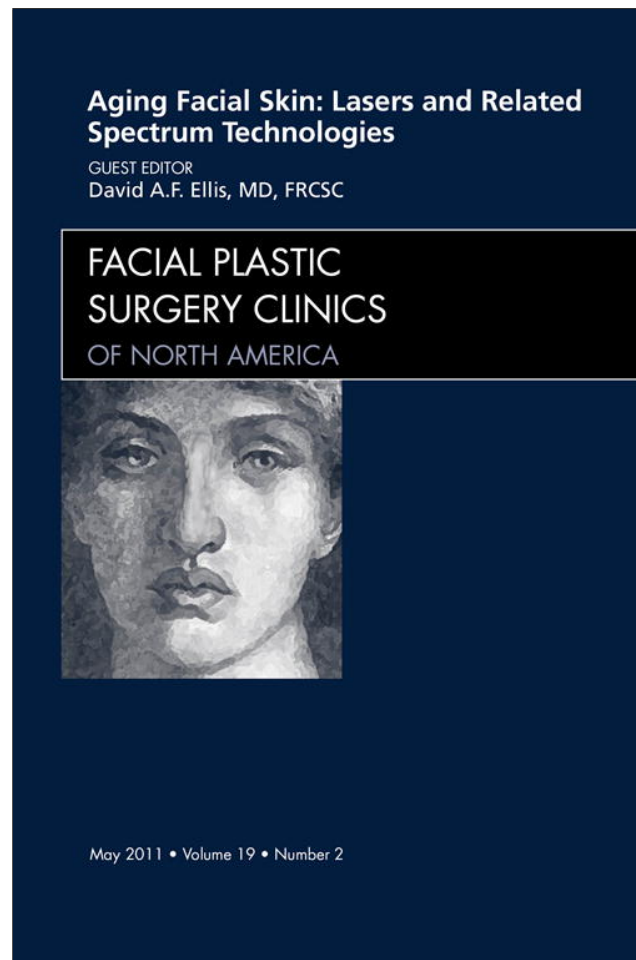


Provided for non-commercial research and education use.
Not for reproduction, distribution or commercial use.



This article appeared in a journal published by Elsevier. The attached copy is furnished to the author for internal non-commercial research and education use, including for instruction at the authors institution and sharing with colleagues.

Other uses, including reproduction and distribution, or selling or licensing copies, or posting to personal, institutional or third party websites are prohibited.

In most cases authors are permitted to post their version of the article (e.g. in Word or Tex form) to their personal website or institutional repository. Authors requiring further information regarding Elsevier's archiving and manuscript policies are encouraged to visit:

<http://www.elsevier.com/copyright>

Radiofrequency: Thermage

Kristel D. Polder, MD^{a,b,*}, Suzanne Bruce, MD^b

KEYWORDS

- Radiofrequency • Thermage • Nonablative procedures
- Aesthetic medicine

The demand for safe and effective modalities to improve laxity and appearance of wrinkles has steadily risen over the last several decades. Although ablative laser technology and surgical treatment, such as rhytidectomy and blepharoplasty, provide a proven, evidence-based method of rejuvenation of aging skin, patients often opt for procedures with less downtime and risk for complications, such as pigmentary changes, scarring, and infection. The development of minimally invasive procedures, such as nonablative laser and radiofrequency (RF) treatments, has boomed since the 1990s, leading to a paradigm shift in the field of aesthetic medicine. Patients are willing to accept less dramatic results if there is minimal recovery and risk.

One such nonablative system, the Thermage CPT (Solta Medical, Hayward, CA, USA) uses monopolar capacitively coupled radiofrequency (MRF) to tighten the skin and reduce laxity. This device garnered US Food and Drug Administration (FDA) approval for the treatment of periorbital wrinkles in 2002, facial rhytids in 2004, and all rhytids in 2005. Although there are other radiofrequency devices on the market, Thermage has the most literature and clinical trials published to date that support monopolar radiofrequency as

an effective modality for rejuvenation. Facial contouring and mild to moderate tightening is achieved through volumetric heating and dermal collagen remodeling, and epidermal cooling and the maintenance of an intact epidermis protects the skin from complications, such as infection, scarring, and pigmentary changes.

MECHANISM OF ACTION

The Thermage CPT system consists of 3 components: a generator, a cryogen unit, and a hand piece connected to a disposable treatment tip (**Figs. 1 and 2**).^{1–6} The generator provides an alternating electrical current that creates an electric field through the skin that shifts polarity 6 million times per second. The charged particles change their orientation within the electric field. Heat is generated by the tissue resistance to particle movement. Precooling, parallel cooling, and post-cooling is delivered via a digitally pulsed cryogen spray on the inside of the treatment tip, thereby protecting the epidermis. For this reason, MRF can safely be performed with all Fitzpatrick skin types (FST).¹ Pressure, current flow, and skin temperature (measured with thermistors inside the treatment tip surface) are monitored using

Author contributions: Drs Polder and Bruce had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis; Study concept and design: Polder, Bruce; Acquisition of data: Polder, Bruce; Analysis and interpretation of data: Polder, Bruce; Drafting of the manuscript: Polder, Bruce; Critical revision of the manuscript for important intellectual content: Polder, Bruce; Study supervision: Polder, Bruce.

Financial disclosure: none reported.

Conflicts of interest: Dr Polder is a principal investigator and has received research support from Solta Medical and Dr Bruce is a consultant for Solta Medical.

^a Department of Dermatology, University of Texas, 6655 Travis Street, Suite 650, Houston, TX 77030, USA

^b Suzanne Bruce and Associates, The Center for Cosmetic Dermatology, 1900 Street James Place, Suite 650, Houston, TX 77056, USA

* Corresponding author. The Center for Cosmetic Dermatology, 1900 Street James Place, Suite 650, Houston, TX 77056.

E-mail address: kristelpolder@hotmail.com

Facial Plast Surg Clin N Am 19 (2011) 347–359

doi:10.1016/j.fsc.2011.04.006

1064-7406/11/\$ – see front matter © 2011 Elsevier Inc. All rights reserved.



