

PROCEDURES IN COSMETIC DERMATOLOGY
Series editor Jeffrey S Dover
Associate editor Murad Alam

Non-surgical Skin Tightening and Lifting

Edited by **Murad Alam**
Jeffrey S Dover



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Non-Surgical Skin Tightening and Lifting

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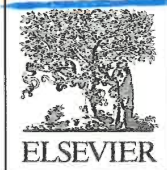
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First published 2009
ISBN: 978-1-4160-5960-8

British Library Cataloguing in Publication Data

A catalogue record for this book is available from the British Library

Library of Congress Cataloging in Publication Data

A catalog record for this book is available from the Library of Congress

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Radiofrequency Energy and Hybrid Devices

Melissa A. Bogle

INTRODUCTION

Radiofrequency (RF) energy is a form of electromagnetic energy ranging from 300 MHz to 3 kHz. The technology has been used in many areas of medicine including cardiology, urology, and sleep medicine. In skin surgery the technology has been used for electrocoagulation, hemostasis, endovenous closure, and skin rejuvenation. In aesthetic dermatology, RF systems have become accepted for skin resurfacing and improvement of facial laxity. Box 3.1 lists the key points in using RF energy and skin tightening devices.

RF energy is similar to laser and light sources in that its interaction with tissue induces thermal changes; however, it is different in that it does not follow the principles of pulsed light-induced selective photothermolysis. Rather than inducing heat by selectively targeting a particular chromophore, RF devices generate heat as a result of tissue resistance to the movement of electrons within the RF field (Ohm's law) (Fig. 3.1).

A RF generator produces an alternating current that creates an electric field through the skin. The electric field shifts polarity millions of times per second, causing a change in orientation of charged particles within the electric field. Tissue resistance to this particle movement generates heat. Thus, heat is generated by the skin's resistance to the flow of current within an electric field, not by photon absorption as with a laser. Energy is able to be dispersed to 3-dimensional volumes of tissue at controlled depths. Epidermal cooling is used to assure protection of the superficial skin layers. While certain lasers such as those in the infrared (IR) spectrum are able to affect upper dermal collagen and improve fine wrinkles and textural irregularities, they are less suited to adequately address the problem of deep or subdermal skin laxity. Energy from laser or light sources tends to scatter or absorb in the upper layers of the skin, making it difficult to deliver sufficient energy to the deep dermis without causing damage.

The depth of energy delivered by a RF device depends on a number of factors including the configuration of RF electrodes (i.e. either monopolar or bipolar), the type of tissue serving as the conduction medium (i.e. fat, blood,

skin), temperature, and the frequency of the electrical current applied.

The configuration of electrodes in a RF device can be either monopolar or bipolar (Fig. 3.2). The two systems create different electromagnetic fields; however, the interaction of the energy with the target tissue is similar. In a monopolar system, the electrical current passes through a single electrode in the hand piece to a grounding pad. Without surface cooling, there is a high density of power close to the electrode's surface and a relatively deep power penetration. This makes monopolar RF particularly well suited for electrosurgery, but can lead to safety concerns and high pain levels in non-ablative tissue tightening if not used appropriately. In a bipolar system, the electrical current passes between two electrodes at a fixed distance over the skin. This creates a more controlled current distribution, but the depth of penetration is limited by the distance between the electrodes. The flow of current between two electrodes in a bipolar system is illustrated in Figure 3.3. Current flows between two electrodes perpendicular to an electromagnetic field.

In electromagnetic theory the penetration depth of energy into any material is called the skin depth. While the skin depth is influenced by the type of tissue serving as the conductor, temperature, and the frequency of electrical current applied to the conductor, this number is generally equal to the depth at which the current density is reduced by a factor of $1/e$, where e is the base of the natural log (2.72). At the skin depth, roughly two-thirds of the current ($1-1/e$) will be flowing above the line and one-third ($1/e$) below. If the current density is plotted as a function of the penetration depth for different distances between electrodes, it will become apparent that at the point where the current density falls to $1/e$, the penetration depth equals approximately half the distance between the electrodes. Thus, in a bipolar system the penetration depth of the energy into the tissue is roughly half the distance between electrodes (Fig. 3.3).

Electrical conductivity varies among different types of tissue (Table 3.1). Blood has the highest electrical conductivity, while fat, bone, and dry skin have low conductivities such that current tends to flow around these structures rather than passing through them. Wet skin has a higher

Box 3.1 Key points to use of radiofrequency energy skin tightening devices

- ❖ Results with current RF skin tightening protocols are mild to moderate and are not intended to replace surgical procedures
- ❖ Many patients will choose more subtle tightening to avoid the risks and down-time associated with surgery
- ❖ Newer treatment protocols have improved treatment predictability and extent of efficacy

$$\text{Energy (joules)} = I^2 \times Z \times t$$

Fig. 3.1 Ohm's law states the impedance (Z) to the movement of electrons creates heat relative to the amount of current (I) and time (t)

