

Radio Frequency Energy for Non-invasive and Minimally Invasive Skin Tightening

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KEYWORDS

- Radiofrequency • Nonablative • Fractional radiofrequency
- Invasix • RFAL • Skin tightening • Skin contraction
- Tissue tightening

Much of the surgical effort in plastic surgery is devoted to the enhancement of patients with skin laxity. The gold standard of skin laxity therapy has always been, and remains, skin excision. Whether face-lift, breast-lift, abdominoplasty, or brachioplasty, removal of excess skin through well-placed incisions most often results in excellent clinical results and a happy patient. However, the scars, stigmata, morbidity, and fear of excisional procedures keep most patients looking for less-invasive skin-tightening procedures and, in many cases, away from the plastic surgeon's office.

As this timely issue in *The Clinics in Plastic Surgery* is devoted to noninvasive and minimally invasive plastic surgery, this article focuses on the rapidly growing area of "nonexcisional" skin tightening. The aging baby boomers are a formidable demographic force. There is a person turning 60 years old every 10 seconds, and it is estimated that more than one-fourth of the total US population in 2006 was between 42 and 60 years old.¹ This represents more than 100 million potential patients with skin laxity of the head, neck, and body. As there are approximately

150,000 face-lifts, breast-lifts, arm-lifts, and tummy-tucks per year in the United States, only 1% to 2% of patients with skin laxity ever present for a skin excisional procedure.² Over the past 10 years, there have been tremendous technological developments and marked growth in skin-tightening devices that can be performed non-invasively or minimally invasively. In fact, skin tightening is one of the fastest growing market segments, accounting for \$56.9 million in device sales and 668,100 patient treatments.² With a sales growth of 10.3% annually, it is anticipated that this market will grow to 2 million treatments in 2013.²

Clearly, many aging patients will accept less significant results with noninvasive and minimally invasive skin tightening than the more effective skin-excisional procedures. It is important for plastic surgeons to keep current with patient alternatives and to become familiar with and in some cases, master, the nonsurgical options available to patients with lax skin. Further, many plastic surgeons can and do benefit from offering noninvasive skin tightening to those patients who might not want surgery and offer nonsurgical skin tightening for those patients who undergo skin excision

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and are looking to “protect their investment.” Whether the nonexcisional skin-tightening procedures are part of a postoperative maintenance treatment regimen, or a totally nonsurgical skin-tightening program in the plastic surgeon’s office, skin-tightening devices can be a valuable adjunct in treating patients with lax skin.

Practice growth for the plastic surgeon can benefit from using the right noninvasive skin-tightening strategy, as controlling the patients’ “upstream” nonsurgical experiences through neurotoxins, soft tissue fillers, skin tightening, color correction and texturizing laser, and light and radiofrequency (RF) technologies can enhance the downstream volume of patients presenting for surgical procedures, as they already have a noninvasive relationship with their surgeon. Excisional surgeons who offer noninvasive, nonexcisional treatments in their practice have the ability to offer patients all options in the skin-laxity market.

This article reviews the noninvasive and minimally invasive options for skin tightening, focusing on peer-reviewed articles and presentations and those technologies with the most proven or promising RF skin-tightening results for surgeons who perform skin excision. RF has been the mainstay of noninvasive skin tightening and has emerged as the “cutting edge” technology in the minimally invasive skin-tightening field. Because these RF skin-tightening technologies are capital equipment purchases with a significant cost associated, this article also discusses some business issues and models that have proven to work in the plastic surgeon’s office for noninvasive and minimally invasive skin-tightening technologies.

It is the author’s hope that this information provides a good overview of the evolution, growth, and opportunities for nonexcisional RF skin-tightening technologies available to plastic surgeons who treat skin laxity.

CLASSIFICATION OF SKIN-TIGHTENING DEVICES

Over the past 2 decades, there has been an explosion in noninvasive and minimally invasive therapies to enhance skin rejuvenation. Characteristics of the aging face include fine rhytids and dynamic rhytids in early aging followed by fixed, deep rhytids both dynamic and static in the glabella area of the forehead and around the eyes. There is a loss of dermal substrate, including functional collagen, elastin, and ground substances.³ The epidermis tends to thicken and there is general loss of subcutaneous fibrous connectivity with loss of midface soft tissue volume, periosteal absorption, and ptosis of soft tissues, leading to

a more prominent naso-labial fold, labial mental lines, the elongation of the lid-cheek junction, and jowls. Superficial epidermal-dermal changes include dyschromias, brown discoloration, hyperpigmentation, erythema, telangiectasia, rosacea, and dark melanin dyschromia, especially in photo-damaged skin.³ For the past 15 years there has been tremendous growth and development of technologies that address these various aging facial changes.

Older chemical ablative techniques and macrodermabrasion gave way to ablative laser resurfacing, including carbon dioxide and erbium YAG lasers.^{4–6} Full-face laser ablation, although tremendous at rhytid reduction and significant superficial skin tightening, often led to an unacceptable degree of postoperative recovery and erythema, swelling, and downtime, in addition to long-term complications of demarcation, pigmentation abnormalities, and scarring.^{7,8} As the aging population over the past 10 to 15 years has increasingly sought esthetic enhancement procedures, there has also been an increasing desire to seek therapies that have less recovery downtime and morbidity than traditional ablative laser or chemical treatments.²

The busy social and professional lives of our patients have necessitated the growth and expansion of a whole minimally invasive or noninvasive area of skin rejuvenation. Enhanced improvements in laser technology design and experiences and procedures around the world have resulted in the evolution of many nonablative technologies that have attempted to simulate the results of ablative carbon dioxide and erbium YAG lasers. Although the downtime and recovery from these nonablative laser and light-based technologies is far more desirable than full ablative lasers, multiple treatments are often required and the long-term results of rhytid reduction, skin tightening, diminishment of pores, and texture irregularities are often subtle at best.^{9–11}