Fig. 1. The Thermage CPT system consists of a generator, a cryogen unit, and a hand piece connected to a disposable treatment tip.

a microprocessor in the treatment tip. Constant feedback from the treatment tip to the computer regulates whether a pulse is fired and the amount of energy fired from the tip. If the treatment tip is not in full contact with the skin surface, or if the skin temperature is too high, a pulse will not be discharged. Heating the dermis to the appropriate temperature while sparing the epidermis is essential for MRF to work and provide the optimal aesthetic result. The MRF system uses the reverse thermal gradient principle in which the epidermis is cooled and preserved while the deeper tissue (including dermal collagen) is heated (**Fig. 3**). The epidermis is kept at 40°C as the cryogen coolant



Fig. 2. The Thermage CPT hand piece display demonstrates the fluence setting on the left and the vibration setting on the right. Vibration may be delivered throughout the pulse and decreases pain as perceived by patients.

is delivered. Collagen denaturation occurs at approximately 65°C. Exposure to heating for 10 minutes results in 10% shrinkage of collagen fibers, whereas 60% shrinkage occurs after only 1.5 minutes at 80°C.⁷ Thus, the higher the maximum temperature reached during heating, the greater the shrinkage. The MRF system heats the dermis to 65°C to 75°C, which has been confirmed in histologic studies.⁸ If suboptimal

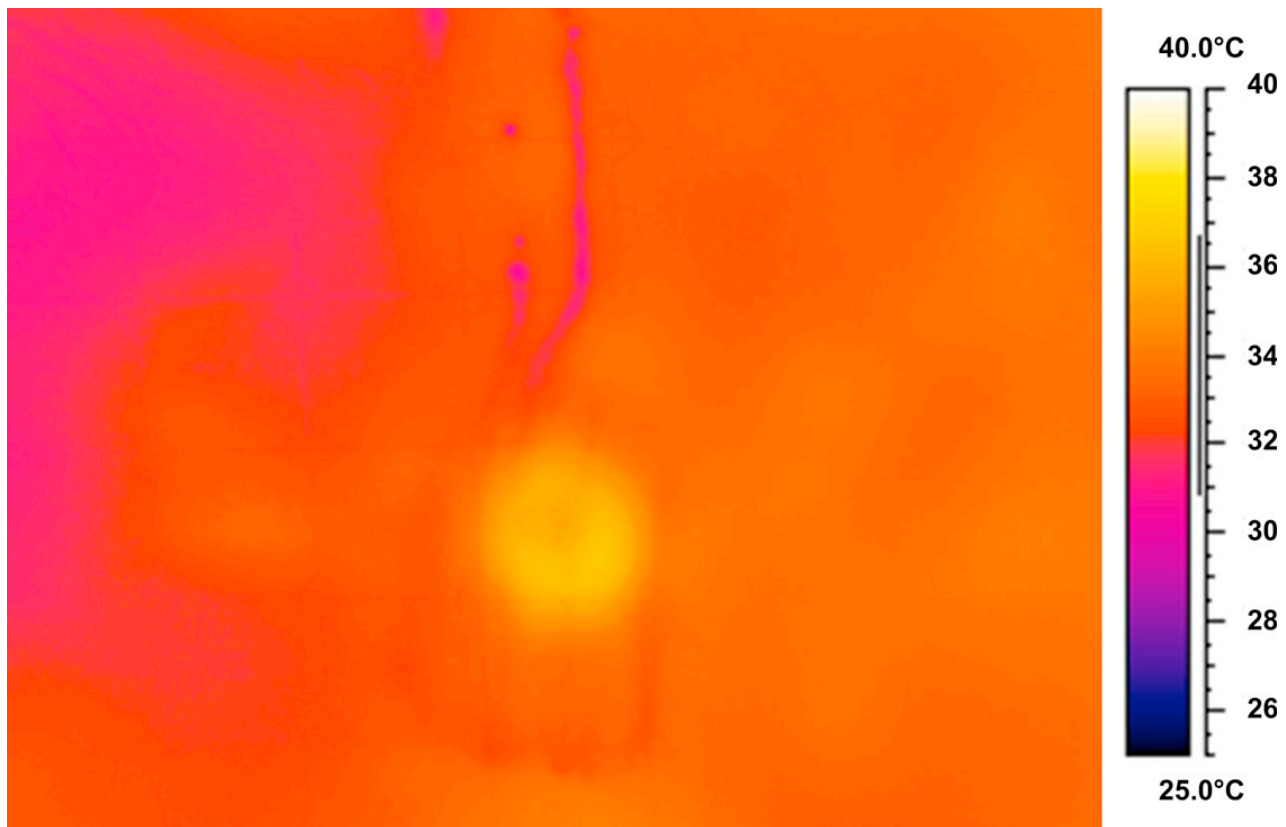


Fig. 3. The thermogram illustrates the heat generated by the radiofrequency energy delivered to the skin and subcutaneous tissue during a given pulse. The different colors demonstrate the heat gradient. Thirty seconds after one pulse of the Thermage CPT, 92% of the surface tissue is more than 34°C.

heat is generated, there will be no significant clinical improvement in laxity or rhytids. If excessive heat is generated, erosions, atrophy, scarring, or pigmentary changes may ensue.⁹⁻¹¹

To ensure a controlled path of travel for the RF energy, a return pad is placed on patients' back and electrically connected to the generator module. Coupling fluid is applied before treatment to ensure full contact with the skin's surface. Cryogen spray is delivered throughout the treatment cycle, and the pressure and delivery of this cryogen coolant is electronically controlled. When the coolant canister is low, a message is displayed on the computer screen for notification.

The MRF device has undergone several name changes since its inception. Multiple names will be mentioned throughout this article, depending on when the clinical study was published. The first MRF device was the Thermancool TC (Thermage, Inc, Hayward, CA, USA) (2002), which was followed by the TC-3 (Thermage, Inc, Hayward, CA, USA) (2005), and then the NXT (Thermage, Inc, Hayward, CA, USA) in 2007. The Thermage CPT (Comfort Pulse Technology, Solta Medical, Hayward, CA, USA), the most recent device at the time of this publication, was released in August of 2009.