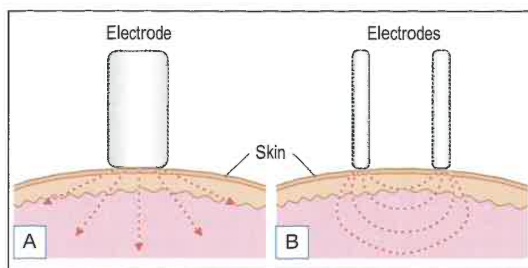


Fig. 3.2 The flow of electrical current through the skin using a (A) monopolar electrode system and (B) bipolar electrode system

electrical conductivity allowing greater penetration of current. This is why in certain RF procedures improved results can be seen with generous amounts of coupling fluid and increased hydration of skin. The main consequence of this is that not all patients will be equal regarding how much energy will be deposited in a particular area with otherwise equal parameters. The structure of each individual's tissue (dermal thickness, fat thickness, fibrous septae, number and size of adnexal structures) plays a role in determining impedance and heat perception.

Tissue conductivity is also influenced by temperature, and the distribution of electrical current can be influenced by preheating or cooling selected targets within the field. Every 1°C increase in temperature lowers the skin impedance by 2%. Mathematically, this is expressed by the thermal coefficient of skin conductivity (a), roughly equal to 2% C⁻¹. Surface cooling will increase resistance to the electrical field near the epidermis, driving the RF current into the tissue and increasing the penetration depth. Conversely, target structures that have been prewarmed with optical energy will, in theory, have greater conductivity, less resistance, and greater selective heating by the RF current. The precise impact of these theoretical constructs on the clinical application of these devices is currently under investigation.

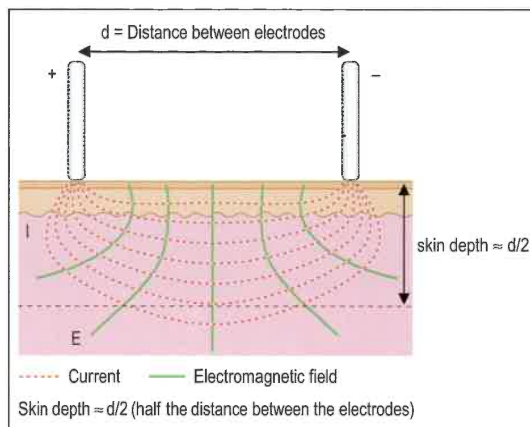


Fig. 3.3 Schematic diagram illustrating the distribution of current density between electrodes in a bipolar system. Current can be seen flowing between the two electrodes perpendicular to the electromagnetic field. The penetration depth of the energy into the tissue is roughly half the distance between electrodes

Table 3.1 The dielectric properties of human tissue at 1 MHz, room temperature

Tissue	Electrical conductivity (Siemens/m)
Air	0.00
Bone	0.02
Nail	0.02
Fat	0.03
Dry skin	0.03
Nerve	0.13
Cartilage	0.23
Wet skin	0.22
Mucosa	0.22
Muscle	0.50
Lymphatics	0.60
Thyroid	0.60
Blood	0.70

Historically, the first RF device on the market was the Visage unit for skin resurfacing (ArthroCare Corp., Sunnyvale, CA, USA). It introduced a process called 'coblation' (cold ablation) in which bipolar RF energy rather than heat from a laser was used for skin resurfacing. The concept involved applying RF energy to a conductive medium (saline) to form a plasma field of highly ionized particles with sufficient energy to break molecular bonds within the skin. Because there was no cooling, epidermal damage ensued and tissue could be removed in successive layers with each pass of the styllet through low tempera-

ture molecular disintegration. The most common adverse effects were erythema, edema, crusting, pain, and hyperpigmentation. This device is no longer in popular use, and trends in the use of RF energy for skin rejuvenation have since focused on non-ablative technologies.

MONOPOLAR RADIOFREQUENCY

The first device to use monopolar RF energy for skin tightening was the ThermoCool device (Thermage Inc., Haywood, CA, USA), introduced in 2001. Monopolar RF devices can deliver uniform heating at controlled depths to the deep dermis and subdermal layers of the skin, causing immediate collagen contraction and subsequent remodeling over the course of months.

The ThermoCool device is unique in that it uses capacitive coupling rather than a standard RF-conducting electrode. Standard conducting electrodes deposit heat at a concentrated point. With capacitive cooling, RF energy is coupled to the skin by a thin capacitive membrane in the treatment tip that distributes the energy over a 3-dimensional volume of tissue beneath the membrane.

With the ThermoCool device, it is thought that volumetric heating of the dermis causes direct tissue tightening by breaking hydrogen bonds in the collagen triple helix, causing contraction. Heat-induced denaturation of collagen typically occurs at a threshold temperature of 65°C. Electron microscopic evaluation of skin immediately after treatment supports a morphological change in individual collagen fibrils with contracted, partially denatured collagen in the mid to deep dermis. Studies have also found selective contraction of fibrous septae in the subcutaneous fat, which is thought to be responsible for the inward (Z-dimension) tightening. This gives the patient immediate, visible improvement the day of the procedure with continued improvement over the course of 4–6 months from neocollagenesis and a delayed wound healing response.