These nonablative laser and light devices work by a photon interaction with a dermal chromophore, melanin, deoxygenated or oxygenated hemoglobin, and/or dermal water. The end pathway of these photon-chromophore interactions is the generation of heat, which may lead to a resolution of the chromophore, a subablative, noncoagulative inflammatory response, and, over time, mild to modest enhanced dermal levels of elastin, collagen, and ground substance.¹⁰ This nonablative, selective photothermolytic remodeling process will often result over several months, in very subtle rhytid improvement, some subtle to moderate tightening or texture improvements, and, depending on the device, improvements in melanin and/or vascular discoloration. Examples

of these devices include early infrared devices, such as the Cool Touch Infrared Laser (1320 nm) (Roseville, CA, USA), the 1064 Neodymium Lag Laser, the 1440 ND YAG Laser, the Smooth-beam Infrared Laser (1450 nm diode) (Wayland, MA, USA), as well as numerous intense pulse-light technologies (585 to 1100 nm) and pulse-dye laser technology (585 nm and 595 nm). Virtually every wavelength between 500 nm and 2000 nm has been developed and used in conjunction with some aspect of skin rejuvenation: color correction, skin tightening, or rhytid textural diminishment. Although all of these technologies work to a greater or lesser degree, they often fall far short of the type of skin-tightening results that patients are seeking.⁹⁻¹¹

The advantages of these noninvasive, nonablative technologies and probably why they have proliferated, is that many esthetic physicians have a comfort level using them. The technical barrier to entry in using these nonablative devices is minimal. Often, nonablative technologies lend themselves well to delegation to nonmedical health professional staff under a physician direction and can be combined with Botox, soft tissue fillers, microdermabrasion, and other minimally invasive techniques to achieve quite pleasing esthetic results.¹² Color correction has been an important part of nonablative enhancement over the past 10 to 15 years. Intense pulse-light photorejuvenation and pulse-dye technologies have dominated the sector of laser technology revolving around correction of vasculature and melanin-based dyschromia.¹²

The need for a nonablative technology that results in significant tissue tightening without disrupting the epidermal-dermal junction, led to the development of nonablative RF skin-tightening technologies. The RF tightening technologies, led by Thermage™ (Solta Medical, Hayward, CA, USA) and, later, by Syneron Medical Ltd (Yokneam Illit, Israel) and other companies, have created a nonablative, transepidermal skin-tightening array of treatment protocols and techniques that have proven to be quite successful in achieving moderate and potentially pleasing skin tightening for patients.^{3,12-18} In deciding on a method of classifying these RF skin-tightening technologies, a more anatomic approach has been adopted that takes into account the very exciting growth areas of minimally invasive RF skin tightening through the delivery of skin-tightening laser or RF energy to the immediate subdermal space and bypassing altogether or combining at a later date classic transepidermal-dermal RF skin heating. The following list sets out the classification system. One can divide skin-tightening devices into 2 broad categories: transepidermal delivery of energy and subdermal delivery of energy.

Classification of RF and energy-based skin-tightening devices

1. Transepidermal Energy Delivery
 - a. Transepidermal Laser Energy Devices

Various wavelengths, pulse durations, and pulse configurations: 585, 595 pulse-dye technology, nm pulse dye, 755 nm, 810 nm, 900, 980 nm diodes, 1064 nm, 1320 nm, 1440 nm, and 1500 nm series lasers
 - b. Infrared lamp technology, 700 nm and 2000 nm infrared lamps
 - i. Sciton SkinTyte (Palo Alto, CA, USA)
 - ii. Cutera Titen (Brisbane, CA, USA)
 - c. Monopolar RF energy
 - i. Thermage™ (Solta Medical, Hayward, CA, USA)
 - ii. Accent (Caesarea, Israel)
 - d. Bipolar RF energy in combination with other light sources
 - i. Syneron Medical Ltd (Yokneam Illit, Israel) intense pulse light and bi-polar RF
 - ii. 810 nm diode and bipolar RF
 - iii. 950 nm diode and bipolar RF
 - iv. Infrared lamp bipolar
 - e. Multipolar Transepidermal Skin-Tightening RF Devices
 - i. TriPollar (Pollogen, Tel Aviv, Israel)
 - ii. Octopolar, Freeze (Tel Aviv, Israel)
 - f. Intense pulsed light
 - i. 500 nm to 1200 nm intense pulse-light systems
 - ii. Lumenis Lume 1 (Yokneam, Israel), the Palomar Starlux (Burlington, MA, USA), Syneron Medical Ltd E-Max (Yokneam Illit, Israel), the Sciton BBL (Palo Alto, CA, USA), the Alma laser Harmony (Caesarea, Israel)
2. Transepidermal Fractional Energy Delivery
 - a. Transepidermal fractional carbon dioxide resurfacing
 - i. Active and DeepFX Lumenis (Yokneam, Israel)
 - ii. Fraxel Repair, Solta Medical (Hayward, CA, USA)
 - iii. Affirm CO2 Smart Skin, Cynosure (Westford, MA, USA)
 - b. Transepidermal fractional delivery of infrared wavelengths
 - i. Fraxel Renew, Solta Medical (Hayward, CA, USA)
 - ii. Affirm MPX 1320/1440, Cynosure (Westford, MA, USA)
 - iii. Lux 1540, Palomar (Burlington, MA, USA)
 - iv. Matrix IR, Syneron Medical Ltd (Yokneam Illit, Israel)
 - v. Fractional Pearl, Cutera (Brisbane, CA, USA)

