



Radiofrequency Devices for Body Shaping: A Review and Study of 12 Patients

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Radiofrequency (RF) devices such as ThermoCool TC (Solta Medical Inc., Hayward, CA) offer a nonablative and noninvasive treatment option for unwanted skin concerns of the head, neck, and body. Relatively fewer studies address RF treatment on the body when compared with the head and neck. The purpose of this report is to investigate the use of the ThermoCool TC system with the novel Thermage Multiplex Tip for the enhancement of body shape. Additionally, this report will review the literature of RF technology with a concentration on body shaping. Twelve subjects underwent ThermoCool TC treatments using the Thermage Multiplex Tip. Waist circumference, standardized photographs, skin laxity score, global aesthetic improvement score, and patient satisfaction surveys were assessed at baseline and several follow-up visits after treatment. Average waist circumference and skin laxity scores decreased after ThermoCool TC treatment, using the Thermage Multiplex Tip at follow-up visits held at 1, 2, 4, and 6 months after treatment. Global aesthetic improvement score and patient satisfaction surveys reflected these objective clinical improvements. RF devices, such as the ThermoCool TC offer a nonablative and noninvasive treatment option for unwanted skin findings of the head, neck, and body.

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Body skin encounters a number of aesthetic insults over time causing sagging, cellulite, photodamage, striae distensae, and scars, which ultimately diminish skin texture and body contour. Physicians have responded to these concerns with a number of effective noninvasive approaches, and newer technologies show further promise.

Aesthetic grievances are influenced by the body area under evaluation, since different areas are more susceptible to particular insults. Cellulite, often more pronounced and abundant in women, favors the buttocks, thighs, abdomen, and arms. Photodamage largely affects the routinely sun-exposed areas of the head, neck, and dorsal hands, generating unwanted effects, such as rhytides, dyschromia, and laxity. Striae distensae are observed commonly in the intertriginous and abdominal areas of men and women, particularly during

corticosteroid use, obesity, growth spurts of adolescence, and following the substantial changes in body dimensions experienced by women during pregnancy. These same changes in pregnancy can lead to sagging of the abdominal skin. Surgical and traumatic scars have little predisposition to body site, other than iatrogenic scars often respecting cosmetic subunits and traumatic scars favoring exposed surfaces.

Treatment options are expanding for these unwanted changes on body skin. In the 1980s, carbon dioxide ablative laser resurfacing offered a powerful tool to modify several of these unwanted findings, particularly photodamage and scars.¹ However, these devices showed significant risks for depigmentation and scarring, particularly when used off the face. Despite modifications on ablative strategies, postprocedure downtime and risk aversion triggered the emergence of fractional and nonablative alternatives.

Radiofrequency (RF) devices, such as ThermoCool TC (Solta Medical, Inc., Hayward, CA) offer a nonablative and noninvasive treatment option. By delivering RF energy in the form of a monopolar electric current, heat is generated because of tissue resistance to flow. Heat damage, and the subsequent inflammatory cascade, alters collagen and produces

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a tightening effect.² Initially, in 2002, the Food and Drug Administration granted clearance for an RF device to treat periorbital rhytids. Later, the device was cleared for facial laxity and, in 2006, the device was cleared for treatment of nonfacial skin, including the abdomen, thigh, and buttocks.

Although a number of studies exist that demonstrate RF effect on facial skin, relatively fewer clinical studies have evaluated RF on nonfacial skin. The objective of this report is 2-fold. First, we present findings from the treatment of abdominal skin laxity with the ThermoCool TC, using the novel Thermage Multiplex Tip. Second, we will review the science and literature of RF devices with a focus on its role in body shaping.