COMBINED ELECTRICAL AND OPTICAL ENERGY

Combined electrical and optical energy, or selective electrothermolysis, is another type of RF technology that combines RF energy with optical energy from laser or light sources. Whereas the Thermage tightening device delivers RF energy to the skin using monopolar electrodes, the RF component of the combined electrical and optical energy units currently available uses bipolar electrodes (Fig. 3.4). This technology has shown efficacy in hair removal, skin tightening, wrinkle reduction, and the treatment of both pigment and vascular disorders. The effect contributed by each of the energy sources, light vs. RF, has not, however, been demonstrated.

There are several devices currently on the market using combined RF and laser or light technology including the Aurora, Polaris, and Galaxy and ReFirme systems (Syneron Medical Ltd, Yokneam, Israel). The Aurora uses com-

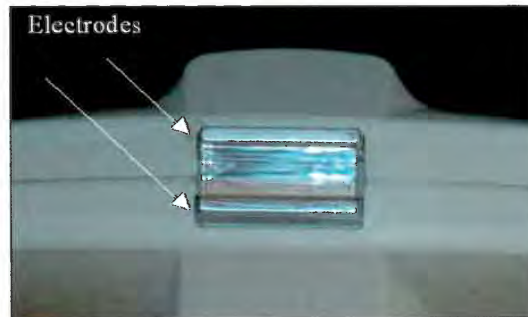


Fig. 3.4 Combined RF and intense pulsed-light treatment head illustrating bipolar electrodes between which an electrical current passes. (Syneron Medical Ltd., Yokneam, Israel)

bined RF and intense pulsed light with systems available for hair removal, skin rejuvenation, and acne treatment. The Polaris uses combined RF and a 900-nm diode laser with systems available for wrinkle reduction and leg vein and vascular lesions. The Galaxy incorporates the Aurora and Polaris in a single device. The ReFirme combines broadband IR light (700–2000 nm) and bipolar RF to address both skin tightening and rhytides.

For skin rejuvenation, the theoretical advantage to this technology is that the RF component penetrates into the skin, limited to a depth of one-half the distance between the bipolar electrodes, potentially heating deeper tissues than standard non-ablative lasers. The diode laser or intense pulsed light addresses superficial lentigines and telangiectasias, which RF does not affect. In the case of the ReFirme system, the IR laser component is absorbed by water, thereby heating collagen within the dermis and adding a synergistic effect to the RF energy.

For hair removal and the treatment of vascular lesions, the goal is to heat the target to a sufficient temperature that causes permanent injury. The two forms of energy are thought to act synergistically to generate heat at the target. RF energy is preferentially absorbed by the target structure because higher temperatures correlate with decreased impedance and electrical current likes to follow the path of least resistance (Fig. 3.5).

Conversely, target structures that have been prewarmed with optical energy, in theory, have greater conductivity, less resistance, and greater selective heating by the RF current. The precise impact of these theoretical constructs on the clinical application of these devices is currently under investigation.

HYBRID MONOPOLAR AND BIPOLAR RADIOFREQUENCY

A relatively new RF system uses two RF-configured hand pieces (one monopolar, one bipolar) in a single device (Accent RF, Alma Lasers, Ltd, Caesarea, Israel). The device theoretically takes advantage of two mechanisms

of RF-induced tissue heating. The monopolar hand piece achieves heating via the rotational movement of water molecules in the alternating current of the electromagnetic field. The end result is volumetric heating at deeper levels in the skin (up to 20 mm). The bipolar hand piece, on the other hand, has more superficial (2–6 mm), localized (non-volumetric) heating based on tissue resistance to the RF conductive current.

VACUUM-ASSISTED BIPOLAR RADIOFREQUENCY

Another relatively new device (Aluma, Lumenis Inc., Santa Clara, CA, USA) combines bipolar RF and vacuum technology in what has been termed FACES technology (functional aspiration controlled electrothermal stimulation). The device has incorporated a vacuum into the hand piece to suction a fold of skin in alignment between two

electrodes (Fig. 3.6). This limits the volume of treated tissue to the skin between the electrodes. This is thought to allow more specific treatment of targeted layers of the skin or subcutaneous fat with lower overall energy. Non-target structures such as muscle, fascia, and bone are avoided.

It is also hypothesized that mechanical stress on fibroblasts from the vacuum suction may lead to increased collagen formation and contribute to increased clinical efficacy. In addition, others have speculated that increased blood perfusion via exposure to vacuum as well as heat may enhance fibroblast activity. Comparative clinical data to back up these hypotheses are awaited.

PATIENT SELECTION

Non-surgical skin tightening is best suited for patients with mild to moderate skin laxity without significant underlying structural ptosis. Patients with underlying laxity of the facial musculature, laxity of the superficial muscular aponeurotic system, or those with an excessive amount of skin laxity are likely to have less improvement with non-surgical skin tightening and should be carefully counseled to ensure reasonable expectations and to discuss other methods of rejuvenation, including surgery.