- c. Fractional infrared delivery of erbium YAG Er:YSGG (Yttrium Scandium Gallium Garnet)
 - i. Profractional, Sciton (Palo Alto, CA, USA)
- d. Fractional transepidermal RF energy
 - i. E-Matrix and Matrix RF, Syneron Medical Ltd (Yokneam Illit, Israel)
 - ii. Fractora, Invasix (Yokneam, Israel)
- 3. Subdermal Delivery of Energy
 - a. Subdermal delivery of fiber-optic laser energy
 - i. SmartLipo, Cynosure (Westford, MA, USA)
 - b. Subdermal delivery of RF energy
 - i. BodyTite, NeckTite, FaceTite, and CelluTite RF
 - ii. Liposuction and skin-tightening devices, Invasix (Yokneam, Israel).

This anatomic classification is significant because a clinician can now divide the skin-tightening opportunities using RF energy sources and laser devices into those that deliver their energy across the epidermal-dermal junction, resulting in nonablative treatment of the epidermal-dermal junction, or a complete dermal ablative procedure through traditional ablative carbon dioxide and erbium YAG technology, or a fractional transepidermal nonablative and/or ablative experience. All of these devices will interact with dermal water, resulting in a photothermolytic thermal response and, depending on whether the device is principally ablative, nonablative coagulative, or a combination, an inflammatory stimulus of various magnitudes will affect the tissue. The more ablative devices will require an epidermal-repair process and some remodeling of the ablated or coagulative nonablative injury to the dermal substrate. Generally, the more ablative the laser or photon device, the better the tightening results will be.³

Into this transepidermal delivery of laser energy has evolved the transepidermal delivery of RF energy. Through minimal to no epidermal-dermal ablation, one can deliver RF energy into the dermis, where, rather than targeting traditional chromophores, such as hemoglobin, melanin, or water, all molecules in the RF pathways are oscillated 1 million to 6 million times per second.^{3,14} It is the resistance to RF traveling through tissue that results in molecular oscillation and thermal energy. RF, either fractional or nonfractional, can be selective and targeted in different depths of the dermis and combined with other energy sources.^{3,14}

The subdermal space has recently become the focus of an intense excitement for skin-tightening technologies and esthetic physicians. As reviewed in this article, new evidence and research has shown that if the energy source, either a laser-based or RF-based device, is placed in the immediate subdermal space, significant soft tissue skin

contraction and correction of laxity can be induced without an excisional procedure or epidermal-dermal ablation. With this new subdermal delivery of RF, the kind of nonexcisional skin-tightening results that many patients are looking for is approached, without seeking the gold standard excisional rhytidectomy or skin-repositioning procedures. The maturation in the transepidermal delivery of monopolar RF (Thermage™) has given patients and clinicians noninvasive options for skin tightening when even subdermal, nonexcisional delivery techniques remain too aggressive.

BASIC SCIENCE OF RF SKIN TIGHTENING

The basic science of skin tightening is really the basic science of controlled dermal heat generation, which is the common final pathway for laser and RF devices. In standard chemical ablation, the chemical agent results in a nonthermal chemical dissolution and coagulation of the associated dermal proteins and the wound healing that occurs over several weeks results in new collagen, elastin, and skin tightening. As the ablative chemical and dermabrasion techniques gave rise to ablative carbon dioxide and erbium YAG lasers, so does the promise of more selective depth control and precision injury. The photothermolytic process involved the photons (10,600 nm for carbon dioxide and 2940 nm for erbium) being attracted to dermal water, resulting in ablative and nonablative coagulative disruption.⁴⁻⁶ Immediate disruption of the collagen triple helix accounted for immediate, "on-the-table" skin-tightening effects and then a secondary tightening effect over 6 months from secondary neocollagenesis, elastin, and ground substance production.^{3,4} The original ablative laser technologies were associated with excessive patient morbidity, potential complications and patient downtime, and resulted in the growth and development of nonablative technologies that attempted to affect the collagen triple helix the same as the more ablative laser wavelengths.^{7-12,15-18} The proliferation of wavelengths and energies from intense pulsed light, pulse dye, the infrared diodes, and infrared heating lamps resulted in a nonablated, intact epidermal-dermal junction, whereas dermal water was the principal chromophore for the infrared devices. Hemoglobin and melanin were the chromophores for very near infrared and invisible skin-tightening light devices. Although there was some superficial papillary dermal collagen and ground substance response to these devices, the clinical results were often difficult to see with standard photography and follow-up results.⁹⁻¹¹ Unless the results were a correction of vascular or melanin dyschromia's

discernable tightening and textural improvement, results were difficult to detect.

