Thermage Radiofrequency for Noninvasive and Nonablative Body Contouring

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Thermage is a noninvasive and nonablative body-contouring technology that applies monopolar radiofrequency energy. This radiofrequency technology induces dermal collagen remodeling and eventual tightening of the skin and improvements in skin quality. Since rejuvenation with Thermage treats rhytides, skin laxity, and cellulite without damaging the epidermis, there is minimal recovery time and minimal risk of complications. The Thermage device is found to be an effective and safe method of body contouring.

Body skin encounters a number of aesthetic insults over time, causing sagging, cellulite, photodamage, stretch marks, and scars, which ultimately diminish skin texture and body contour. The challenge faced by physicians is to improve the appearance of any or all of the above in a safe manner. Although, for many years, surgery in its many forms has been the standard treatment for the aesthetic aspects of aging, the demands of today's cosmetic patient with busy work and social schedules require techniques where downtime and potential for adverse outcomes are limited. Noninvasive procedures with minimal downtime and favorable side-effect profiles are thus advantageous and gaining in popularity.

Thermage is a radiofrequency (RF) device that offers a nonablative and noninvasive treatment option for body contouring and skin laxity. The device delivers monopolar RF energy in the form of an electrical current that generates heat through the inherent electrical resistance of dermal and subcutaneous tissue. The generated heat produces alteration to collagen, and, in combination with the inflammatory cascade that is induced by heating, a tightening effect is realized. In 2002, the US Food and Drug Administration granted Thermage clearance for the treatment of periorbital rhytides and later facial laxity. In 2006, the device was cleared for the treatment of nonfacial skin, including the abdomen, thighs, and buttocks. Since then, a number of clinical reviews and controlled studies have evaluated RF for the treatment of body contouring, cellulite, and tissue tightening. The objective of this report is to review the science and literature on the use of Thermage for body contouring with a focus on RF application and treatment of specific concerns.

RADIOFREQUENCY PROPERTIES

Radiofrequency treatment is based on the principle of volumetric heating. Unlike laser technology that depends on chromophore concentration, RF treatment depends on the electrical properties, or impedance, of the target tissues. Radiofrequency exerts its effect through the production of a uniformly distributed 3-dimensional heat over the epidermis and dermis. Heat is generated by impedance, or innate tissue resistance to the flow of electrical current. Factors such as size and depth of tissue and its various layers (dermis, muscle, fat, and fibrous tissue) must be considered, as they

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impose different degrees of impedance to the RF energy. High-impedance tissues, such as subcutaneous fat, generate greater heat and account for the deeper thermal effects of RF devices.[1] Thermage monopolar RF is able to reach heating depths of 15 to 20 μm, an effective depth for reaching the subcutaneous layer for body contouring.[2] Unlike light energy, RF current is not scattered by tissue or absorbed by epidermal melanin, which allows patients of all skin types to be safely treated.

Radiofrequency performs 2 collaborative functions: initial collagen contraction and a wound-healing response.[3] Heat primarily disrupts collagen bonds, altering the molecular structure of the triple-helix molecule. Collagen shrinkage occurs through the cumulative effect of "unwinding" the individual triple-helix molecules due to the destruction of the intramolecular cross-links, while maintaining the residual tension of the heat-stable intramolecular cross-links. The secondary, more gradual contraction is due to heated fibroblasts and a wound-healing response. This stage takes 2 to 6 months and leads to a thicker remodeled dermis, which is seen histologically as epidermal and papillary dermal thickening and shrinkage of sebaceous glands.[4] Only one treatment is recommended, although a second treatment can be performed 6 months after the first treatment.