CLINICAL EFFICACY AND STUDIES

The ThermanCool TC system represented the first nonsurgical treatment for periorbital skin laxity and rhytids approved by the FDA. FDA clearance of the device took place in November of 2002 for periorbital rhytids, 2004 for facial laxity, and subsequently for the rest of the body in 2005. The initial device had been developed with a 1.0-cm² tip, which possessed a slow discharge time. The highest energy tolerated was used and a single pass was performed.¹⁻⁶ Because of significant pain, anesthetic blocks and oral pain medication was needed. Further, the results were modest. In 2004, the 1.0-cm² tip was then improved upon by a faster discharge time, and later, a larger tip was introduced. However, the treatment was still painful and the results remained modest. In 2006, Kist and colleagues¹² noted that twice the amount of collagen denaturation occurred when 3 passes were performed at lower energy settings rather than 1 pass at higher energy settings.^{12,13} Even the highest energy settings did not produce as much collagen denaturation as 3 passes at the lowest settings. Histology was confirmed on facial preauricular skin treated before facelift surgery. This discovery represented a major shift in the treatment

algorithm for MRF. Subsequent clinical studies confirmed the previous histologic findings.^{9,14,15}

In 2003, Fitzpatrick and colleagues¹ treated 86 patients with a single treatment of the ThermoCool TC system with a follow-up of 6 months to assess periorbital tissue tightening. In this multicenter trial, wrinkle score improvements of at least 1 point on the Fitzpatrick scale were noted in 83.2%, whereas 61.5% of eyebrows were lifted by at least 0.5 mm. Abraham and colleagues¹⁶ found a statistically significant increase in mean vertical brow height of 1.6 to 2.4 mm at 12 weeks when 35 patients with moderate facial aging were treated with a single session of MRF. Hsu and Kaminer² treated 16 patients between May 2002 and December 2002 with the ThermoCool TC on the lower face. Eleven of the patients had 3 areas treated, including the cheeks, jawline, and upper neck. Ten patients graded the treatment as mild to no improvement. Five patients graded the response moderate to excellent. Despite the disappointing results, this study brought forth a few points. First, 3-dimensional improvement was difficult to demonstrate via standard photography, and it was determined that more accurate methods were needed to measure skin tightening changes. Younger patients fared better than older patients in this trial, although because of the small numbers in this study, the results were not statistically significant. Third, patients that had all 3 areas treated had a higher percentage of moderate to excellent scores at follow-up.

Several smaller clinical trials indicated mild to moderate improvement in facial and eyelid laxity, with minimal down time and complications using the early ThermoCool TC system. Fritz and colleagues¹⁷ treated 11 patients with a single MRF treatment and 9 patients with 2 MRF treatments. In this study, 2 treatments yielded higher scores in all categories of photographic analysis with the difference in improvement being statistically significant for the nasolabial folds ($P = .04$). Significant improvement in laxity after treatment was seen between the 1- and 4-month follow-up visits in both groups (single and 2-treatment groups). On self-assessment, patients who received 2 treatments reported more improvement than those in the single-treatment group 4 months after treatment ($P = .05$). Results were modest in both groups as noted by both physicians and patients, however. Despite the modest results, 75% ($n = 15$) reported that they would consider paying for additional treatment, and more than 50% (11/20) reported they would strongly consider doing so.

Tanzi and Alster¹⁸ found significant improvement in cheek and neck laxity observed in the majority of a cohort of 50 patients treated with 1

session of MRF. Consistent with prior data, they found the nasolabial and melolabial folds more responsive to treatment than the jowls and mandibular ridge. A decreased response was found in the neck region. They found a 35% to 40% subjective improvement of nasolabial and melolabial folds and a 30% to 35% improvement in neck laxity. Jacobson and colleagues⁴ treated 24 patients with laxity of the neck, nasolabial folds, marionette lines, and jawline with 2 passes performed on the forehead, 3 on the cheeks, and 1 on the neck. Each patient received 1 to 3 treatments spaced 4 weeks apart. Seventeen of the 24 patients demonstrated visible improvement at the 1-month follow-up evaluation. Bogle and colleagues¹⁵ evaluated the multiple-pass, low-fluence algorithm for lower facial laxity in 66 patients at 3 treatment centers. At the 6-month follow-up, independent photographic review revealed improvement in 84% of patients. Patients were treated with 2 passes to the cheeks, upper neck, perioral area, chin, and submentum with the 1.5-cm tip, and 3 additional passes were performed at investigator discretion to areas needing the most skin tightening. The average number of pulses per treatment was 480. At the 6-month follow-up, 92% of patients had a measurable improvement in overall appearance.

MRF has also been shown to improve acne and acne scarring. Ruiz-Esparza and Gomez¹⁹ evaluated the effects of one MRF session in 20 patients and 2 sessions in 2 patients at 72 J/cm², with a follow-up of 1 to 8 months. Patients had moderate to severe scarring, cystic, and active acne vulgaris. An excellent response (75% or better diminution in active acne lesion counts) was seen in 92% ($n = 18$). Acne was not made worse in any of these patients.

Meshkinpour and colleagues²⁰ treated 6 patients with hypertrophic scars and 4 patients with keloid scars with MRF. They found no significant differences between control and treatment sites clinically or with hematoxylin and eosin evaluation. There were differences in collagen morphology with increased collagen production (type III > type I) observed. This increase peaked between 6 and 10 weeks after treatment and did not return to baseline even after 12 weeks.

MRF AND FILLERS: COMBINATION THERAPY

As MRF is one part of a larger aesthetic armamentarium, many physicians began to combine MRF with botulinum toxin injections, filler injections, and light- and laser-based technology. Goldman and colleagues²¹ conducted a randomized, evaluator-blind study of 36 patients to confirm or