With the evolution, growth, and refinement of Thermage™ and monopolar transepidermal RF technology, moderate, consistent, and pleasing skin tightening can be achieved very reproducibly and comfortably.¹⁴ Since the inception and release of Thermage™ in 2002, the evolution to what type of monopolar nonablative RF skin tightening was available in 2010 (the time of this writing) is a testament to a company that has been very much committed to basic science research and understanding the evolution of the effect of RF on biologic tissues. Over the past 8 years, advances have been seen in tip geometry and shape.^{3,14} Although there are other nonablative transepidermal RF devices available, Thermage™ remains the number 1 monopolar RF delivery system in the world.^{2,15–18} Thermage™ also has the most abundant nonablative, RF peer-reviewed science behind it and in this article is the main focus of the transepidermal discussion of RF energy delivery for skin tightening. Thermage™ consists of 3 important components: a generator, a coolant, and an applicator tip. Refined and patented delivery of the monopolar RF energy occurs across a thin membrane.^{3,14} Synchronous cryogen-based cooling and a very sophisticated volumetric delivery of RF energy, depending on the tip size and configuration and pulse configuration, heat a specific volumetric amount of papillary superficial reticular dermis.^{3,14} Over the past 8 years, refinement in Thermage™ tip sizes has improved treatment time.¹⁴ Elegant studies of preauricular biopsies before rhytidectomy have shown that multiple passes at lower Thermage™ fluences result in better, more significant, and enhanced collagen and elastin ground substance production and tissue tightening than fewer passes and higher fluence.¹⁹

Over the years, transepidermal, monopolar Thermage™ delivery of RF energy has become a much more patient-acceptable procedure with less pain and recovery.¹⁴ The monopolar energy delivered by the Thermage™ tip is delivered to a specific volumetric amount of the dermis or subcutaneous space. RF energy does not rely on a classic chromophore or chromophore photon interaction, as in the laser-based technologies but rather it is the resistance to RF energy traveling through tissue that results in generation of heat. It is the volumetric generation of heat through the oscillatory vibration of molecules along the resistant pathways of RF that results in energy. The RF energy can be used on all skin types and is chromophore independent. The clinical results of Thermage™ monopolar RF energy is discussed in the next section on clinical outcomes.

The basic science of subdermal thermal energy delivery is a very new area of intense clinical interest. Barry DiBernardo, in his seminal work²⁰ on subdermal delivery of fiber-optic laser energy, specifically a 1064 nm laser fiber, Smart Lipo, Cynosure, was able to show that subdermal delivery of thermal energy resulted in significant tissue tightening using quantitative and reliable techniques. Studies were able to show that area contraction of the skin of 17% can occur over 3 months following subdermal thermal laser energy delivery.²⁰ That degree of soft tissue area contraction is a very significant amount of soft tissue tightening given that this skin tightening occurs in a nonexcisional fashion. The subdermal laser heating is indeed minimally invasive, as opposed to noninvasive, as local anesthesia must be used and a stab access port must be created to insert the heating device under the skin and into tissue. Most esthetic surgeons who inject a large volume of fillers, make small excisions and are comfortable with human facial anatomy, and are capable of local anesthesia and subdermal delivery of a laser fiber. There is an increased complication rate and risks to subdermal laser and RF delivery. What Dr DiBernardo²⁰ was able to show was that by keeping the epidermal temperatures at 40 to 42°C and a subreticular dermal temperature of 50 to 55°C, the result is a nonablative, coagulative disruption of deep reticular collagen fibers and that a neocollagenesis, which was biopsy proven, occurs over the subsequent 3 to 6 months with significant measurable and quantitative skin and tissue tightening.

The basic science behind the delivery of this subdermal thermal laser energy is quite straightforward. The laser emits a wavelength of light, which can be from 900 nm up to 1400 nm, and in the presence of local anesthesia and subdermal tumescent fluid, the infrared laser photon will be attracted to the chromophore's water and to a lesser extent, hemoglobin and adipose tissue. These chromophores interact with the photons, resulting in a selective photothermolytic response and release of heat. When the tissue heats to critical temperatures higher than 50 to 55°C, it will result in a nonablative coagulative disruption of collagen and then new collagen forms and tissue tightening occurs over approximately 3 to 6 months.

Taking this subdermal laser-tightening paradigm further, Invasix (Yokneam, Israel) introduced into the marketplace a bipolar RF hand piece and device, which is a novel and proprietary technology that attempts to simulate both the nonablative, transepidermal delivery effects of Thermage™ and the subdermal laser heating effect achieved with a laser fiber optic. There are various Invasix

applicators and configurations of the hand pieces, depending on where the internal electrode will be inserted, which can be a very small bipolar hand piece for the face called FaceTite, or neck device called NeckTite, or a much larger device for the body called BodyTite. Each applicator consists of an internal RF probe. This probe can be a hollow RF-emitting suction cannula, if it is to be used for body fat aspiration, used for corporeal body liposuction, or, in the face and neck, it can be a non-aspirating, very small internal RF probe designed to pass directly under the dermis. The internal electrode-probe is coated with Teflon so only the tip emits RF energy. The RF energy from the internal probe then travels directionally in a confined way up to the external electrode, which travels smoothly, in tandem with the internal electrode along the skin (**Fig. 1**). Unlike a monopolar system, which needs to have a return electrode pad somewhere on the body, this bipolar electrode configuration from Invasix allows intense internal RF energy to create heat in the subcutaneous or subdermal space around the internal electrode-probe, while gentle transepidermal dermal heating occurs from the external electrode, which serves as the return electrode for the internally generated RF current (see **Fig. 1**). This unique device, therefore, allows physicians to deliver transepidermal "monopolar" Thermage™ nonablative-type RF heating to the mid and deep dermis and then a more significant RF thermal experience to the