DEVICE

The device consists of 3 main components: a generator, a handpiece with a disposable tip, and a cryogen unit. The generator changes the electric field polarity at the tissue interface to generate heat via impedance. It maintains an RF signal at a frequency of 6 MHz, set to an energy level by the clinician. The handheld tip, containing a cooling apparatus, is applied to the skin and protects the epidermis with pre-, parallel-, and postcooling. Sensors in the handpiece monitor temperature and pressure. To prevent epidermal burning, the handpiece stops the delivery of energy when all 4 tip corners are not in complete contact with the skin. It is estimated that the device heats tissue to 65°C to 75°C, the critical temperature range at which collagen denaturation occurs.[5] Use of a cooling tip allows the device to provide volumetric heating of the tissue without damaging the epidermis. Achieving the correct balance between sufficient deep-heat generation needed for collagen contraction and effective epidermal cooling to avoid injury is essential to good clinical outcomes. Although cooling is essential for patient comfort, anesthesia via local or nerve block is not recommended because patient feedback is an important consideration for safe treatment. Additionally, edema secondary to anesthesia infiltration could impair efficacy of the procedure by decreasing the depth of RF penetration.

The depth of heating with the Thermage generator depends on treatment tip size and geometry.[2,6] Currently, body-contouring procedures with Thermage use the Thermage Multiplex tip, most commonly known as the Body 16.0 tip, which was launched in 2009. This tip differs from the original deep contouring body tip 3.0 in several ways. The Multiplex tip is 4 times larger than the previous body tip and has the ability to sequentially deliver energy around the surface of the tip, which cuts treatment time in half. In addition to the new body tip, the current Thermage platform offers an innovative energy-delivery system called Comfort Pulse Technology, a proprietary energy-delivery system that gradually reduces the amount of energy delivered in a succession of short, rapid pulses during treatment. By tapering the amount of heat applied in each pulse, patients enjoy more tolerable treatments, while still maintaining the same body-tightening and body-firming results.

APPROPRIATE CANDIDATES

Proper patient selection is critical for the successful treatment of patients using Thermage. From results seen at our center as well as those of others, we have found that Thermage does not offer considerable benefit to obese patients or those with extreme skin redundancy. From our experience with this body-contouring application, patients in their 30s to 60s with moderate skin laxity and cellulite grade I or II have the best results. Typically patients achieve a 0.5- to 1.0-in circumference reduction following one treatment. Localized areas of adiposity such as the flanks or upper/lower abdomen also can be addressed (Figure 1). The device can be used safely for patients of all skin types. In addition, no damage to hair follicles occurs with this treatment; therefore, the risk of hair loss following treatment is not a potential problem.[7] For those patients who undergo Thermage treatment and subsequently decide to have additional body-contouring procedures, it is best to wait at least 6 months because the tightening effects continue for months following the treatment. Additionally, patients with pacemakers should not be treated, and those with any sort of underlying metal implant should be approached cautiously, if at all.

TREATMENT WITH THERMAGE

All patients should have accurate and standardized pre- and postprocedure photographs to allow for appropriate evaluation of improvement. We use a blue background screen set up in the same room with consistent lighting. A foot placement mat is provided to standardize patients' stance during photography. We photograph the treatment area from the front, both sides, and a

3-quarter turn. Weight and circumference measurements are recorded prior to treatment, and degree of skin laxity is determined. Several scales can be used to determine skin laxity with equal efficacy, and this measurement is used primarily to document continued improvement. The patient is examined in a standing position, and the treatment area is marked with vectors to reference the direction of skin tightening (Figure 1). A temporary treatment grid system that is supplied by the company is applied. The grid directs the placement of the handheld tip with each successive pressure point. Pressure with the tip needs to be applied evenly or an error message is displayed and the tip cannot fire until the machine is reset. Pressure points should be adjacent but not overlapping each other. When more than a single pass is done, an entire region should be treated with the first pass before a successive pass is initiated, allowing for tissue cooling between passes and minimizing epidermal injury.

During our initial period of clinical experience with Thermage, when the device was still primarily used on facial skin, we used relatively high energies and fewer treatment passes. Currently, treatments for all body areas have shifted toward lower-energy, multiple-pass protocols for better efficacy, greater tolerance, and a lower-risk profile. For optimum treatment results, it is recommended that the treatment area for one tip be no greater than 8×11 in. Therefore, if treating thighs and buttocks in the same session, our center will typically use two 16.0 treatment tips (Figure 2). The 16.0 body tip is able to deliver 400 pulses, and treatment is continued until these pulses are exhausted, at which point the device will cease to discharge RF energy.