refute any possible subtractive effects on augmentation of the nasolabial folds when followed by 1320-nm Nd:YAG laser, 1450-nm diode laser, MRF, or intense pulsed light (IPL) treatment. Thirty-six patients were treated with hyaluronic acid (HA) gel (Restylane, Medicis Pharmaceutical Corp, Scottsdale, AZ, USA) on one side of the face and HA gel followed by one of the nonablative laser/MRF/IPL therapies on the contralateral side. An unblinded treating investigator administered HA gel to each nasolabial fold and bilateral postauricular regions, followed immediately by administration of one of the following treatments: 1320-nm Nd:YAG laser (CoolTouch, CoolTouch Corp, Solta Medical, Hayward, CA, USA), 1450-nm diode laser (Smoothbeam, Candela Corp, Wayland, MA, USA), MRF, or IPL therapy (Lumenis One, Lumenis Inc, Yokneam, Israel). The postauricular area was chosen as the site for retrieval of cutaneous biopsies without cosmetic detriment. Skin biopsies were obtained on the bilateral postauricular regions on postoperative days 0, 14, and 28 in every patient to assess the histologic effect of each laser, RF, or IPL therapy. Blinded investigator evaluations did not identify statistically significant differences in wrinkle severity scores between the nasolabial fold that were injected with HA alone compared with those treated with HA gel and the nonablative laser/IPL/RF modalities. Histologic studies from the small number of acceptable samples showed that HA gel was indistinguishable among patients and between laser/IPL/RF-treated and untreated sites. There was no evidence in this study that concomitant nonablative dermal treatment modified the implanted HA gel. The investigators concluded that clinical and extrapolated histologic data supported the use of laser/MRF/IPL directly over HA gel dermal implants without affecting patient safety or implant efficacy. Alam and colleagues²² found similar results when RF treatment occurred at 2 weeks after implantation of hyaluronic acid and calcium hydroxylapatite in 5 patients. Each filler product was placed in the deep dermis, 3 cm apart on the forearm in each patient. Light microscopy did not reveal any differences in the filler material between the control arm and the experimental arm on punch biopsy 3 days after RF treatment. Further, Shumaker and colleagues²³ demonstrated the aforementioned findings in an animal model.

However, an earlier study (2005) by Sukal and Geronemus²⁴ reported one patient with postoperative biopsy-proven granulomas in the nasolabial folds that had previously undergone silicone injections. The granulomas resolved over a 1-year period with steroid injections.

CONTRAINDICATIONS

The Thermage CPT system is contraindicated in patients with a pacemaker, defibrillator, implantable cardioverter-defibrillator (ICD), or other implanted electronic device. An inquiry into the presence of metal implants, hardware, and braces is also important, and treatment should be avoided over these areas. The presence of active skin infection or pathology at the treatment site is a contraindication to treatment. Smoking, autoimmune conditions, prior radiation therapy, and other conditions that impair wound healing are also relative contraindications. Patients who are or might be pregnant are not treated with this device in the authors' practice. Regarding the Thermage Eyes procedure, patients should not have intraocular eye shields inserted if they have had recent corneal surgery, and therefore should not have the eye treatment. Further, after Lasik, patients should wait several months to heal before eye shields can be safely placed.²⁵

PATIENT SELECTION

Patient selection is a critical aspect to achieving the desired outcome with MRF. MRF can be safely used in all Fitzpatrick skin types. Ideal candidates for MRF are between 35 and 60 years of age with mild to moderate facial and neck laxity and rhytids, crepey or wrinkled skin, after pregnancy, after weight loss, and with appropriate expectations (**Figs. 4A–6**).^{25,26} Patients with severe laxity and deep rhytids are poor candidates for this procedure and would better benefit from surgical rhytidectomy. Patients who are not candidates for surgical intervention or who are unwilling to undergo surgical intervention for rhytids and laxity are also candidates for this minimally invasive procedure. Obese patients or those with extreme skin redundancy are poor candidates for Thermage.²⁶ Patients who are not ideal for the procedure are those with poor skin quality (excessive photodamage, severe elastosis), poor general or mental health, severely obese, or patients with fluctuating weight.²⁵ Patients on chronic corticosteroids or nonsteroidal antiinflammatory medication are also poor candidates for the MRF. This procedure is safe to perform on patients who have had prior rhytidectomy or blepharoplasty, laser surgery, botulinum toxin, or fillers.^{21–23} Male patients can be treated with MRF without fear of facial hair loss from treatment. For MRF augmentation of the eyelids, optimal candidates are those with mild to moderate dermatochalasis, good skin tone,