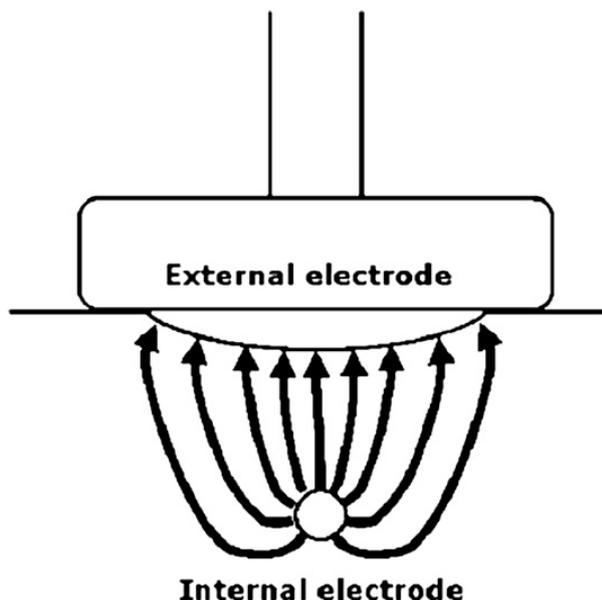


Fig. 1. Radiofrequency energy travels directionally from the internal cannula to the external electrode. The external electrode provides gentle heating of the papillary dermis as well as low and high impedance and temperature cut of control. The internal electrode provides strong coagulative tissue tightening and ablation.

septofascial cutaneous structures in the hypodermis, resulting in matrix-tightening effects in the subdermal and subcutaneous spaces. The various Invasix bipolar applicators, FaceTite, NeckTite, and BodyTite, can be performed under local anesthesia and, like subdermal laser fiber delivery, a physician needs to be skilled in the art of applying anesthesia and know the relevant subcutaneous structures to avoid.

Peer-reviewed results of skin-tightening effects of this novel subdermal and subcutaneous RF delivery, combined with epidermal-transdermal RF delivery from Invasix, have been quite significant.²¹⁻²⁸ Using the BodyTite, RF-assisted liposuction device, the internal cannula can be used to stimulate the septofascial cutaneous fibers in the adipose tissue while the external electrode through transepidermal heat stimulates the dermis. Linear contractions of 15% to more than 30% can be achieved and area contractions averaging 40% to 60% have been reported.^{21-23,25} In addition, work with innovative applicators specifically designed for cellulite and treating in the immediate hypodermal space result in an enhanced collagen barrier in the deep hypodermis, which has been shown to improve the appearance of cellulite, both clinically on cell tissue cultures and histologically. Taking the bipolar applicator, called the FaceTite, onto the face, allows the areas of the brow, infraorbital and supraorbital, malar, jowl, and neck to be treated and preliminary results show significant tightening, brow elevation, and jowl and neck tightening. Clinical results for the internal and external delivery of RF energy are discussed in the sections on clinical results and complications.

CLINICAL PROTOCOL AND RESULTS

Over the 8 years that Thermage™ monopolar RF transepidermal delivery has been available, there have been significant advances on both how the RF is delivered and the patient perception of the treatment as well as the clinical outcomes. Recent studies of a very large number of patients show significant improvement over the original Thermage™ treatment algorithm for rhytid reduction in the face and neck skin tightening.^{3,14} The original algorithm in Thermage™ systems used very high energy and the patient's discomfort was significant. In the original algorithm, studies were able to demonstrate that approximately 26% of patients exhibited immediate tightening and that 50% to 60% of patients observed evidence of skin tightening that was measurable 6 months after treatment. However, almost one-half of patients found the procedure too painful

and only approximately 70% of patients found treatment results met their expectations.³ With continued evolution in tip size, tip algorithms, and energies delivered, and based on pain as an end point for clinical outcome and biopsy results of different energy thresholds, new Thermage™ multiple-pass algorithms with a larger tip and shorter RF pulse configurations showed that almost 90% of patients observed immediate tightening and that more than 90% of patients had visible and measurable moderate skin tightening 6 months after treatment. Only 5% of patients now find the procedure too painful and more than 94% find the treatment meets their expectations.¹⁴ In addition, studies on the transepidermal delivery of monopolar RF energy or bipolar RF energy, with or without the addition of intense pulse light and infrared energy, showed that the procedure can be done safely in the presence of soft tissue fillers, especially when injected in the supraperiosteal space and even when injected in the deep dermal space¹⁴⁻¹⁷ In addition, these transepidermal RF procedures can be delivered in the presence of neurotoxin and can be combined with intense pulse light sources, either during the same treatment session or at subsequent dates and as well as microdermabrasion to enhance the synergistic esthetic results.

By 2010, the transepidermal delivery of monopolar RF energy or bipolar RF energy with or without the addition of visible light sources had become the standard of nonepidermal dermal ablative skin tightening.¹⁴ When patients are appropriately selected, the outcomes tend to be good.¹⁴ The success of Thermage™ and of the nonablative transepidermal delivery of RF resulted in the evolution of other monopolar RF devices and fractional RF epidermal dermal ablative technologies that would conceivably improve the epidermal-dermal junction superficially, as well as provide some deep RF tightening effect. The market leader in this transepidermal fractional delivery of RF energy has been Syneron Medical Ltd's E-Matrix and Matrix RF.²⁹ Results from this technology show that consistent and notable skin tightening can occur and that this can be particularly advantageous in patients with acne and that the fractional RF can be combined with other neurotoxins, soft tissue filler, and intense pulse-light color-correction technologies.¹² Other fraction RF devices that have launched and are pending approval by the Food and Drug Administration (FDA) include the Fractora (Invasix) with deep RF transepidermal fractional needle stimulation for additional skin tightening that can be achieved without the insertion of subdermal or subcutaneous devices. New transepidermal RF tightening devices delivering

RF energy and therapeutic effect with multiple RF electrodes (TriPollar and octopolar) have been developed.²¹⁻²⁸

