflammatory drugs may impair the efficacy of skin-tightening devices that exploit the body's immune/inflammatory pathways. Linear dyschromia (in the form of hyperpigmentation or hypopigmentation), which is seen rarely and probably in conjunction with the use of more superficially acting RF or US modalities (at the level of papillary dermis), should be protected from ultraviolet by sunblock when outdoors and treated with topical bleaching agents in case of persisting hyperpigmentation.[2,13,14] Skin surface depressions secondary to nonuniform 2- and 3-dimensional recontouring was occasionally observed with monopolar RF devices (**Fig. 9**).[19] These late effects of monopolar RF treatments may resolve spontaneously (or with massage). Scarring of the dermis or fibrous septa of between lobules of subcutaneous fat may require surgical subcision, fat, or synthetic filler administration for contour augmentation.

Fig. 9. Some loss of pigmentation (medial arm skin) and linear subcutaneous arm fat atrophy noted in a patient previously treated with RF.

SUMMARY

Few would dispute that the introduction of energy-based devices to aesthetic surgery and medicine has not been successful. However, the variability in tissue response in terms of restructuring by energy-based devices is rooted in the individual differences in chemical and physical properties, such as tissue stiffness, fat architecture, water content, heat absorption, and many other factors, and may sometimes impact consistency.[11,18,20–22] Although some physically different modalities (eg, use of heat for lipolysis vs use of cool) seem to produce a similar clinical effect, there is no doubt that continued research will establish evidence assisting in the optimal selection of safe energy-based tools that address specific patient objectives for the best possible result.

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