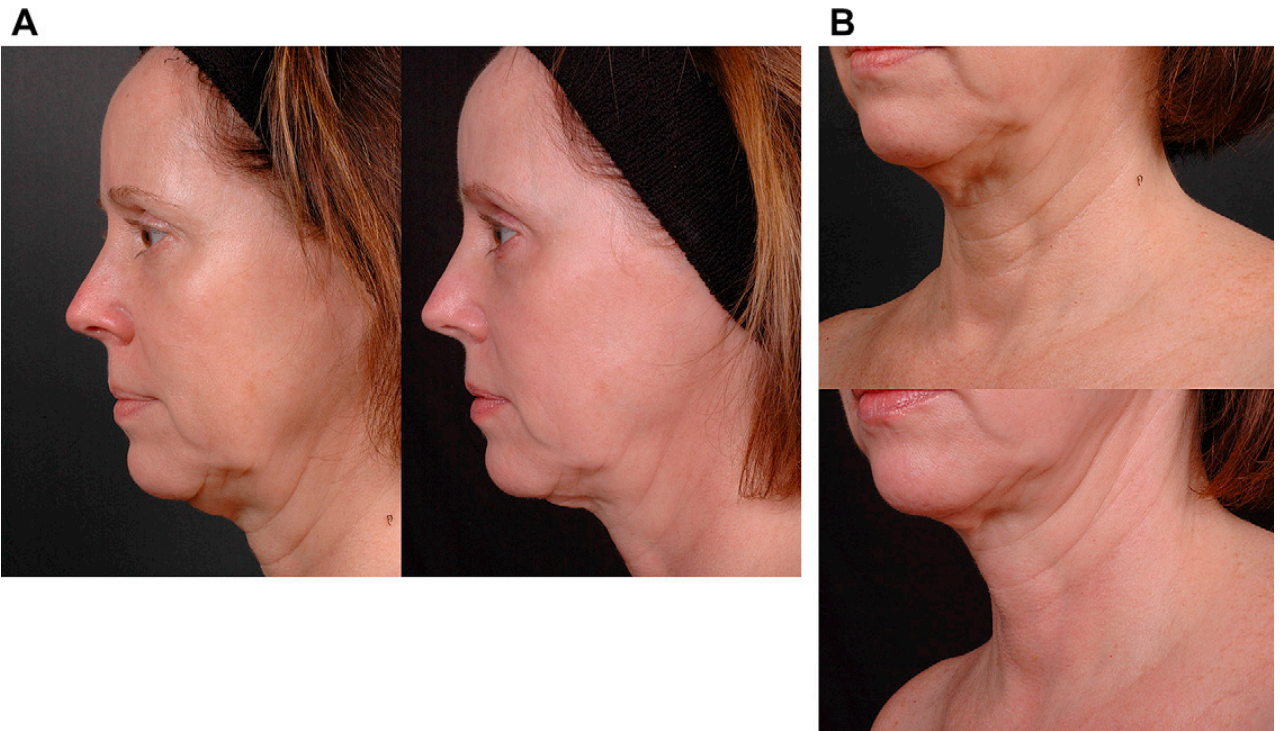


Fig. 4. (A) A 55-year-old patient at baseline (*left*) and 3 months after treatment (*right*) with 1200 pulses of MRF to the full face and neck. (B) A 55-year-old patient's lower jawline and upper neck at baseline (*above*) and 3 months after treatment (*below*) with 1200 pulses of MRF to the full face and neck.



Fig. 5. A 43-year-old patient at baseline (*left*) and 3 months after treatment (*right*) with 900 pulses to the lower face and upper neck.



Fig. 6. A 57-year-old patient at baseline (*above*) and 3 months after treatment (*below*) with 900 pulses to the lower face and neck.

with no significant eyelid ptosis, eyebrow ptosis, or herniated orbital fat.⁸ Ideal candidates either do not want or do not need blepharoplasty surgery. Those patients who have previously undergone blepharoplasty and who experience a gradual development of laxity are also good candidates for this procedure. Patients must be educated that results are less dramatic as compared with surgical alternatives.

PHOTOGRAPHY

Preoperative and postoperative photography is a necessity for patients undergoing the MRF procedure.^{25,26} The authors' practice employs identical lighting, position of the patient, removal of jewelry and makeup, black headband, and a black cape to produce standardized photos (see **Figs. 4A–6**; **Figs. 7–9**). Patients are photographed via a frontal view, left and right side views, and a left and right three-quarter turn angle. Photographs are taken at baseline (pretreatment), at 3 months posttreatment, and at 6 months posttreatment.²⁵

TECHNIQUE

Prior to treatment, patients should be educated about expected and potential side effects, complications, and informed consent should be obtained. Patients should be told that the treatment should feel hot, but not painfully hot. A 0 to 4 feedback system is often employed: (0) nothing; (1) warm (this does not hurt at all); (2) hot (just starting to hurt, but easily tolerable); (3) very hot (I can take it but not for long); (4) intolerable (do not do that to me again).²⁵ Patient feedback is important and is a safety mechanism that prevents epidermal overheating and resultant complications.^{9–11}

Patients are positioned on the treatment table, with a grounding pad attached to them. All metal jewelry, makeup, and lotions should be removed before treatment. The treatment area should be gently cleansed. The cable connected to the device is clipped onto the grounding pad and secured, usually on the patients' back. A temporary grid system, supplied by the company, is placed on the treatment area, which guides the provider on pulse placement with the treatment tip. This grid uses a temporary ink transfer that guides the technician on where to place the tip. The grid size will correspond to the area being treated (a grid with larger squares for treatment on the buttocks and thighs is available). The skin should be cleaned with isopropyl alcohol. While the skin is still damp, the paper is placed ink side down over the treatment surface. The paper is dabbed lightly with isopropyl alcohol-moistened gauze until the grid shows through the paper. Prior to and during treatment, the membrane on the treatment tip should be checked to ensure integrity. If there is a breach in the membrane, the energy will not be applied properly and epidermal or dermal injury may result.

Pressure is evenly applied to the skin after coupling fluid is placed on the treatment area. A generous amount of coupling fluid should be used. If pressure is applied unevenly, an error message is displayed on the monitor, which prevents excessive energy from being delivered at one end of the treatment membrane. Pulses are laid down in an adjacent, but not overlapping, fashion. There are 3 main pass techniques: 2 single passes, 1 staggered pass, or 1 super pass. The super-pass technique is the one recommended for use with the most recent upgraded device, the Thermage CPT.²⁵ This technique corresponds to completing 1 row of squares followed by 1 row of circles on the grid, alternating rows. Staggered, partially overlapping pulses are no longer recommended with the Thermage CPT because this technique is thought to be too



Fig. 7. A 62-year-old patient at baseline (*left*) and 3 months after treatment (*right*) with 400 pulses to the bilateral upper arms (200 pulses per arm, Body Tip 16.0 [Solta Medical, Hayward, CA, USA] used).



Fig. 8. A 48-year-old patient at baseline (*left*) and 3 months after (*right*) 400 pulses to the bilateral posterior inferior buttocks and upper thighs (200 pulses per side, Body Tip 16.0 [Solta Medical, Hayward, CA, USA] used).

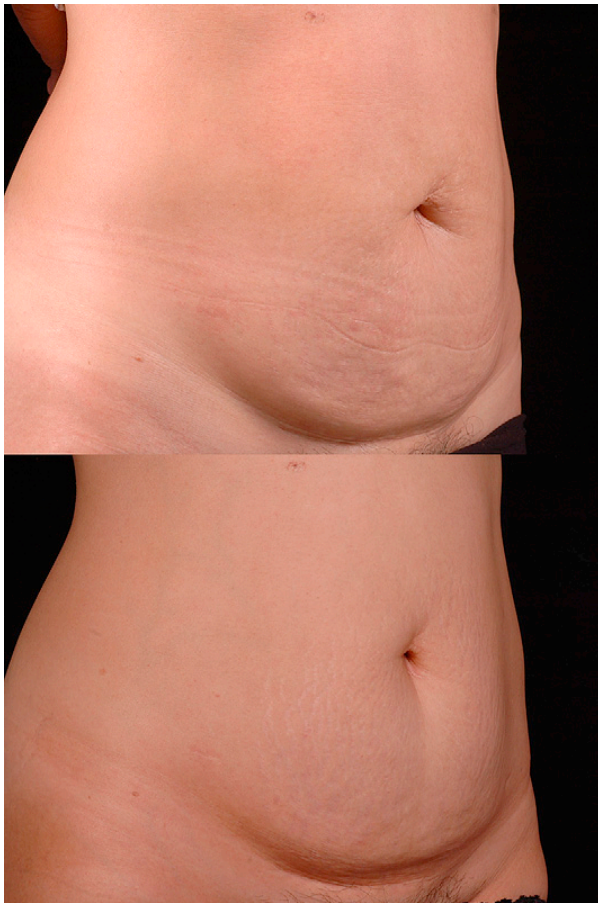


Fig. 9. A 46-year-old patient at baseline (*above*) and 15 months after (*below*) 800 pulses to the lower abdominal area.