FRACTIONAL LASER RESURFACING

Although not RF in nature, fractional laser resurfacing deserves some special mention because there had been a tremendous resurgence in fractional carbon dioxide and fractional erbium YAG resurfacing. The wonderfully simple advent of fractionating the carbon dioxide or erbium YAG beam leaving intact epidermal dermal tissue between the columns of photons results in very rapid reepithelialization through marginal epithelialization rather than prolonged reepithelialization by a deep dermal adnexa that was an obligatory component in previous carbon dioxide and erbium YAG ablative procedures. By fractionating or treating only a proportion of the epidermal dermal junction in dermis, the areas of laser thermal zones can occupy between 15% and 85% of the dermis. The more surface area covered by the proportion of fractional injury, the longer the recovery and the longer reepithelialization and resolution of erythema takes. There are various fractional carbon dioxide and fractional erbium YAG manufacturers on the market now. Good results have been achieved with all of them, including the Lumenous, Active and Deep FX, the Reliant Repair, the Cynosure Affirm CO₂, and the Sciton Pro Fractional device. The skin-tightening results of these devices, even after multiple treatments, are not quite as impressive as the full ablative non-fractionated carbon dioxide resurfacing of a decade ago, but the rhytid results exceed those of RF nonablative treatment. In addition, if used with appropriate settings, the risks of hypopigmentation and scar formation are much less than their ablative ancestors. The degree of rhytid reduction with fractional transepidermal RF or fractional laser resurfacing can be quite notable.²⁹

BIPOLAR TRANSEPIDERMAL AND SUBCUTANEOUS RF ENERGY DELIVERY

The advent and introduction of Invasix's RF-assisted liposuction of BodyTite ushered in a very safe and refined method of RF: subdermal and subcutaneous rejuvenation. The bipolar applicators allow internal RF delivery to the septofascial and fasciocutaneous structures of the hypodermal space during a BodyTite RF-assisted liposuction (RFAL) case, or to the immediate subdermal space when using the NeckTite, FaceTite, or CelluTite applicators. Although the internal electrode can function as an electrode or electrode cannula,

depending on the applicator, the external electrode functions both as a return electrode and as a gentle transepidermal nonfractionated RF energy delivery system to the papillary and reticular dermis. The electrode is connected to the internal electrode via the hand piece and various depths can be selected, depending on the applicator. The external electrode also constantly measures the all-important epidermal temperature when working superficially, whereas the internal probe can measure the important subdermal or deep subcutaneous temperature. The moving external, Thermage™ like electrode and internal RF electrode have proven to have some very unique uses and clinical results. At the time of this article, the BodyTite is approved by Conformité Européenne, Health Canada, Korean FDA, and Australia, and is sold worldwide and is pending FDA clearance. Studies at 20 US-based institutional review board sites have provided some compelling data. The BodyTite RF-assisted liposuction device has been used to treat all areas of the body.^{21–28} Purported advantages include speed; extreme thermal uniformity of tissue heating; safety in thermal monitoring; reduced swelling, pain, and ecchymosis; and synchronous coagulation and aspiration of fat, which can speed up the time required for cutaneous and subcutaneous tightening before, during, or after standard suction-assisted lipoplasty. Perhaps the most important clinically significant effect of internal subdermal and subcutaneous RF is 3-dimensional soft tissue area contraction, which can range from 25% to 60%.²³

The BodyTite device can be used on its own for small or medium areas, as it aspirates at the same time as the internal electrode emits RF energy and is also a hollow-bore Mercedes tip cannula. The tightening results from BodyTite are impressive, with linear contraction measured between 15% and 40%, the average being 25%.^{21–23,25} Area contraction averages, depending on the size of the subcutaneous envelope of the patient can measure between 30% and 60%.^{21–23,25} The significant cutaneous skin tightening has allowed the exploration of many new clinical RFAL and RF skin-tightening applications and minimally invasive plastic surgery to evolve. Postpartum individuals or patients who have had massive weight loss with lax abdominal skin and soft tissue may now be acceptable candidates for RF-assisted liposuction contouring and skin tightening rather than full, formal abdominoplasty. RFAL can also be used in combination with a “mini”-abdominoplasty, skin excisions, and diffuse abdominal and flank RF-assisted liposuction.^{21–28} Other areas where RFAL appears to be very advantageous in skin tightening and

contour enhancement are the upper arms and inner thighs, back, bra line, and flanks, which traditionally can be very difficult areas for suction-assisted lipoplasty, ultrasound assisted liposuction, or laser assisted liposuction alone.^{30,31}

The newest skin-tightening and contour bipolar applicators from Invasix include NeckTite, FaceTite, and RF CelluTite. These RF applicators are smaller and can be used in the submental cervical region where the external electrode of the bipolar configuration continuously moves along the epidermis, providing gentle RF heating to 40°C, as well as epidermal safety temperature and impedance sensing, while the internal electrode heats the subreticular dermal collagen up to 50 to 55°C. The author’s experience with long-term contraction results of the cervical mental region with NeckTite applicator have been impressive. Another very small bipolar internal and external electrode applicator, called FaceTite, has been designed for RF tightening of the brow, lids, cheeks, and face. Like NeckTite, FaceTite is performed under local anesthesia and the internal electrode can be passed directly under the reticular dermis of the brow, lower lid, cheeks, upper lip, and jawline, heating the reticular dermis up to 50 to 55°C. The external epidermal electrode provides RF heat to the papillary and reticular dermis, heating it to 40°C and constantly measuring epidermal temperature, cutting off the RF energy when the physician-selected threshold is met. FaceTite RF skin tightening can be applied to the brow, to the under eye, to the cheek, and to the nasal labial fold, upper lip, and perioral region. Because of the thermal containment between the 2 electrodes, it is unlikely for the facial nerve to suffer a thermal injury, which can occur by passing non-confined laser energy beams in the immediate subdermal space. The FaceTite applicator can be combined with synchronous volumization with micro fat grafting, or deep supraperiosteal hyaluronic acid or particulate stimulate fillers performed after or before the procedure. After the FaceTite procedure, synchronous Botox can be applied. In addition, once the FaceTite procedure is performed on the brow, under eye, cheek, and neck, fractional transepidermal ablative laser technology or fractional RF ablative technology can be used. Significant 1-step results have been achieved by the author by combining the FaceTite bipolar epidermal and subdermal RF skin-tightening applicator to the brow, under eye, cheek, and neck with synchronous, aggressive full-face and neck-fraction RF ablation (Fractora, Invasix), or fractional carbon dioxide resurfacing (Affirm CO2, Cynosure). The combination internal RF tightening combined with external RF (fractional or