Materials and Methods

Study Design

This blinded, multicenter, and IRB-approved study evaluated the efficacy and safety of the RF device, ThermoCool TC, to treat mild to moderate abdominal skin laxity using the Thermage Multiplex Tip. Patients were initially screened for clinical trial eligibility with detailed inclusion and exclusion criteria. Informed consent and photo releases were received from all patients before any participation in the study. Before the study procedures, the investigators performed physical examinations and obtained detailed medical histories. Additionally, weight and waist circumference were measured, and degree of skin laxity was determined on a scale from 0-3, where 0 = none, 1 = mild, 2 = moderate, and 3 = severe. Finally, standardized photographs were obtained for each subject. Subjects had the option to receive systemic Toradol, percocet, or valium 1 hour before treatment. Ten of the 12 subjects received all 3 medications while 2 subjects received only toradol. At the procedure (baseline) visit, subjects underwent the ThermoCool TC treatment using the Thermage Multiplex Tip. The procedure was performed over a washable grid pattern applied to the subject's treatment area, which was removed after treatment. All but 2 patients received 300 pulses during the Thermage treatment. The 2 others received 250 and 276 pulses. Treatment duration spanned 35-55 minutes, averaging 42 minutes. Treatment energies ranged from 28 to 46 J/cm². Immediately following treatment, and at follow-up visits at 1, 2, 4, and 6 months after treatment, weight, waist circumference, skin laxity score, and photographs were again obtained. Also, at these follow-up visits, investigators determined global aesthetic improvement scores (Table 1). At 2, 4, and 6 months after treatment, satisfaction surveys were completed by the subjects to indicate whether they were very satisfied, somewhat satisfied, neutral, somewhat dissatisfied, or dissatisfied with the treatment results.

Study Population

A total of 12 subjects, all women, participated in the study. Enrollment criteria called for subjects aged 21-65 years; with no previous procedures or surgeries on or near the targeted treatment area, including Cesarean sections; with no diastasis

Table 1 Global Aesthetic Improvement Scores Definitions

Rating	Description
Very much improved	Optimal cosmetic result for the treatment rendered to this patient
Much improved	Marked improvement in appearance from initial condition, but not completely optimal for this treatment. A touch up would slightly improve the result
Improved	Obvious improvement in appearance from the initial condition, but a touch up or re-treatment is indicated
No change	The appearance is essentially the same as the original condition
Worse	The appearance is worse than the original condition

of the rectus abdominal muscles; having less than 5% variation in body weight during the past year; and being within 20% of his or her normal body weight. Throughout the study, subjects were to avoid products formulated to change the appearance of the skin, such as retinoids and vitamin creams. Additionally, no topical steroids were to be used to the treatment area for 8 weeks before treatment initiation and throughout the study. Subjects were also to avoid sun exposure to the treatment area or, alternatively, wear oil-free sunscreen for at least 1 week before treatment initiation and throughout the study. Additionally, subjects were to maintain constant body weight.

RF Device

The ThermoCool TC System is a nonablative, noninvasive, monopolar RF device that provides pre-, parallel, and post-cooling for epidermal protection. By coupling RF to the skin by a capacitive membrane, RF energy is distributed to a targeted volume of tissue. It maintains a 6 MHz alternating current RF signal, set to an energy level by the clinician, along with a handpiece with an electrode treatment tip, in this case the Thermage Multiplex Tip, and a cryogen module to deliver the cooling protection. The Thermage Multiplex Tip differs from the original "deep contouring" body tip 3.0 in several ways. These differences include its being 4 times the size of the original. Additionally, energy is delivered sequentially around the surface of the tip. These changes allow for more rapid treatment of targeted areas.

Results

All 12 subjects underwent the ThermoCool TC System treatment using the Thermage Multiplex Tip. Seven subjects returned for all planned follow-up evaluations at 1, 2, 4, and 6 months after treatment, while 5 subjects missed 1 or at most 2 of the 4 follow-up visits.

At each of the 4 follow-up visits, a decrease in average skin laxity was observed when compared with baseline assessment (Table 2). Similarly, at each of the 4 follow-up visits, a