aggressive with the upgraded device. Two passes are performed over the entire treatment area. Then, additional vector passes are performed in the direction in which the skin tightening/lift is desired (**Table 1**).^{27,28} Three to 5 vector passes are performed in the direction of the desired lifting. If the upper lip is treated, wet gauze can be placed between the teeth and upper lip for comfort. When treating over bony prominences, many providers move the tissue such that more skin and subcutaneous fat is centered over the bony area, which decreases pain and sensitivity over the site during treatment. Similarly, treatment on the forehead can be more painful, therefore, fluence may need to be decreased at this site. Typically, fluence is also decreased when transitioning from the facial skin to the neck. Proper technique is essential on the neck so excess energy is not concentrated under the mandible, where superficial erosions may occur. Full contact with the treatment tip membrane is important to ensure the energy is dispersed appropriately.

Erythema, edema, and mild skin tightening are expected outcomes, and are indicators of clinical efficacy. The provider should observe the skin at

all times during treatment, and patient feedback is important to determine if adverse events are occurring, such as epidermal injury. The clinical endpoint is visible or palpable tightening, which has been found to maximize long-term efficacy with the device.^{1–6,15,18,25,26,28} The grid is removed after treatment with isopropyl alcohol and the skin is gently cleansed.

If patients are undergoing treatment of the upper and lower eyelids, sterile plastic eye shields must be placed to prevent ocular injury. We place 2 to 3 drops of proparacaine or tetracaine in each eye before ocular shield placement. A small amount of eye lubricant is applied to the sterile shield and secured in place. A small 0.25-cm² tip is used when treating the eyelids. A smaller grid is also applied to the treatment area when the eyelids are being treated. A nonoverlapping, nonstaggered method of applying pulses is performed over both upper and lower eyelids after coupling fluid is applied.²⁵

Patients are given written instructions on post-procedure care, including expected side effects, timeline for follow-up photography, potential complications, and the clinic number to call if any questions or complications arise.

POSTPROCEDURE CARE

Erythema and edema are expected after MRF treatment. If erosions occur, patients are instructed to call the clinic, and are typically evaluated for concurrent infection or other complications. Biafine topical emulsion (OrthoNeutrogena, Titusville, NJ, USA) or Aquaphor healing ointment (Eucerin, Beiersdorf, Inc, Hamburg, Germany) can be applied to the erosions until they heal. Patients should be followed closely to ensure these lesions do not become infected and are treated appropriately. Cultures are indicated if the erosions develop honey crusting indicative of potential impetigo, or if there is persistent pain, erythema, pus, or drainage.

COMPLICATIONS

The incidence of complications with MRF is low.^{9,10} Weiss and colleagues⁹ performed a retrospective chart review of more than 600 consecutive patient treatments between 2002 and 2006 using the MRF device and found that the most common immediate and expected side effect was erythema and edema lasting less than 24 hours. Six patients reported edema lasting up to 1 week. Other reported side effects included acneiform eruptions and linear superficial crusts, both of which resolve by 1 week. Tenderness of the neck lasting 2 to 3 weeks was also rarely

Table 1
Tip selection

Area Treated	Lower Face	Lower Face and Neck	Full Face	Eyes Only	Eyes and Periorbital	Eyes and Full Face	Small Torso, Under Bra Areas, Just Above Knees	Average Torso, Thighs, Arms	Large Torso, Love Handles, Buttocks, Larger Thighs
Tip Suggested	Face tip 600 REPs	Face tip 900 REPs	Face tip 900 REPs	Eye tip 450 REPs	Eye tip 450 REPs plus face tip 100–200 REPs	Eye tip 450 REPs plus face tip 600–900 REPs	1 Body 16.0 tip 175–250 REPs	1–2 Body 16.0 tips 250–325 REPs	2–3 Body 16.0 tips 325 or more REPs
Full Passes	2 passes 4–5 vector passes	2–3 passes 4–5 vector passes	2–3 passes 4–5 vector passes	4–5 passes with eye tip	4–5 passes with eye tip 2–5 passes with face tip	4–5 passes with eye tip 2–5 passes with face tip	2 passes 1–2 vector passes	2 passes 2–3 vector passes	2–3 passes multiple vector passes
Procedure Time (min)	45–60	60–90	60–90	20–30	30–45	60–120	30–40	40–50	50–60 +

Abbreviation: REPs, repetitions, or pulses.

reported. This group found the overall rate of temporary unexpected adverse effects to be 2.7%. Fritz and colleagues¹⁷ reported that most patients experienced mild to moderate erythema and mild edema after treatment in their small study of 20 patients; however, 1 patient experienced an exacerbation of her temporomandibular joint symptoms after her first treatment. These symptoms resolved fully after 2 months. Abraham and Ross²⁶ reported transient skin numbness in 5 patients (14%) after treatment; however, this was in the early studies using MRF with a high-fluence, single-pass algorithm that is no longer employed with MRF. As physicians adopted the low-fluence, multiple-pass technique, complication rates fell.

In 2007, De Felipe and colleagues¹⁰ performed a retrospective review of 290 patients treated with 757 MRF treatments. This group found second-degree burns in 2.7% of their treatment sessions, with persistent erythema (1.22%), headaches, scarring, fat atrophy, burn in the return pad site, neuralgia, and facial palsy occurring less frequently. The group acknowledged that the facial palsy was possibly coincidental. The overall percentage of edema lasting 24 hours was 0.68%; edema lasting 48 hours was 0.53%; and third-degree burn with scar was 0.26% of 757 sessions of MRF performed.