Thermage™) can deliver very nice skin-rejuvenation results.

The small FaceTite applicator can also be used for skin tightening anywhere on the body. Good reports have been achieved by using FaceTite on the neck, either in the absence of a cervical facial rhytidectomy or for residual skin laxity after a facelift. The investigators^{21–27} also use the FaceTite and NeckTite RF tightening devices to undermine skin flaps of the neck, lateral cheek, and brow before their surgical elevation as part of a rhytidectomy. Combined with BodyTite or traditional liposuction, the SkinTite applicator can be used for loose supra-umbilical skin, inner thigh skin, or arm skin, either alone or in combination with excisional or suctioning procedures.

The clinical results of internally delivered RF are significant and this opens the opportunities for plastic surgeons and cosmetic physicians to offer a nonexcisional, minimally invasive option for skin tightening in those patients who are not seeking a larger, more successful skin removal technique. The internal-external RF skin tightening can be combined with other currently successful minimally invasive techniques to optimize the nonexcisional results.

COMPLICATIONS

The complications from Thermage™ and the other devices that deliver nonablative transepidermal delivery of RF energy are negligible.³ In patients properly selected for Thermage™ and external RF nonablative procedures, more than 90% of patients are happy with their treatment. Early disappointment with the original Thermage™ algorithms and tips with 50% of patients finding the treatment too painful and unacceptable levels of patient dissatisfaction have given rise to larger tips, modified algorithms, and technology with multiple passes where more than 90% of well-selected patients are quite happy with the modest skin tightening and rhytid reduction that they see. Other external RF nonablative technologies, with or without combination light-based energies, report similar high happiness indexes for properly selected patients for these nonablative procedures. The instances of transepidermal monopolar or bipolar, TriPollar, or octopolar burns has been reported to be far less than 0.1%. The dreaded complication of fat atrophy, which was a rare but unacceptable complication with the initial high-fluence Thermage™ algorithm, has fortunately been virtually eliminated.³ The incidence of prolonged edema, swelling, scabbing, erythema, vesiculation, and scarification is again far less than 1%.³

The safety and efficacy of the transepidermal delivery of fractional ablative RF energy, or laser

carbon dioxide and erbium yag ablative fractional energy has improved significantly over the full ablative complications and morbidity of a decade ago.^{2–18} There is still risk of hypopigmentation if the fractional density fluence or pulse durations are too aggressive, and fractional ablative technologies, even fractional erbium yag, fractional carbon dioxide, and fractional RF, can lead to postinflammatory hyperpigmentation in those patients predisposed or prone to this complication.^{2–18} The transepidermal fractional RF ablation, when used in appropriate settings, can be indicated in those patients in whom ablative technology may be contra indicated, specifically sun exposure and skin type 4 and occasionally 5.

The complications associated with the Invasix bipolar RF-assisted devices are clearly going to be higher and more substantive than the risks and complications associated with nonablative or minimally ablative transepidermal devices. In the hands of skilled plastic surgeons and cosmetic physicians, who are used to elevating the anatomic structures in the face, neck, and body and are able to apply local anesthesia and assess the epidermal-dermal junction, the Invasix technology can be very safe. There are many safety features built into the bipolar RF-assisted skin-tightening and liposuction devices. The epidermal external return electrode has impedance sensors (with automated high-impedance and low-impedance cutoffs) that greatly minimize the risks of “end dermal hit” burns and prevent eschar formation around the internal electrode. The external electrode has built-in epidermal temperature sensors and the physician can set the device to automatically cut off the RF energy at any epidermal temperature. This negative feedback loop allows the FaceTite, NeckTite, or BodyTite to be used and maintained at target epidermal temperatures of 40 to 42°C. In addition, when performing RF-assisted liposuction with the BodyTite device, the internal electrode-cannula constantly measures internal temperature and will also notify the physician when the internal temperature target has been met (usually 60 to 65°C). When performing superficial treatments, such as RF-assisted CelluTite, FaceTite, or NeckTite, because the distance between the internal electrode and moving epidermal electrode is so small, constant epidermal monitoring is all that is required to help avoid a thermal injury. When performing deeper techniques, such as RF liposuction, then an internal temperature monitor and feedback, as well as epidermal temperature-monitoring feedback and impedance safety measurements are provided to minimize the risks of overheating the structures internally, as well as creating epidermal-dermal

thermal disruption. Reported incidents of a thermal injury using the Invasix RF internal and external device is less than 1%; however, there is a significant learning curve and the first 10 to 15 cases performed by any surgeon need greater care and attention. When a subdermal RF or laser energy results in a burn, it is full-thickness in nature and will often require surgical management when it has healed. Hyperpigmentation and hypopigmentation are not generally features of the internal and external RF devices. Excessive heating of the internal fat space and adipose tissue can lead to persistent subcutaneous nodules, which resolve with time and represent adipose tissue that was overheated and died, but was not removed with aspiration.^{20–28,30,31} Although, with the advent of the internal thermistor on the cannula, the incidence of these soft tissue nodules is much lower.