EXPECTED BENEFITS

The expected benefits of RF technology are controversial. The technology has shown benefit in the eyelid, eyebrow, midface, melolabial folds, jowl, jawline, and neck regions. In addition, the technology has been used to tighten off-face areas such as the thighs, arms, abdomen, and chest.

Several studies have suggested that younger patients may respond better than older patients. This is thought to occur because heat-labile collagen bonds are progressively replaced by irreducible multivalent cross-links as the tissue ages, such that the skin of older individuals is less amenable to heat-induced tissue tightening.

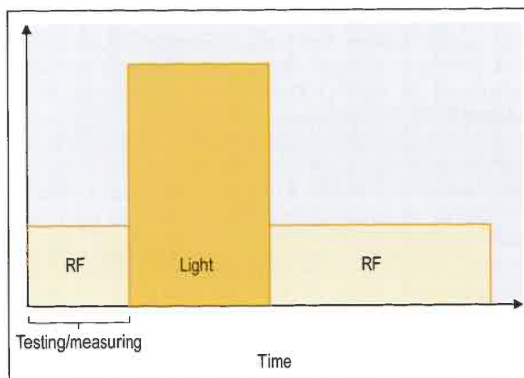


Fig. 3.5 Pulse sequence of combined RF and optical energy devices. The initial RF pulse is for calibration by the device; then pulses of optical and RF energy are initiated at the same time, with the RF pulse having a longer duration

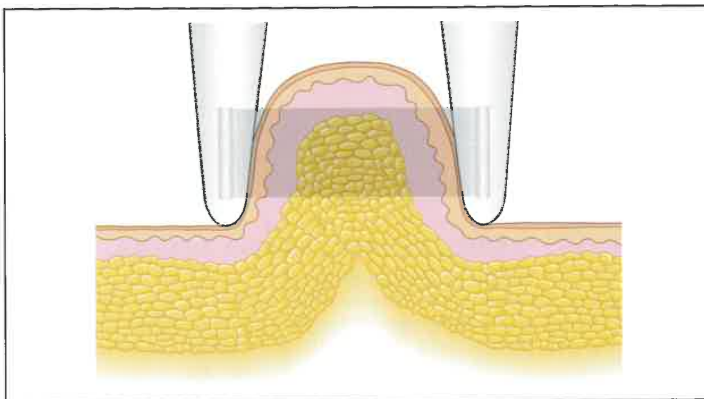


Fig. 3.6 Schematic illustrating vacuum aspiration of skin to a targeted depth with RF heating between two bipolar electrodes (Aluma, Lumenis Inc., Santa Clara, CA, USA)

MONOPOLAR RADIOFREQUENCY

The clinical results for non-ablative RF skin tightening were first reported in the periorbital area. In a multicenter trial, Fitzpatrick and colleagues reported some degree of clinical improvement in 80% of subjects.

A study using the original 1.0-cm³ Thermage tips in the treatment of cheek, jawline, and neck laxity revealed clinical improvement of nasolabial and melolabial folds in 28 of 30 patients, with peak improvement occurring 1 month after treatment, measuring approximately 35–40% by independent subjective evaluation. In the same study, improvement in submandibular and neck laxity was observed in 17 of 20 patients, with peak improvement occurring 3 months after treatment, measuring approximately 30–35%. Average treatment fluences were 130 J/cm² on the cheek and 110 J/cm² on the neck. A split-face study analyzing changes to the eyebrow and superior palpebral crease using treatment fluences of 97–143 J/cm² revealed an average 4.3-mm eyebrow elevation and 1.9-mm superior palpebral crease elevation along the midpupillary line, and an average 2.4-mm eyebrow elevation along the lateral canthal line. The same study also attempted to measure jowl surface area changes during split-face treatment of the cheek and found a mean decrease of 22.6% on the treated side. No improvements in either region were noted on the untreated side.

In an attempt to better quantify subjective results, a physical measuring device (BTC-2000, SRLI Technologies, Nashville, TN, USA) has been used to measure elasticity and skin stiffness by extrapolating data from a stress strain curve. Lower face treatments were done with the newer, larger tips with a low-energy, multiple pass technique and patients were analyzed by total number of pulses delivered. The group with the highest number of pulses delivered (556) had an 80% increase in skin stiffness and an 80% improvement in elasticity. The medium pulse group (216) had a 74% improvement in stiffness and a 52% improvement in elasticity, whereas the lowest pulse group (139) had only 26% improvement in stiffness and 33% improvement in elasticity.

A multicenter survey conducted in 2006 compared the original single pass, high-energy technique with the newer low-energy, multiple pass technique using immediate tissue tightening as a real-time endpoint. With the original treatment algorithm, 26% of patients saw immediate tightening, 54% observed skin tightening at 6 months, 45% found the procedure overly painful, and 68% said the treatment results met their expectations. With the updated algorithm, 87% had immediate tissue tightening, 92% had some degree of tightening at 6 months, only 5% found the procedure overly painful, and 94% stated that the procedure matched their expectations. The low-energy, multiple pass protocol has also been reported to be significantly safer, lowering the incidence of adverse events to less than 0.05% from the previous incidence of less than 1%.