De Felipe and Redondo studied an animal model to determine the etiology of fat atrophy post MRF treatment.²⁹ In contrast to the dermis, fatty tissue may more readily heat because of high inherent electrical resistance. The temperature in the fat is estimated to rise 7 times that of the dermis when treated with a radiofrequency device. Three age-matched pigs were tattooed with 3 16-cm² surface area (4 × 4) treatment squares per pig. Treatment was then performed using a 1-cm² tip. Area A was treated with 150 J/cm² (precooling was performed and skin contact occurred over 2.0 seconds); area C received a total of 4 seconds of cooling (precooled for 2 seconds, plus an additional frozen gel pack for 2 seconds) and the same amount of MRF at 150 J/cm²; area B served as the control with no treatment. Treated and untreated areas were biopsied with a 6-mm punch biopsy at 4, 8, and 20 weeks after initial treatment. Area A was treated much the same way the earlier high-fluence, single-pass algorithm was performed (2 seconds of cooling followed by 2.3 seconds of 150 J/cm² MRF followed by 2 seconds of postcooling), and in all 3 pigs, a clinical scar developed, which was confirmed histologically. Area C was treated with the same energy density; however, precooling time was increased to 4 seconds and a frozen gel pack was applied

before treatment. No scars developed in area C; however, several depressions were noted 1 month after treatment. It was therefore postulated that the increased precooling resulted in heating of the deeper layers of tissue, leading to disruption of the fat lobules, including dissolution of adipocyte cell membranes at 8 and 20 weeks after treatment and confirmed on punch biopsy. In contrast, 2 seconds of precooling with treatment at 150 J/cm² allowed for more energy to heat the dermis, precipitating a dermal scar (area A). Atrophy has been attributed to pulse stacking and accumulation of heat in the lower layers of skin. Newer treatment tips (since 2007) deliver MRF more readily, decreasing the cycle of the tip, and have reduced posttreatment atrophy to almost zero. Further, coolant is now delivered concurrently throughout the entire treatment cycle on the CPT device. Finally, there is a 10-fold lower risk of subcutaneous fat atrophy (estimated risk based on incidents reported to the manufacturer, 1/10,000 cases) when more passes are performed at lower fluences.

As more and more physicians adopted the multiple-pass, low-fluence treatment algorithm, the overall adverse event rate has declined. With the newest treatment algorithm, the overall adverse event percentage has fallen to less than 0.05%.¹¹

NONFACIAL TREATMENTS

Anolik and colleagues³⁰ performed a blinded, multicenter study evaluating the safety and efficacy of the MRF to treat mild to moderate abdominal skin laxity in 12 patients using the Thermage Multiplex Tip. All patients were women with no previous procedures or surgeries on or near the targeted treatment area, including cesarean sections; having less than 5% variation in body weight during the past year; and being within 20% of her body weight. Seven patients returned for all follow-up evaluations at 1, 2, 4, and 6 months after treatment. At each of the follow-up visits, a decrease in skin laxity was observed when compared with baseline assessment, and a decrease in waist circumference was also reported. Twelve patients demonstrated an average 1.4-cm reduction in waist circumference at the 1-month follow-up. The 9 patients who returned for the 6-month follow-up evaluation demonstrated an average 0.9-cm reduction in waist circumference from baseline. All patients but one demonstrated global aesthetic improvement. Patient satisfaction scores paralleled global aesthetic improvement scores. The percentage of patients claiming satisfaction (scores of either very or somewhat satisfied) among those who followed

up was 89%, 80%, and 78% at follow-up visits 2, 4, and 6 months after treatment, respectively. Transient erythema and edema of treated skin was observed immediately following treatment and subsided within hours of the procedure. There were no unexpected side effects or adverse events observed during the trial.

Suh and colleagues³¹ treated 37 FST III to IV patients with abdominal striae with both the 585-nm pulsed dye laser and the Thermacool TC. Patients underwent both treatments at baseline, and then were treated with the pulsed dye laser at fluences of 3.0 J/cm² (10 mm spot size) at weeks 4 and 8. Skin punch biopsies were performed on 9 of 37 patients, demonstrating increased and thickened dermal collagen. Staining of elastic fibers revealed increased uptake in the upper dermis or mid-dermis. All 9 specimens showed increased collagen, but only 6 specimens were found to have increased elastic fibers. Thirty-three of 37 patients were assessed as “good or very good” with respect to overall improvement of striae. Also, 33 (89.2%) of 37 patients had a net decrease in the width of the widest striae at week 12.

SUMMARY

In summary, MRF represents a minimally invasive method of facial, eyelid, neck, and nonfacial rejuvenation. Many clinical studies have shown this device to improve mild to moderate rhytids and reduce skin laxity. Although there are other radiofrequency devices currently available, MRF has the most literature and clinical trials published to date, which support this method as an effective modality for rejuvenation. Facial contouring and mild to moderate tightening is achieved through volumetric heating and dermal collagen remodeling. The optimal candidate for this procedure is a patient in his or her 30s to 60s with mild to moderate facial laxity that lacks the need for a surgical procedure. MRF using the Thermage CPT system offers minimal downtime with a favorable side-effect profile. Future studies should focus on the nonfacial use of the device on the upper arms, anterior thighs, as well as combination treatments with laser resurfacing, injectables, and intense pulsed light to determine qualitatively and quantitatively if additive effects on dermal collagen can be obtained.

TIPS FOR BEGINNERS

1. Realistic expectations must be set before the procedure.

2. Standardized photography is essential pretreatment and at 3 and 6 months after treatment. Many physicians also obtain immediate posttreatment photographs. Photographs taken at several angles assist in detecting subtle differences and 3-dimensional effects.
3. Absolute contraindications include treatment on patients with a pacemaker, defibrillator, ICD, or other implanted electronic device.
4. Appropriate patient selection is paramount for treatment with MRF.
5. The low-fluence, multiple-pass technique has been shown to attain greater collagen denaturation and skin tightening than the earlier single-pass, high-fluence technique.
6. Vector passes should be performed in the direction the tissue is desired to move.
7. The clinical endpoint is visible or palpable tightening, which has been found to maximize long-term efficacy with the device.