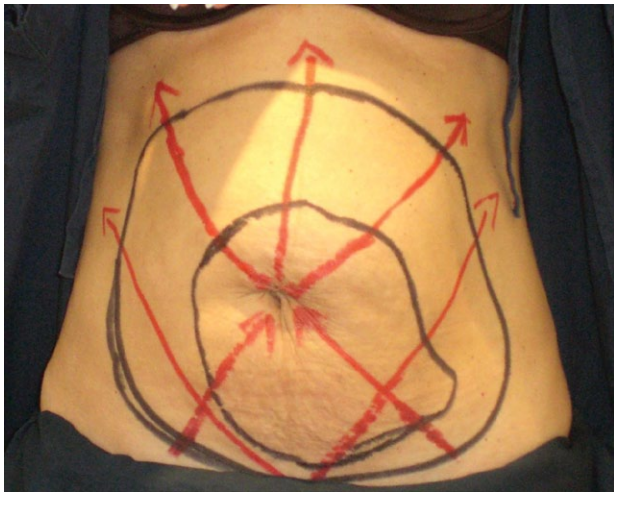

Figure 1. Markings of abdomen prior to Thermage treatment on a 36-year-old woman with postpartum skin laxity. Primary areas are marked in black and vectors are marked in red.

Prior to treatment, coupling fluid is applied generously to the entire treatment area. Eye protection for the physician and patient is not required. During treatment, 2 full-treatment passes are performed over the whole area using the grid. Afterwards, 3 or more additional passes are made in the area of concern following the vectors marked prior to treatment. Four different settings from treatment level 1.0 to 4.0 are available to be selected during treatment. The higher setting levels correspond to increased energy output by the device. Patients typically are started on level 3.0, and the level is adjusted depending on their tolerance of the procedure. Treatment duration for a single tip ranges from 55 to 75 minutes. During treatment, patients are evaluated constantly for signs of erythema and edema. Keen intraoperative observation and patient feedback are crucial because they allow the physician to determine if there is adequate anesthesia or potential for epidermal injury. Mild edema and erythema are considered expected outcomes and correlate with clinical efficacy. External temperature monitoring can be performed to ensure an external temperature rise of 40°C to 42°C, which has been shown to correspond to 65°C to 75°C subcutaneously.[8] Follow-up visits are scheduled at 1, 3, and 6 months posttreatment (Figures 3 and 4).

ANESTHESIA

Proper anesthesia is important to allow the patient to comfortably tolerate the procedure but also mild enough to allow for patient feedback. At our center, we use excessive pain/heat as important feedback and a possible indication that treatment should be altered, either by decreasing energy or moving to another area. Pain during the procedure can vary from patient to patient depending on the body area treated, if the treated area encompasses bony prominences, and the innate pain threshold of the patient. Patients most often describe the pain as a brief burning sensation that rapidly dissipates. A study conducted by Fitzpatrick et al[3] reported that most subjects characterized the pain as mild to moderate. It is not surprising that most report a minimal amount of discomfort because the device can achieve ultrastructural changes down to 5 mm.[4] To allow for patient feedback and comfort, we routinely use oral anesthesia: Percocet 5 mg/325 mg 30 minutes prior to treatment. Aside from the cryogen cooling from the treatment tip, oral anesthesia is the only adjunctive pain control method employed at our center. Topical anesthesia, local nerve blocks, or unconscious sedation are not used to avoid thermal injury from excess heating of the dermis.