The safety of monopolar RF treatment has been established for eyelid skin laxity with the ThermoCool 0.25-cm² shallow treatment tip using treatment fluences of 68–100 J/cm². The tip has a penetration depth of approximately 1.2 mm, and plastic corneoscleral protective lenses must be put in place to protect the eye before treatment. Evaluation of its clinical effectiveness at shrinking eyelid skin was found to be mild to moderate with 87% of subjects showing at least 25% tightening of the upper eyelids and 67% showing at least 25% tightening of the lower eyelids. Settings were between 32 and 34 (12–14 J) with five passes. The upper eyelid was found to respond more favorably than the lower eyelid, with 13% of upper eyelids and 33% of lower eyelids showing no improvement at 6 months. However, in terms of patient satisfaction, more patients were pleased with their results on the lower eyelids than the upper eyelids. One patient in the study had more passes than the others (eight vs. five), and this patient had the greatest degree of tightening.

Generally, a single monopolar RF treatment is performed; however, one study reported that 80% of patients achieved significant eyebrow lifting after four treatments compared with 60% after a single treatment. Similarly, another study reported greater improvement in tightening of the nasolabial fold with two treatments spaced 1 month apart.

COMBINED ELECTRICAL AND OPTICAL ENERGY

Facial treatments using a bipolar electrode combined with a 900-nm diode laser revealed that more than half the study population showed greater than 50% improvement in the appearance of wrinkles. All subjects in the study reported improvement in skin texture.

The effect of combined broadband IR light and bipolar RF energy for facial skin laxity in 19 Asian patients revealed that 89.5% of subjects reported moderate to significant subjective improvement in skin laxity of the cheek, jowl, periorbital area, and upper neck at 3 months after three treatment sessions at 3-week intervals (IR 10 W/cm²; RF 70–120 J/cm²). In the same study, however, masked observers rated overall tightening as mild, with most improvement in the cheek, jowl, and nasolabial fold.

A study evaluating the effect of combined optical and RF energy on adult women with blond or white facial hair using 15–30 J/cm² of light energy and 10–20 J/cm³ of RF energy in four treatments 8–12 weeks apart revealed hair clearance of 40–60%. As with other technologies, hair removal efficacy appears to be greater in patients with darker hair (mean clearance 80–85%). A series of three to five treatments on photoaged skin revealed a 70% improvement in erythema and telangiectasia, a 78% improvement in lentigines, and a 60% improvement in skin texture as determined by subject satisfaction levels.

HYBRID MONOPOLAR AND BIPOLAR RADIOFREQUENCY

In a study with 16 adult women with facial rhytides and skin laxity, 56% of participants had some degree of improvement in the appearance of rhytides and skin laxity. A total of 12 participants had cheek treatments, with 5 achieving 51–75% improvement and 2 achieving greater than 75% improvement. Nine women had jowl treatments, with 4 achieving 51–75% improvement and 1 achieving greater than 75% improvement. Three of 7 women had 51–75% improvement in the periorbital region, and 3 of 8 women had 51–75% improvement of the forehead. The same study reported that younger women (25–45 years of age) had a higher satisfaction rate than older patients in the treatment group.

In a study using the Accent device for the treatment of cellulite on the buttocks and thighs, 68% of patients achieved a 20% volumetric reduction of the fat layer (determined by ultrasound) after two treatment sessions, indicating contraction of the subcutaneous adipose tissue.

VACUUM-ASSISTED BIPOLAR RADIOFREQUENCY

In a pilot study of 46 adults undergoing eight facial treatments spaced 1–2 weeks apart, significant improvement in skin texture has been seen. Using the Fitzpatrick–Goldman Classification of Wrinkling and Degree of Elastosis scale, the mean elastosis score went from 4.5 pretreatment to 2.5 6 months after treatment, indicating a shift from moderate to mild elastosis. Similar to other devices, the author noted a short-term tightening effect due to collagen contraction followed by a gradual, long-term improvement due to the wound healing response and neocollagenesis.

In the same study the author noted that although subjects were generally pleased with the treatment outcome, their satisfaction levels declined somewhat during the follow-up period. This is thought to be a common finding in RF skin treatments due to delayed neocollagenesis and long-term wound healing response. Subjects may have difficulty accurately remembering the exact condition of their skin pretreatment, particularly when 6–8 months have passed.

OVERVIEW OF TREATMENT STRATEGY

• Treatment approach

While there is significant agreement concerning the basic science behind RF-induced skin tightening through thermal modification of connective tissue, the optimal treatment parameters are still being established. The ThermoCool device is the best studied and has been through a major shift in treatment algorithms from its debut to the present time. These developments have made treatment outcomes trend toward increased tightening with more predictable

results, yet the overall improvement is still modest in most patients. Thus, while each device discussed has a currently recommended treatment protocol, much research needs to be done to further define these protocols. We have yet to determine the impact of a number of treatment parameters such as power, pulse duration, and precooling and postcooling combinations. More research also needs to be done comparing the RF devices and other non-surgical skin tightening devices to determine any particular advantages of one over another.