REFERENCES

1. Fitzpatrick R, Geronemus R, Goldberg D, et al. Multi-center study of non-invasive radiofrequency for peri-orbital tissue tightening. *Lasers Surg Med* 2003;33:232–42.
2. Hsu TS, Kaminer MS. The use of nonablative radiofrequency technology to tighten the lower face and neck. *Semin Cutan Med Surg* 2003;22:115–23.
3. Iyer S, Suthamjariya J, Fitzpatrick RE. Using a radiofrequency energy device to treat the lower face: a treatment paradigm for a nonsurgical facelift. *J Cosmet Dermatol* 2003;16:37–40.
4. Jacobson LG, Alexaidis-Armenakas M, Bernstein L, et al. Treatment of nasolabial fold and jowls with a noninvasive radiofrequency device. *Arch Dermatol* 2003;139:1371–2.
5. Ruiz-Esparza J, Gomez JB. The medical facelift: a noninvasive, nonsurgical approach to tissue tightening in facial skin using nonablative radiofrequency. *Dermatol Surg* 2003;29:325–32.
6. Narins DJ, Narins RS. Non-surgical radiofrequency facelift. *J Drugs Dermatol* 2003;2:495–500.
7. Arnoczky SP, Aksan A. Thermal modification of connective tissues: basic science considerations and clinical implications. *J Am Acad Orthop Surg* 2000;8:305–13.
8. Biesman BS. Advances in technology-based eyelid skin rejuvenation. *J Cosmet Dermatol* 2007;20:751–6.
9. Weiss RA, Weiss MA, Munavalli G, et al. Monopolar radiofrequency facial tightening: a retrospective analysis of efficacy and safety in over 600 treatments. *J Drugs Dermatol* 2006;5:707–12.
10. De Felipe I, Del Cueto SR, Perez E, et al. Adverse reactions after non-ablative radiofrequency: follow-up of 290 patients. *J Cosmet Dermatol* 2007;6:163–6.

11. Narins RS, Tope WD, Pope K, et al. Overtreatment effects associated with a radiofrequency tissue-tightening device: rare, preventable, and correctable with subcision and autologous fat transfer. *Dermatol Surg* 2006;32:115–24.
12. Kist D, Burns AJ, Sanner R, et al. Ultrastructural evaluation of multiple pass low energy versus single pass high energy radiofrequency treatment. *Lasers Surg Med* 2006;38:150–4.
13. Zelickson BD, Kist D, Bernstein E, et al. Histological and ultrastructural evaluation of the effects of a radiofrequency-based non-ablative dermal remodeling device. *Arch Dermatol* 2004;140:204–9.
14. Sasaki G, Tucker B, Gaston M. Clinical parameters for predicting efficacy and safety with nonablative monopolar radiofrequency treatments to the forehead, face and neck. *Aesthet Surg J* 2007;5:376–87.
15. Bogle MA, Ubelhoer N, Weiss RA, et al. Evaluation of the multiple pass, low fluence algorithm for radiofrequency tightening of the lower face. *Lasers Surg Med* 2007;39:210–7.
16. Abraham M, Chiang S, Keller G, et al. Clinical evaluation of non-ablative radiofrequency facial rejuvenation. *J Cosmet Laser Ther* 2004;6:136–44.
17. Fritz M, Counters JT, Zelickson BD. Radiofrequency treatment for middle and lower face laxity. *Arch Facial Plast Surg* 2004;6:370–3.
18. Alster TS, Tanzi E. Improvement of neck and cheek laxity with a nonablative radiofrequency device: a lifting experience. *Dermatol Surg* 2004;30:503–7.
19. Ruiz-Esparza J, Gomez JB. Nonablative radiofrequency for active acne vulgaris: the use of deep dermal heat in the treatment of moderate to severe active acne vulgaris (Thermotherapy): a report of 22 patients. *Dermatol Surg* 2003;29:333–9.
20. Meshkinpour A, Ghasri P, Pope K, et al. Treatment of hypertrophic scars and keloids with a radiofrequency device: a study of collagen effects. *Lasers Surg Med* 2005;37:343–9.
21. Goldman MP, Alster TS, Weiss R. A randomized trial to determine the influence of laser therapy, monopolar radiofrequency treatment, and intense pulse light therapy administered immediately after hyaluronic acid gel implantation. *Dermatol Surg* 2007;33:535–42.
22. Alam M, Levy R, Pavjani U, et al. Safety of radiofrequency treatment over human skin previously injected with medium-term injectable soft-tissue augmentation materials: a controlled pilot trial. *Lasers Surg Med* 2006;38:205–10.
23. Shumaker PR, England LJ, Dover JS, et al. Effect of monopolar radiofrequency treatment over soft-tissue fillers in an animal model: part 2. *Lasers Surg Med* 2006;38:211–7.
24. Sukal SA, Geronemus RG. Thermage: the nonablative radiofrequency for rejuvenation. *Clin Dermatol* 2008;26:602–7.
25. Thermage Treatment Reference Guide. Hayward (CA): Solta Medical; 2010. p. 1–37.
26. Abraham MT, Ross EV. Current concepts in nonablative radiofrequency rejuvenation of the lower face and neck. *Facial Plast Surg* 2005;21:65–73.
27. Finzi E, Spangler A. Multipass vector (mpave) technique with nonablative radiofrequency to treat facial and neck laxity. *Dermatol Surg* 2005;31:916–22.
28. Dover JS, Zelickson B, 14-Physician Multispecialty Consensus Panel. Results of a survey of 5,700 patient monopolar radiofrequency facial skin tightening treatments: assessment of a low-energy multiple-pass technique leading to a clinical end point algorithm. *Dermatol Surg* 2007;33:900–7.
29. De Felipe I, Redondo P. Animal model to explain fat atrophy using nonablative radiofrequency. *Dermatol Surg* 2007;33:141–5.
30. Anolik R, Chapas AM, Brightman LA, et al. Radiofrequency devices for body shaping: a review and study of 12 patients. *Semin Cutan Med Surg* 2009;28:236–43.
31. Suh DH, Chang KY, Son HC, et al. Radiofrequency and 585-nm pulsed dye laser treatment of striae distensae: a report of 37 Asian patients. *Dermatol Surg* 2007;33:29–34.