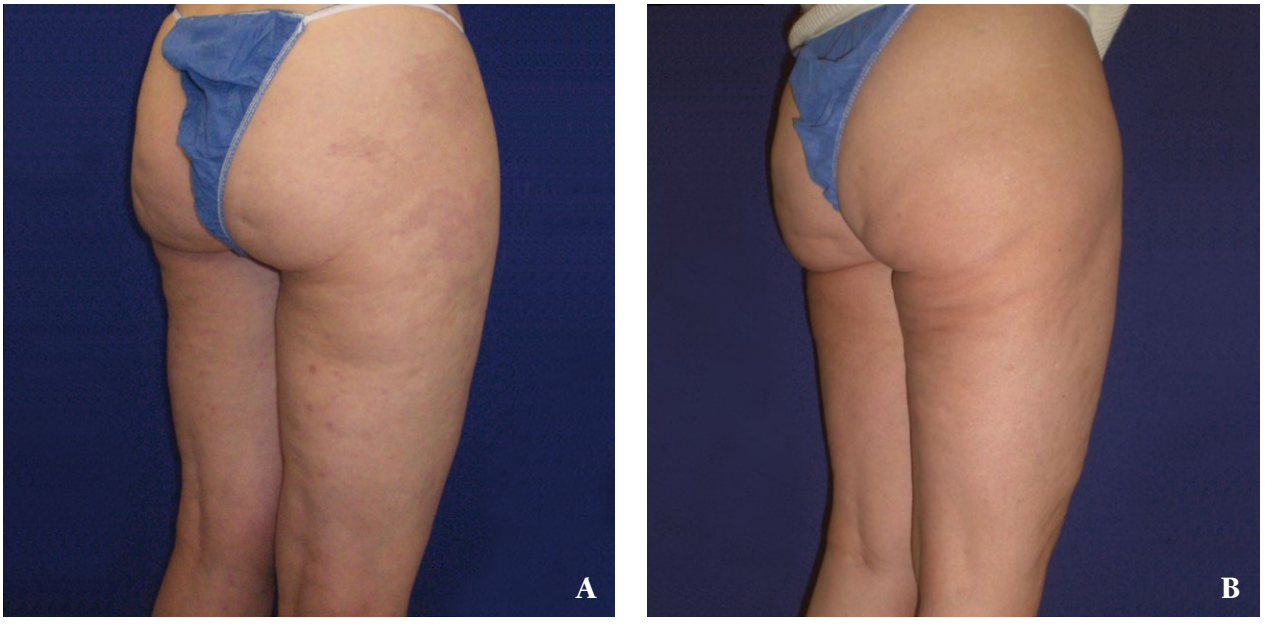

Figure 2. Thermage treatment for cellulite and reduction of thigh circumference on a 46-year-old woman. Single treatment with two 16.0 body tips: 200 pulses right buttock, 200 pulses left buttock, 200 pulses right posterior thigh, 200 pulses left posterior thigh. Images are preprocedure (A) and 6 months postprocedure (B).

CLINICAL STUDIES

To date, very few studies that specifically evaluate improvement in body contour, off-face texture, or cellulite have been performed with Thermage. Therefore, the discussion in this section will include published data from several studies on other devices that used RF as monotherapy for treatment of nonfacial skin.

Emilia del Pino et al[9] evaluated unipolar RF for the treatment of cellulite and changes in subcutaneous tissue thickness. Twenty-six female patients aged 18 to 50 years with thigh and buttock cellulite were treated and evaluated via ultrasound imaging. Ultrasound scans performed before and after treatment measured the distance between the stratum corneum and Camper's fascia, as well as the distance between the stratum corneum and the muscle. Results showed that 68% of patients demonstrated a volume reduction of at least 20%.

Goldberg et al[2] studied the effects of unipolar RF on thigh circumference and cellulite on 30 female patients, while also incorporating biopsy, magnetic resonance imaging, and blood lipid analysis at baseline and 6 months posttreatment. Twenty-seven of the 30 patients showed substantial improvement in body contour, as analyzed by 2 independent blinded dermatologists. Mean thigh circumference decreased by 1 in. No substantial weight, magnetic resonance imaging, or blood lipid level changes were appreciated. Biopsy reviews showed dermal fibrosis and thickening, with a background of mildly increased fibroblasts and elastin fibers.