Like all energy-assisted devices, such as ultrasound and laser, the instance of seroma when performing RF liposuction and internal RF skin tightening is increased over suction assisted lipoplasty alone. Although the complications of simultaneous internal and external delivery of RF energy are greater than those seen with nonablative Thermage™ devices, the advantages of up to 40% to 60% area contraction and the relatively low incidence of complications make the internal delivery of RF and the Invasix devices a very exciting area of growth for the plastic surgeon performing nonexcisional and excisional skin tightening. The advantage of being able to combine the internal and external RF energy with fractional ablative RF devices or fraction laser devices, Botox, and fillers adds to the armament of the plastic surgeon, providing yet another opportunity to keep patients in the practice, as they are seeing significant skin-tightening and skin-rejuvenation results without an excisional procedure.

NONINVASIVE AND MINIMALLY INVASIVE SKIN-TIGHTENING BUSINESS MODEL

Clearly, as plastic surgeons and as cosmetic surgeons interested in excisional procedures, there is great forethought, care, and attention to the business plan of nonexcisional skin-tightening devices before bringing noninvasive and minimally invasive technologies into one's practice. In general, each of these noninvasive and nonablative RF or nonablative laser devices will cost upwards of \$100,000 or more. The lease payments alone on each of these devices can reach \$2500 to \$3000 per month, in addition to disposables and consumables. When adopting a nonexcisional skin-tightening technology into the practice of a plastic surgeon, whose livelihood is devoted to

excisional surgery, it is important that the right business model and expectations, both for the practice as well as the patient, are created.

As successful paradigm that the author has seen used in many plastic surgeons' offices is to add significant nonablative and minimally ablative facial technologies as an adjunct to the facial excisional practice. The marketing advantages of combining a minimally and noninvasive skin-tightening program with an excisional skin-tightening practice can be synergistic. If the plastic surgeon is committed to internal and external marketing and positions these technologies well, properly selected patients will be happy with their noninvasive and minimally invasive results, which can create an ongoing revenue stream that can be significant, and one day many of these patients will, in fact, move up to more excisional procedures.

NONINVASIVE AND MINIMALLY INVASIVE COMBINATION THERAPY

When patients present for facial rejuvenation, who are not quite sure exactly what procedure they may benefit from, seeking the advice of their plastic surgeon, it is wise to be armed with all the opportunities for skin rejuvenation. Many patients present for skin rejuvenation for primary facial or body skin laxity. Following excisional procedures with or without contouring, these individuals will be seeking some type of maintenance therapy that can be offered as well. Noninvasive and minimally invasive combinations that work well to generate good results include combinations of transepidermal monopolar RF, or bipolar and multipolar RF combined with intense pulse light, neurotoxin, and fillers. This basic combination delivers rhytid reduction skin tightening supported by neurotoxin, and soft tissue volumization of the midface and perioral region with color correction delivered by intense pulse light. It is quite common now with the combination therapy for the average individual who is 50 to 60 years old to look 5 years younger without an excisional procedure. Many patients are happy with this type of rejuvenation and enhancement and may never present for cervical facial rhytidectomy. For these patients and for the survival of plastic surgery, it is important that enough plastic surgeons become familiar with these therapies and become expert in the delivery of these therapies so that patients think of their plastic surgeon and not just their dermatologist or non-plastic surgery cosmetic physician for the delivery of these therapies. The disadvantage is that the business model can be expensive if not executed properly with proper patient selection and sound marketing and it can be an

expense drag on practice profitability. Done well, however, with current and up-to-date marketing techniques, specifically Web site optimization; pay-per-click advertising; and basic, solid, good word-of-mouth referral, this can be an important adjunctive revenue stream that at least is expense and revenue neutral but can deliver significant patients for excision procedures as these minimally noninvasive patients stay in the practice.

SUMMARY

The nonablative Thermage™ RF device has evolved into a consistent, reproducible, and tolerable nonablative skin-tightening procedure with an abundance of clinical and basic science behind the current treatment algorithms. For more significant RF skin-tightening results, incorporating technology that can deliver subdermal and subcutaneous RF energy into the septofascial and fasciocutaneous hypodermal space of the face, neck, and body is more effective in achieving the desired result. With minimally invasive internal-external RF techniques, performed under local anesthesia, one can now begin to offer nonexcisional procedures to selective patients who would benefit from an augmented form of RF skin tightening. These patients can achieve skin-tightening results that are significant and impressive but do not replace traditional abdominoplasty, arm-lift, thigh-lift, neck-lift, or face-lift results. However, like the noninvasive facial business model, these individuals can be kept in the practice and can be offered noninvasive transepidermal nonablative RF Thermage™ maintenance treatments after their minimally invasive RF tightening results. One day, some patients will move up to the optimal skin-excisional procedures to give them the best possible result. Again, the goal is to ensure that safety and efficacy are maintained, that patient expectations are managed, and that patients who do not desire excisional procedures are given current and up-to-date, realistic optimal noninvasive or minimally invasive options.

THE FUTURE

It is an exciting time in skin tightening and the control of soft tissue laxity with nonexcisional techniques. Over the next few years, more published results will emerge that will help potentially turn the management of cellulite into a surgical disease, and plastic surgeons can continue to improve their ability to offer those patients who want significant skin tightening a minimally invasive nonexcisional, internal, and/or external RF

skin rejuvenation result that even traditional excisional plastic surgeons can be happy with.

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