Table 2 Net Changes in Skin Laxity When Compared With Baseline Measurement

Patient	Baseline	1 mo	Net Change	2 mo	Net Change	4 mo	Net Change	6 mo	Net Change
1	1.5	1.5	0.0	2.0	0.5	N/D	N/D	1.5	0.0
2	2.5	3.5	1.0	2.5	0.0	3.5	1.0	3.5	1.0
3	1.5	1.5	0.0	1.0	-0.5	1.0	-0.5	1.0	-0.5
4	2.0	1.0	-1.0	1.0	-1.0	1.0	-1.0	1.5	-0.5
5	2.5	2.0	-0.5	1.5	-1.0	2.0	-0.5	2.0	-0.5
6	2.0	2.0	0.0	2.5	0.5	2.0	0.0	2.5	0.5
7	2.0	1.5	-0.5	N/D	N/D	2.5	0.5	N/D	N/D
8	1.0	1.0	0.0	N/D	N/D	1.0	0.0	1.0	0.0
9	1.5	2.0	0.5	1.5	0.0	N/D	N/D	N/D	N/D
10	1.5	1.5	0.0	N/D	N/D	1.0	-0.5	N/D	N/D
11	2.5	2.0	-0.5	1.5	-1.0	2.0	-0.5	2.0	-0.5
12	2.5	2.0	-0.5	1.5	-1.0	1.5	-1.0	1.5	-1.0
Average change		-0.13		-0.39		-0.25		-0.17	

Skin laxity: 0 = None; 1 = Mild; 2 = Moderate; 3 = Severe.

N/D, no data collected.

decrease in average waist circumference was determined compared with baseline (Table 3). All 12 patients returned for their 1-month follow-up evaluation, and demonstrated an average decrease in waist circumference of 1.4 cm. The 9 patients who returned for the 2 months follow-up evaluation demonstrated an average decrease in waist circumference of 1.7 cm from baseline. The 10 patients who returned for the 4 months follow-up evaluation demonstrated an average decrease in waist circumference of 0.2 cm from baseline. Finally, the 9 patients who returned for the 6 months follow-up evaluation demonstrated an average decrease in waist circumference of 0.9 cm from baseline.

Global aesthetic improvement scores revealed a trend toward improved appearance. The percentage of subjects showing improvement (scores of either improved, much improved, and very much improved) among those who followed-up was 67%, 78%, 60%, and 44% at follow-up visits at 1, 2, 4, and 6 months after treatment, respectively. Only 1 subject showed aesthetic worsening. This event occurred at the 2 months follow-up visit and showed no change from baseline at the subsequent 2 follow-up visits. A representa-

tive photograph of a patient who showed improvement in body contour and skin texture is shown in Figure 1.

Finally, patient satisfaction scores echoed the trend of the global aesthetic improvement score toward improved appearance. The percentage of subjects claiming satisfaction (scores of either very satisfied 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. These numbers contrast those claiming dissatisfaction (scores of either somewhat dissatisfied or dissatisfied), which totaled 0%, 10%, and 22% of those who followed-up at visits 2, 4, and 6 months after treatment, respectively.

In general, weight change was minimal over the course of study, with an average change of less than 1 pound. However, despite counseling to the contrary, a few patients were not able to maintain a relatively constant weight profile. Three subjects showed weight changes of more than 5% of their baseline body weight. One subject gained 7% of her original body weight, another lost just over 5%, and finally another lost 13%. Excluding these subjects from the analyses, however, has little impact on the results described above. In fact,

Table 3 Net Changes in Waist Circumference (cm) When Compared With Baseline Measurement

Patient	Baseline	1 mo	Net Change	2 mo	Net Change	4 mo	Net Change	6 mo	Net Change
1	82.0	78.5	-3.5	76.7	-5.3	N/D	N/D	80.0	-2.0
2	69.2	68.0	-1.2	65.4	-3.8	66.0	-3.2	65.0	-4.2
3	82.1	78.5	-3.6	76.4	-5.7	78.4	-3.7	78.5	-3.6
4	81.5	78.0	-3.5	78.9	-2.6	82.5	1.0	82.5	1.0
5	95.9	95.0	-0.9	95.1	-0.8	98.2	2.3	99.5	3.6
6	85.1	85.0	-0.1	89.0	3.9	91.5	6.4	88.5	3.4
7	79.2	77.5	-1.7	N/D	N/D	78.5	-0.7	N/D	N/D
8	83.5	82.0	-1.5	N/D	N/D	74.5	-9.0	69.5	-14.0
9	96.1	95.0	-1.1	95.1	-1.0	N/D	N/D	N/D	N/D
10	80.4	79.0	-1.4	N/D	N/D	80.5	0.1	N/D	N/D
11	84.6	84.5	-0.1	84.0	-0.6	84.3	-0.3	85.5	0.9
12	80.1	82.5	2.4	81.1	1.0	84.7	4.6	86.5	6.4
Average change		-1.4		-1.7		-0.2		-0.9	

N/D, no data collected.