Van der Lugt et al[10] evaluated variable-frequency bipolar RF on cellulite of the buttocks and collagen production. Fifty female patients aged 24 to 58 years were treated with a bipolar RF device that varies frequency based on tissue resistance. Fifteen patients underwent biopsies pre- and immediately posttreatment, as well as at a 2-month follow-up. Immediately posttreatment microscopy analysis showed edema, lymphocytic infiltrate, ectatic vessels, and adipocytes with membrane lysis. Two months posttreatment, dermal collagen was appreciated as thicker and better organized. Compared to pretreatment histology, the suggested increase in dermal thickness was 40% to 50%. Ten patients also underwent skin surface examinations using CLIN PRO 3-D optical imaging system at baseline and 2 months posttreatment. Analysis indicated a 42% to 55% improvement in texture.[10]

Anolik et al[11] evaluated the treatment of abdominal skin laxity with the Thermage RF system using the 16.0 body tip on 12 patients. Weight, waist circumference, skin-laxity scores, photographs, and global aesthetic improvement scores were collected at baseline and at 1, 2, 4, and 6 months posttreatment. Weight change was minimal over the course of the study, with an average change of less than 1 pound. Waist circumference

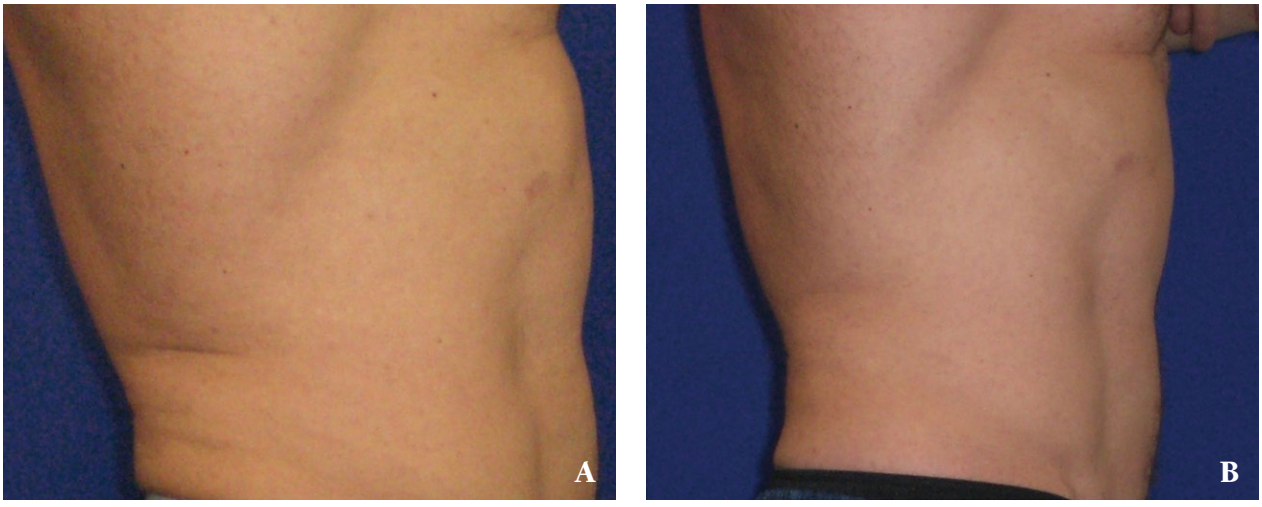

Figure 3. Thermage treatment for localized adipocity of the flanks on a 38-year-old man. Single treatment with one 16.0 body tip: 200 pulses right flank, 200 pulses left flank. Images are preprocedure (A) and 6 months postprocedure (B).

Figure 4. Thermage treatment for circumference reduction and tissue laxity on a 36-year-old woman with postpartum skin laxity. Single treatment with one 16.0 body tip: 400 pulses. Images are preprocedure (A) and 6 months postprocedure (B).

revealed a decreasing trend, with the most dramatic change of an average reduction of 0.7 in occurring at the 2-month follow-up. Skin laxity scores echoed the trend in circumference reduction, with the percentage of subjects showing improvement from baseline being 67%, 78%, 60%, and 44% at follow-up visits at 1, 2, 4, and 6 months posttreatment, respectively.

Although all studies described show the potential of RF for body contouring and as a trend of aesthetic improvement, several limitations exist. A number of studies fail to assess statistical significance and do not incorporate control groups or extended follow-up periods. One of the greatest drawbacks is the lack of a standardized means of evaluation post-RF treatment; methods of comparison generally are limited to investigator opinion. To counter this challenge, techniques such as skin-elasticity measurement and 3-D surface-imaging systems are increasingly helpful tools.