• Major determinants

There are few major determinants favoring one strategy over the other. The ThermoCool device is currently favored for eyelid skin tightening because of the small 0.25-cm² tip, high eye safety profile, and lack of discomfort during treatment.

The hybrid Accent device may be a better choice for tissue tightening and volume reduction on the body when performed at the current protocols. One case report compared treating skin laxity on one arm with the ThermoCool device and the opposite arm with the Accent device. The ThermoCool arm was treated with a single treatment at settings of 351.5–354 with a minimum of six passes on the inner arm and three passes on the outer arm (1200 pulses total). The Accent arm was treated with a series of nine treatments at 2-week intervals using the monopolar hand piece at an epidermal temperature of 42.5°C with three therapeutic phase passes. Although skin texture improved with both treatments, the Accent-treated arm was reported to be tighter and firmer after just two treatments, with a looser-fitting clothing sleeve. Each Accent treatment took approximately 30 minutes whereas the ThermoCool treatment took approximately 2 hours. While continued improvement may have been seen with multiple treatments with the ThermoCool device, the author comments that this would not have been cost- or time-effective due to the expensive (single-use) treatment tips and excessive treatment times. Because the ThermoCool-treated arm did not have a looser fitting clothing sleeve until the physician had gone back at the end of the study and performed two Accent treatments, the author suggests that the Accent RF energy penetrates deeper and may be the device of choice when patients require both tissue tightening and volume reduction. Other authors have commented that overheating of deeper tissue with the ThermoCool device may damage fat cells and over-tighten fibrous septae resulting in fat loss, irregular skin-surface contours, and fibrous scarring.

Combined electrical and optical energy may be the best option for patients who wish to treat their skin laxity in combination with other signs of photodamage such as lentigenes or telangiectasias.

• Patient interviews

During the initial consultation, a complete medical and surgical history should be obtained from the patient. It is

particularly important to establish the patient's motivation for correction and what their ultimate goal is.

The benefits, risks, and limitations of the various types of RF devices should be discussed with the patient in detail, including a mention of alternative therapies so that the patient can make an informed decision.

Appropriate selection of patients and managing realistic expectations is an essential part of using RF procedures for non-invasive skin rejuvenation. Patients should be aware that RF skin tightening is not a substitute for a face lift and should not be marketed as such. It is important to explain that results are modest and that a small group of patients perceive no improvement at all. Patients should also understand that RF alone is not effective for the textural aspects of photoaging including wrinkles and pigmentary alterations.

TREATMENT TECHNIQUES

• Patients

It is essential to take standardized preprocedure photographs before each treatment. The photographer should be careful to use identical positioning and lighting conditions in each session, as subtle differences can distort perceived outcomes.

Pretreatment photographs are helpful at the post-operative follow-up visit given the modest nature of the changes seen with RF procedures.

PREOPERATIVE CONSIDERATIONS

• Monopolar radiofrequency

The ThermoCool RF skin tightening device consists of an RF generator, processing computer, cooling component, hand piece, and single-use treatment tip. The RF generator produces a 6-MHz alternating current that creates an electric field through the skin. The electric field shifts polarity 6 million times per second, causing a change in orientation of charged particles within the electric field. Tissue resistance to this particle movement generates heat. Thus, heat is generated by the skin's resistance to the flow of current within an electric field, not by photon absorption as with a laser.

Contact cooling from cryogen spray on the inner surface of the treatment tip occurs before, during, and after each energy pulse to protect the epidermis and create a reverse energy gradient where temperatures are highest in the deep dermis and coolest near the epidermis. A computer within the device receives and displays real-time data from a microprocessor in the treatment tip on pressure, current flow, and skin temperature. Internal monitors will not permit a complete RF pulse if any parameters fall outside preprogrammed limits. Thus, feedback from the treatment tip to the computer in the RF generator regulates the amount of energy applied to the tissue.

Treatment tips are disposable, intended for single-patient use, and come programmed with a limited number

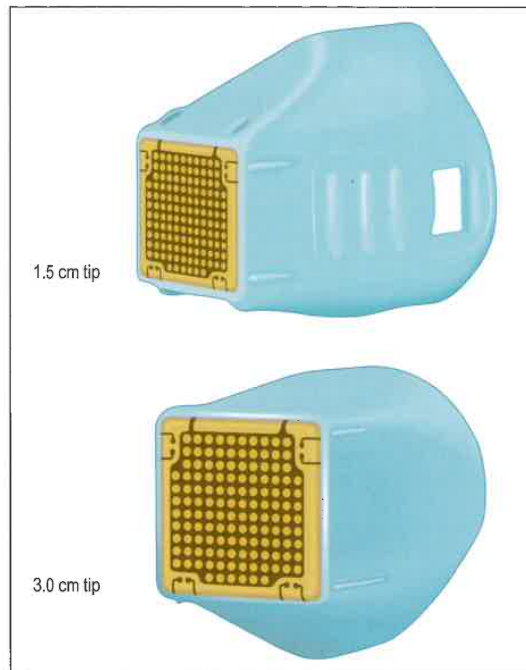


Fig. 3.7 ThermoCool treatment tips contain a microprocessor which sends data on pressure, current flow, and skin temperature back to the device. The figure illustrates the 1.5-cm and 3.0-cm tips used primarily for face and body applications. (Thermage Inc., Hayward, CA, USA)