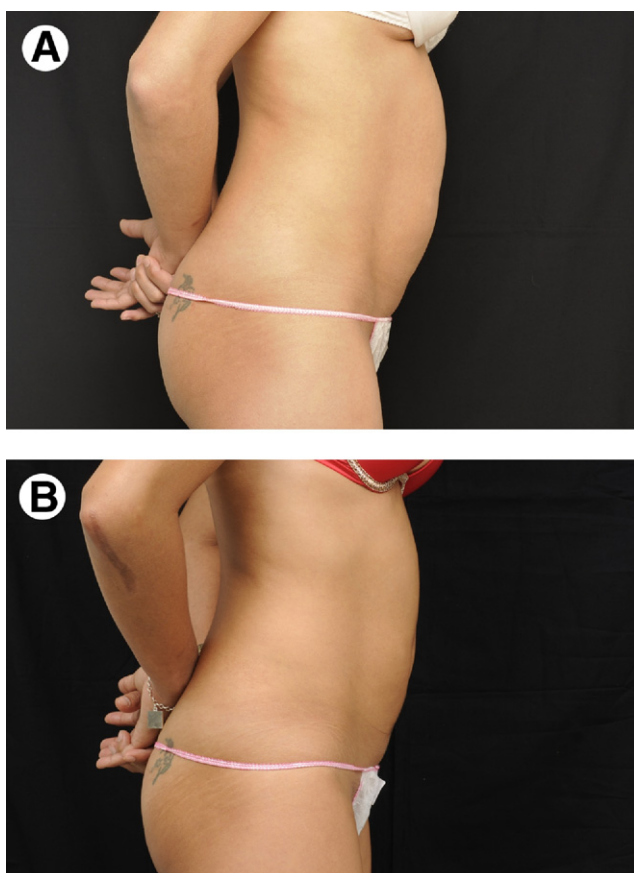


Figure 1 (A) Baseline photograph of patient before initial treatment. (B) Photograph of patient 4 mo following ThermoCool TC treatment using the Thermage Multiplex Tip, demonstrating improved tone and texture.

the most dramatic average change in waist circumference, which occurred at 2 months follow-up, improved from an average decrease of 1.7-1.9 cm when excluding the 3 subjects with greater than 5% change in body weight. Similarly, skin laxity showed greater average improvement across all follow-up visits when the 3 subjects are excluded.

No unexpected side effects or adverse events occurred during the trial. As expected, some patients experienced transient erythema and edema of treated skin immediately following treatment. These changes subsided within hours of onset. All patients tolerated the procedure, experiencing at most mild to moderate tenderness. Several patients benefited from analgesics and anxiolytics during treatment sessions.

Discussion

Mechanism of RF

RF treatment exerts its effect through the production of a uniformly distributed three-dimensional heat over the epidermis and dermis, a principle referred to as volumetric bulk heating. Heat is generated by the innate tissue resistance to flow of electrical current. Unlike laser technology that depends on chromophore concentration, RF treatment depends on the electrical properties of the target tissues. Most

devices in practice today, such as the ThermoCool TC, incorporate contact and air cooling to protect the epidermis. The absence of any incisions and the incorporation of epidermal cooling strategies allow RF procedures to be both noninvasive and nonablative.

RF may be delivered in various polarities: monopolar, bipolar, "TriPollar," and unipolar. In monopolar and bipolar RF systems, 2 electrodes generate current. For monopolar systems, a delivery electrode is placed over a target area, and a return electrode is applied at a distant site. In contrast, bipolar systems incorporate both electrodes into a single handpiece. In general, the monopolar systems have more deeply penetrating effects, but may be more painful, whereas bipolar systems reach relatively less depth, yet are more comfortable. Newer protocols that employ multiple treatment passes at lower energies have resulted in acceptable pain levels of monopolar systems. More recently, a so-called "TriPollar" system has been introduced that incorporate 3 electrodes—1 positive and 2 negative—that is promoted as producing a more densely focused current and therefore result in higher power density and lower power consumption.³ In conclusion, unipolar RF systems function without a grounding plate and consequently generate no current.⁴ Instead, electromagnetic radiation with rapidly alternating polarity induces heat-generating oscillations of water molecules.⁴ This modality is thought to produce heat reaching depths of 15-20 mm.⁴