COMPLICATIONS

The side-effect profile of Thermage treatments is favorable. Most unwanted effects such as mild erythema and edema are temporary and spontaneously resolving.[12] New multiple-pass, low-energy protocols have not been associated with previously noted events of lipoatrophy seen with single-pass, high-energy technologies. However, nonfacial skin can demonstrate transient crusting, depressions, dysesthesias, and other adverse effects but this has been rare in our experience. During early trials with Thermage, erosions, vesiculation, and thermal injuries were seen but have become much less common as treatment protocols have been adjusted and standardized. The relationship between either dysesthesia or tenderness and treatment energy has not been determined; however, it is tempting to speculate that the lower-energy multipass protocol in use today is less likely to produce these unwanted effects. These adverse effects largely are practitioner dependent, either because of lack of epidermal cooling or excessive stacking of pulses. As treatment algorithms evolved to multiple passes at lower fluences, better clinical outcomes and greater patient acceptance have emerged.

CONCLUSION

Thermage offers a noninvasive, nonablative, and innovative treatment option to improve body contour and skin laxity. With the implementation of the Thermage Body 16.0 tip, new possibilities to treat contour irregularities on nonfacial areas have been realized. Practitioners are now able to offer successful treatment for cellulite, postpartum laxity, and localized adiposity to provide a truly nonsurgical solution to these cosmetic concerns. Clinical results and patient satisfaction with Thermage for body contouring have been impressive; however, there is still much room to enhance RF technology and achieve the ultimate goal of precise contouring. As more noninvasive and minimally invasive approaches become the norm, it is important to understand how various technologies may interact in a cooperative or adverse fashion. It will be exciting to see future studies evaluating the effects of RF for improving striae cutis distensae, acne scars, and traumatic scars, as well as becoming an adjunct to liposuction.

REFERENCES

1. Lack EB, Rachel JD, D'Andrea L, et al. Relationship of energy settings and impedance in different anatomic areas using a radiofrequency device. *Dermatol Surg.* 2005;31:1668-1670.
2. Goldberg DJ, Fazeli A, Berlin AL. Clinical, laboratory, and MRI analysis of cellulite treatment with a unipolar radiofrequency device. *Dermatol Surg.* 2008;34:204-209.
3. Fitzpatrick R, Geronemus R, Goldberg D, et al. Multicenter study of noninvasive radiofrequency for periorbital tissue tightening. *Lasers Surg Med.* 2003;33:232-242.
4. Zelickson BD, Kist D, Bernstein E, et al. Histological and ultrastructural evaluation of the effects of a radiofrequency-based nonablative dermal remodeling device: a pilot study. *Arch Dermatol.* 2004;140:204-209.
5. Arnoczky SP, Aksan A. Thermal modification of connective tissues: basic science considerations and clinical implications. *J Am Acad Orthop Surg.* 2000;8:305-313.
6. Alster TS, Tanzi E. Improvement of neck and cheek laxity with a nonablative radiofrequency device, a lifting experience. *Dermatol Surg.* 2004;30:503-507.
7. Sadick NS, Shaoul J. Hair removal using a combination of conducted radiofrequency and optical energies—an 18-month follow-up. *J Cosmet Laser Ther.* 2004;6:21-26.
8. DiBernardo BE, Reyes J, Chen B. Evaluation of tissue thermal effects from 1064/1320-nm laser-assisted lipolysis and its clinical implications. *J Cosmet Laser Ther.* 2009;11:62-69.
9. Emilia del Pino M, Rosado RH, Azuela A, et al. Effect of controlled volumetric tissue heating with radiofrequency on cellulite and the subcutaneous tissue of the buttocks and thighs. *J Drugs Dermatol.* 2006;5:714-722.
10. van der Lugt C, Romero C, Ancona D, et al. A multicenter study of cellulite treatment with a variable emission radiofrequency system. *Dermatol Ther.* 2009;22:74-84.
11. 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;28:236-243.
12. 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;5:707-712. ■