of pulses within a certain period of time (Fig. 3.7). Treatment tips currently come in sizes of 0.25 cm², 1 cm², 1.5 cm², and 3 cm². The small 0.25-cm² tips are for use in small areas such as the eyelids, while the larger 3-cm² tips are designed to efficiently cover larger areas of the body such as the thighs, abdomen, or arms. Because the geometry of the electrode changes the depth of penetration, the smaller tips will not penetrate as deeply as the larger tips.

COMBINED ELECTRICAL AND OPTICAL ENERGY

In all of these systems, the RF energy is applied through electrodes located in the hand piece at an appropriate distance from each other to provide the optimal penetration depth for whatever the indication (Fig. 3.4). The hand piece also contains a fiber that delivers optical energy to the skin and an internal contact cooling mechanism to protect the epidermis. When the tip is brought into contact with the skin surface, pulses of optical and RF energy are initiated at the same time, but the RF pulse has a longer duration (Fig. 3.5). This ensures that the optical component preheats the target, allowing the RF constituent to be preferentially absorbed by it. The tip

measures changes in the skin impedance, allowing active dermal monitoring.

HYBRID MONOPOLAR AND BIPOLAR RADIOFREQUENCY

The Accent system consists of an RF generator operating at a frequency of 40 MHz, considerably higher than the 6-MHz current generated by the ThermoCool device. There are two separate hand pieces within the same platform: a monopolar and a bipolar. Each hand piece contains an RF resonant system, a thermoelectric cooler, and a trigger on the handle to fire the device. The monopolar hand piece transmits RF energy into the contacting tissue via a coupling tip. The bipolar hand piece concentrates the energy in the center of the contacting tissue due to the presence of a circular coaxial grounding electrode that surrounds the coupling tip. The operator is able to vary the time and intensity of the RF output.

VACUUM-ASSISTED BIPOLAR RADIOFREQUENCY

The Aluma device consists of a user interface, programmable logic controller, RF power module, a vacuum pump, and interchangeable treatment tips. The RF power module provides RF energy at 468 kHz to the hand piece. The vacuum pump is connected directly to the hand piece and is capable of 8–28 inches of mercury suction, corresponding to vacuum levels of 1–5. The main purpose of the vacuum is to draw the skin up between the electrodes to a predetermined depth depending on the amount of suction applied (Fig. 3.6).

The treatment tips come in two sizes with a small (3 × 18 mm) and large (6 × 25 mm) aperture. The bipolar electrodes are located in a pocket at the distal end of each tip. When the skin is properly positioned between the electrodes, the RF current passes through the skin at 2–10 W (corresponding to power settings 1–5). The duration of each pulse can be adjusted between 1 and 5 seconds, such that a single pulse is able to deliver 2–50 J of energy to the tissue.

TREATMENT ALGORITHM

• Monopolar radiofrequency

To perform the procedure, it is useful to have the patient arrive at the office about 1 hour before the scheduled treatment time for preliminary preparations. Because the procedure can cause considerable discomfort, some physicians recommend one of several forms of analgesia. Patient pain feedback to the operator is the basis used to choose the appropriate energy for a particular treatment area in a given individual. Anesthetic options include topical anesthetic cream and/or additional analgesics such as lorazepam, 1–2 mg by mouth 1 hour prior to the procedure, and

meperidine, 75 mg (intramuscular) 15 minutes prior to the procedure. Topical anesthetic must be meticulously removed before the procedure begins so that contact between the treatment tip membrane and skin surface is not altered in any way. Localized procedures (such as periorbital treatments) may be tolerated without anesthesia.

Some authors have found topical anesthetics to be unhelpful in alleviating deep dermal heat sensations; it may actually exacerbate discomfort by selectively numbing the epidermis so that the patient does not feel the cooling relief of the cryogen spray when the tip is in contact with the skin. The use of nerve blocks and intravenous sedation are not recommended as some degree of pain feedback from the patient is necessary to limit adverse effects and enhance patient safety. Local infiltration anesthesia should never be used as it alters the tissue impedance and can increase adverse effects and decrease treatment efficacy.

When the skin is thoroughly cleansed, a grid is applied to the treatment area using either the provided dye transfer paper or freehand with a marking pen (Fig. 3.8). While we recommend using the provided grid, a red, fine-point permanent marker works well as it stays visible throughout the treatment session yet is easily removed afterward with an alcohol swab. The grid will need to be spaced depending on the size of the treatment tip used. When the grid is complete, a return pad must be attached to the patient and hooked up to the machine. The return pad provides a low resistance path for current to flow to complete the electrical circuit. It is important to use the proper return pad and to make sure it is applied correctly. If the pad is too small or inaccurately applied, a burn can occur at the site of the pad from unintended high resistance to current.