The various devices in the market deliver RFs at fixed frequencies, which differ from manufacturer to manufacturer. For example, Thermage delivers RF at 6 MHz, while Vela products (Syneron Medical, Yokneam Illit, Israel) use 1 MHz and Alma products (Alma Lasers, Buffalo Grove, IL) use 40 MHz. More recently, some manufactures are developing variable frequency products, which alter based on target tissue impedance.⁵

The consequence of volumetric heating can be viewed as immediate and delayed. Initially, the collagen fibrils incur a small degree of denaturation, which recover with shortening of fibril length. A later effect follows the subsequent inflammatory cascade in response to the initial heat. The cascade is thought to result in new collagen formation, although the exact mechanisms of this process are not well understood. It is the reduction in surface area from fibril tightening, in addition to the new collagen production that is suggested to produce the clinically evident cosmetic enhancement.²

Energy output for a particular treatment device is directly related to the current, impedance and time.^{2,6} This can be represented as Joule's law, $J = I^2 \times z \times t$, where J is energy, I is current, z is impedance, and t is time in seconds.^{2,6}

Appreciation for energy output is valuable in the clinical setting, as impedance (I) varies among different anatomic areas.⁶ Lack et al⁶ demonstrated in 4 patients treated with RF that impedance levels were highest on the dorsal arm, followed by the forehead, medial and lateral cheeks, and lastly back. The impedance variation stems from the make-up of the anatomic areas being treated. Bone and fat offer higher impedance than muscle and dermis.⁶ Therefore, lower impedance levels should be expected in areas, such as the back with thicker dermis. Impedance can also be altered by degree

of tissue hydration as well as pretreatment or simultaneous treatment with other form of energy, such as infrared light.

Practice

Although RF systems vary, ThermaCool TC serves as a good representative. The device is comprised of 3 major components: a generator, handheld tip, and cryogen unit. As it is a monopolar system, a return electrode is placed at a distant site. The generator changes electric field polarity at a frequency of 6 MHz, with subsequent effect on electron movement as already discussed. The handheld tip offers pre-, parallel, and postcooling to protect the epidermis via its cryogen unit. Treatment tip size and geometry can be varied to accommodate different anatomic locations and target depths.⁷

Standardized pre- and post-treatment photography is helpful to document any clinical changes. Ideally, this involves high quality cameras in the same room, lighting, and positioning each time.

In general, treatment has shifted toward low energy, multiple pass protocols for better efficacy, tolerance, and lower risk profile. Coupling fluid is applied to treatment areas. Eye protection for the physician and patient are not required. Energy levels vary for different anatomic sites and can be adjusted by the user. Edema and tightening should be actively monitored by the physician throughout sessions, as these changes suggest efficacious treatment. The handheld tip should be applied with even pressure, without which the system is designed not to fire. A grid system is provided by Thermage to direct handheld tip application, and is particularly helpful to beginners, and helpful when treating body parts with ill-defined landmarks. Throughout the treatment sessions, patients should be assessed for sufficient analgesia and adverse effects. Mild erythema and edema are not uncommon, but the physician should not expect significant pain, skin crusting, depressions, or dysesthesias.

Histology

The histology of RF changes has been reported in the literature. In 2004, Zelickson et al⁸ evaluated abdominal skin in 2 female patients after treatment with the ThermaCool TC. One subject was treated with 95 J using a 1 cm² treatment tip, while the other was treated at varying energy levels, specifically 104, 133, and 181 J, also using a 1 cm² treatment tip. Both patients received pre-, peri-, and post-treatment cryogen cooling. When comparing control vs treatment area biopsies on light microscopy, a scattered mild perivascular and periadnexal inflammatory infiltrate was documented in the initial biopsies. These biopsies were taken on day 2 after treatment for the first subject and within 45 minutes of treatment for the second. These findings were not seen in later biopsies taken up to 8 weeks after treatment in each subject. Electron microscopy was also performed on the tissue samples. Immediately after treatment, an increase in size and loss of distinct border was observed among the collagen fibrils. These fibril changes peaked at 3–4 mm in-depth, and reached 5 mm. The group complemented the microscopy studies with a northern blot analysis, which demonstrated an ele-

vated expression of collagen type 1 messenger RNA. These histologic changes endorse the theories outlined in the mechanism section above that clinical improvement is a result of reduced surface area from fibril tightening and new collagen stimulation.

Numerous other studies address the modified collagen architecture following RF treatments, in addition to increased type 1 collagen levels using immunohistochemistry.^{4,5,9-12} Furthermore, subcutaneous fat changes have been observed following RF.^{5,13,14} These changes include adipocyte membrane lysis or, if not lysed, appreciable reduction in lipid contents.

Head and Neck Studies

Relatively more is known about RF treatments of the head and neck, particularly that of periorbital skin and the lower face, when compared with treatments of the body. Treatment protocols and review of studies for the head and neck have been examined and outlined in earlier manuscripts.⁷ A detailed discussion of these studies is beyond the scope of this report. Briefly, however, Fitzpatrick et al² and Nahm et al¹⁵ reported clinical improvement of the periorbital skin following RF treatment. Others, such as Alster and Tanzi,¹⁶ Fritz et al,¹⁷ and Bogle et al,¹⁸ reported improvement of the lower face, including laxity of the cheek and prominence of the nasolabial folds, following RF treatments.^{2,15}

Body Shaping Studies

Body shape is influenced by both contour and skin texture. This section will review the published data that specifically look for both tightening (ie, contour enhancement) and texture improvement following RF treatment. This discussion excludes studies that bundle RF with other technologies as well as those that limit discussions to cellulite, which can be considered simply a subcomponent of texture. Overall, the findings in these reports are consistent with the data in the study presented in this report. Mild to moderate clinical improvements are documented in patients who present without excessive skin laxity or obesity. Additionally, these changes are noted to last at least for several months.

Emilia del Pino et al¹⁹ evaluated the effect of RF on cellulite and subcutaneous tissue thickness with the assistance of real-time scanning image ultrasound. Twenty-six female patients aged 18–50 years with thigh and buttock cellulite were treated with the Accent RF System (Alma Lasers, Inc., Caesarea, Israel), a unipolar RF device. Each treatment consisted of 3 passes at fluences of 91 J/cm², adjusted for patient tolerance to heat or until the temperature rose to within 39°C and 41°C. Patients underwent 2 treatment sessions 15 days apart. Ultrasound images were generated over the thigh as well as the buttock before the first treatment and 15 days after the second. The images allowed the team to measure the distance between the stratum corneum and Camper's fascia, as well as the distance between the stratum corneum and muscle. On the basis of these measurements, the group concluded that 68% of patients demonstrated a volume contraction of approximately 20%.

Goldberg et al⁴ studied the visible effects of RF on cellulite and thigh circumference, while also incorporating biopsy, magnetic resonance imaging (MRI), and blood lipid level analysis. Thirty female patients over the age of 30 years with thigh cellulite were treated every other week for a total of 6 treatments, using a unipolar RF system from Alma Lasers (Alma Lasers, Buffalo Grove, IL). Each treatment consisted of 3 passes at 150-170 W of energy to maintain skin temperature between 40°C and 42°C. Patient weight, blood lipid level, and thigh circumference were determined before treatment and 6 months after treatment. At that times, standardized photographs, skin biopsies, and MRI images were taken. Two independent, nontreating judges evaluated the photographs and offered a score of 1-4 based on change in leg smoothness (defined as 1 = no improvement and 4 = most improvement). Twenty-seven of the 30 patients showed clinical improvement by this assessment, on an average at a score of 2.9. Mean thigh circumference diminished to 2.45 cm. No significant weight, blood lipid level, or MRI changes were appreciated by the investigators following treatment. Post-treatment dermal fibrosis was observed on biopsy review, although no gross changes were observed in the subcuticular layer.

van der Lugt et al⁵ managed a multicenter study to evaluate the effect of a variable frequency bipolar RF device on cellulite of the buttocks and collagen production. Fifty female patients aged 24-58 years with buttock cellulite were treated with the bipolar RF device known as ThermoLipo (Therma-med, Ltd., Alicante, Spain), which varies frequency based on tissue resistance. Patients received 12 weekly treatments at fluences of 6 J/cm³ and a minimum of 6 passes to maintain skin temperature between 40°C and 42°C for at least 12 minutes. Fifteen patients agreed to skin biopsies before and after initial treatment session, and 2 months after the last session. After initial treatment, light microscopy analysis revealed edema, lymphocytic infiltrate, and ectatic vessels among adipocytes with membrane lysis. Two months after the final treatment, dermal collagen was appreciated as thicker and better organized. At 2 months follow-up, 76% of patients subjectively felt that they demonstrated a very good or good outcome (defined as 65%-80% and 40%-60% improvement, respectively). In addition, 2 blinded, independent investigators compared photographs taken before the first and 12th session and at 2 months follow-up. At the follow-up visit, investigators reported 66% of subjects showed very good or good results (defined as very noticeable and readily apparent, respectively). Ten patients also underwent skin surface examinations using a three-dimensional optical imaging system (CLINIPRO Antiaging SD camera, Barcelona, Spain) at baseline and at the 2-month follow-up. The analysis indicated a 42%-55% texture improvement in these patients.

Manuskiatti et al³ conducted a study that applied a TriPollar RF device known as Regen (Pollogen, Ltd., Tel Aviv, Israel) to 39 female patients aged 23-60 years with cellulite. Each patient underwent 8 weekly treatments at a frequency range of 1 MHz and total RF energies of 20 W to the arms and 28.5 W to the abdomen, thighs, and buttocks. Energies were ad-

justed for patient tolerance and till target sites reached temperatures of 40°C-42°C. Before each treatment and 4 weeks after the last, circumferences of the arms, abdomen, thighs, and buttocks were performed. In addition, ultrasound images at the abdomen and thigh were taken using a real time scanning image ultrasound, like the Emilia del Pino et al study. The distance from the epidermis to Camper's fascia were measured at baseline and at week 8. Furthermore, skin elasticity was calculated based on suction and elongation characteristics of the skin, using a Cutometer MPA 580 (Courage and Khazaka GmbH, Köln, Germany). Finally, cellulite changes were scored by independent blinded investigators using standardized photographs. Thirty-seven patients completed the protocol, while 2 failed for scheduling reasons. Significant circumference average reductions of 3.5 and 1.7 cm were noted at the abdomen and thigh, respectively, although no reduction was observed of the buttocks and arms. Ultrasound evaluation showed a 10.5% average reduction at the thigh and a 4% average reduction at the abdomen, though the latter failed to reach statistical significance. Cutometer readings of elasticity failed to reach statistically significant changes. Cellulite scoring by blinded investigators revealed approximately 50% clinical improvement.

Kaplan and Gat¹² also evaluated the Regen TriPollar RF device (Pollogen Ltd., Tel Aviv, Israel) as a means to achieve skin tightening. Twelve patients were evaluated, although only 4 were treated on sites not found on the head and neck: 1 on the hands, 1 on the arms, 2 on the abdomen. On average, patients underwent 7 weekly treatments at RF settings of 1 MHz and maximum power of 30 W. Treatment was maintained until skin temperature reached 40°C-42°C. Sites were photographed before and after treatments. Furthermore, one of the abdominal patients was enrolled in the study just before a scheduled abdominoplasty. In this patient, the left abdomen was treated while the right served as a control. Three skin biopsies from each side were taken during the abdominoplasty for analysis. The arm patient and 2 abdominal patients reported that they were "highly satisfied," while the hand patient only reported "low satisfaction." No formal evaluation of the photographs was performed, although the authors present sequential photographs of the arm patient that they claim shows gradual skin tightening. Histologic examination showed an average dermal thickness of 5.5 mm on the treated (left abdomen) biopsies, while the nontreated (right abdomen) biopsies showed an average of 3.7 mm. This suggests a 49% increase in dermal thickness, which they attribute to collagen fiber thickening, with a background of mildly increased numbers of fibroblasts and elastin fibers. In contrast, the subcutaneous layer showed no difference in thickness, although some areas of the treated skin showed smaller, irregularly shaped adipocytes, some with ruptured membranes.

Several reports beyond the scope of this article suggest RF is also effective when used in combination with other technologies. For example, the combined effect of bipolar RF, infrared light, and suction-based massage has demonstrated clinical improvement of body shape.²⁰⁻²³

Study Challenges and Future Directions

A number of limitations exist in these studies, and an extensive discussion of limitations for each study is beyond the scope of this article. Several studies fail to assess statistical significance, some study designs do not incorporate control groups, and extended duration of improvement is not evaluated. One of the greatest challenge is the absence of standardized evaluation. Without this, studies often understandably rely significantly on impressions by patients and investigators. Although blinded investigator analysis of pre- and post-treatment photographs is more objective than a patient's self assessment, methods for comparison are generally limited to investigator opinion rather than standardized methods. To counter this challenge, some teams are developing more advanced techniques, as evidenced by skin elasticity measurement devices and three-dimensional surface imaging systems.^{3,24}

In addition to improvements in analysis, new applications for RF treatments on the body are under investigation. Already studies are considering the effects of RF on the treatment of striae distensae, acne scars, hypertrophic and keloidal scars, epilation, liposuction, and leg veins.^{11,25-30} Furthermore, new modes of delivery are being developed, including those combining other technologies as already referenced earlier, or the incorporation of new delivery modalities, such as fractional RF.¹⁰

Patient Selection

Proper patient selection is critical for the successful treatment of patients using RF. Often, this is represented by patients in their 30s-60s who demonstrate laxity not requiring invasive lifting procedures. Patients with mild adiposity are expected to benefit from RF body shaping procedures. In contrast, obese patients and those with substantial skin redundancy will only show mild to no benefit from RF treatments and should therefore be redirected to more appropriate options. Additionally, patients with pacemakers should not be treated, and those with any sort of underlying metal implant should be approached cautiously, if at all. All skin types and hair-bearing surfaces may be treated without risk of pigmentation or hair loss in most settings, except in the new experimental devices incorporating RF into epilation techniques.²⁶⁻²⁸ Other aesthetic treatments, such as rhytidectomy, soft tissue filler (except possibly silicone—see complications), laser surgery, botulinum toxin, are not contraindications to RF treatment. For those planning facial cosmetic surgery, such as rhytidectomy, blepharoplasty, or similar, it is recommended to defer surgery until at least 3 months after RF treatment since the tightening effects of RF are predicted to continue months after treatment.

Anesthesia

Anesthesia requirements and choices vary based on body site and from patient to patient. Tolerance to the procedure, in general, improved once protocols started to follow the multiple pass, low fluence algorithms.

Oral analgesics and anxiolytics can be successfully em-

ployed, particularly in patients with very low thresholds to pain and anxiety. Topical analgesics, such as lidocaine and prilocaine creams, are used by some. However, these topical agents are not used at our center because of 2 drawbacks. First, they offer limited depth of anesthesia and therefore incomplete relief. In some studies, the effect of topical agents reach depths of 2.9 mm.³¹ Incomplete relief during RF treatments would be predicted by the collagen changes seen on histology that reach down to 5 mm.⁸ Second, in our experience, the moisturization of the topical anesthetics changes the RF effect. Forced air cooling is an optimal alternative to topical anesthetics, since it provides topical relief in a safe and unobtrusive manner.

Some patients have been treated with nerve blocks and local infiltration in earlier studies.² However, we generally do not provide local or nerve block infiltration since the edema secondary to infiltration could impair efficacy by inhibiting depth of RF penetration. In addition, when treating body sites as opposed to confined areas of the face, the quantity of local infiltration could reach high levels that invite risks of anesthetic toxicity.

Complications

The side effect profile for RF treatments is very low. Most of the unwanted effects is simply temporary—mild erythema and edema. A number of RF side effects described in the literature do not apply to body treatments, such as jawline and neck sensitivity and transient trigeminal neuralgia. However, other skin changes should be considered when treating the body. For example, transient crusting, depressions, dysesthesias, anesthetics, acneiform, and others have been summarized in past reviews, but are rare in our experience.⁷

Conclusion

RF devices, such as ThermoCool TC offer an innovative, nonablative, and noninvasive treatment option for improving contour and skin laxity of the head, neck, and body.

Despite the growing enthusiasm for the technology, newer studies, evaluation techniques, and applications are continuing to emerge that will help identify ideal candidates, protocols, and indications.

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