Fig. 3.8 ThermoCool treatment session illustrating the importance of the grid in positioning of the treatment tip for the initial passes. (Thermage, Inc., Haywood, CA, USA)

If the eyelids are being treated, plastic corneoscleral lenses must be put in place. These should be gently inserted and removed in order to not cause erosions of the corneal surface. In addition, the operator should be careful not to deliver too much pressure on the globe, as this can result in vasovagal stimulation and bradycardia. Only the 0.25-cm² tip is safe for use on the eyelids, and practitioners should never attempt to use the 1.5- or 3.0-cm² tips due to depth of penetration.

Coupling fluid should be applied generously to all treatment areas and will need to be reapplied as needed during the procedure. As a general rule, the first three passes are carried out over the entire grid to ensure even heating of the skin (Fig. 3.9). Individual pulses should never be stacked or overlapped, and the operator should wait at least 2 full minutes between passes before re-treating an area to allow adequate cooling. To achieve maximal results with minimal adverse effects, the treatment strategy should be to use multiple passes at low to moderate temperature settings until a desired endpoint of visual tightening is seen. Patients should be asked continually throughout the treatment about their level of pain on a scale of 1–10. The goal is to calibrate temperature settings to keep the pain level below a 5 or 6. Greater pain levels mean the temperature is too high and should be turned down to reduce the risk of adverse effects. In addition, persistent erythema, localized swelling, or hives are all indicators that the tissue has not had sufficient time to cool before additional passes can be considered.

After the first three passes are complete, the remaining passes should be concentrated on improving the patient's desired trouble spots, with careful attention to the most

appropriate placement of each pulse to achieve not only tightening in the XY-axis along the surface of the face, but also along the 3-dimensional inward Z-axis. Up to eight or nine passes can be performed if needed. The endpoint of treatment is visual skin tightening in the desired areas.

The low-energy, multiple pass technique has been shown to produce more consistent improvement and a greater amount of collagen denaturation than the original high-energy, single pass technique that was used when the device first debuted.

After the treatment is complete, the face should be gently cleansed with water to remove excess coupling fluid and any remaining grid. The patient should be carefully inspected for areas of persistent erythema, localized swelling, or hives. If such areas are found, it may be of help to apply a mid- to high-potency topical corticosteroid cream immediately after the procedure to reduce the incidence of crusts or pigment alteration.

COMBINED ELECTRICAL AND OPTICAL ENERGY

Before the procedure, the treatment area should be thoroughly cleansed and hydrated with a clear conductive gel. A thicker layer of gel should be applied over bony areas such as the forehead and periorbital regions. In determining the therapeutic energy, it is important to take into account the patient's skin type and the anatomic location being treated. General treatment guidelines can be found in Table 3.2 and Table 3.3. It is a good idea to perform a test spot treatment at the start of every treatment session. If there are any signs of epidermal injury after waiting 5 minutes (intense erythema, blisters, or blanching skin), the optical fluence should be decreased by increments of 2 J/cm². Likewise, if optimal endpoints are not observed (mild erythema and subtle edema), consider increasing the optical fluence by 1 J/cm².

When performing the actual treatment, the applicator tip should be placed onto the skin with slight pressure (Fig. 3.10). The trigger must then be depressed one pulse at a time, ensuring even contact of the applicator tip and both electrodes before each pulse. Slight overlap is acceptable, however, pulses are not routinely stacked; one study has suggested that stacked pulses in the submental area led to reduced fat content.

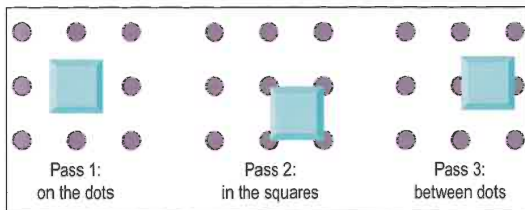


Fig. 3.9 Position of hand piece on grid in first two to three passes to ensure even coverage

Table 3.2 General treatment parameters for combined radiofrequency + intense pulsed light

Skin type	Optical energy (J/cm ²)	Radiofrequency energy (J/cm ³)		Pulse type*	ISL%
		Bony areas	Soft tissue		
I, II	24–26	18	25	Short	30
III	22–24	18	25	Short	30
IV	18–20	18	25	Short	30

*Long pulse mode is recommended for patients with a very deep or extensive vascular component.

Table 3.3 General treatment parameters for combined radiofrequency + diode laser

	Optical energy (J/cm ²)	Radiofrequency energy (J/cm ²)
Bony areas	Skin types I–III 36–40	60–75
Soft tissue	Skin type IV 24–40	75–100

**Fig. 3.10** Combined RF and intense pulsed-light treatment with the applicator placed on the skin with slight pressure over a layer of conductive gel. (Syneron Medical Ltd., Yokneam, Israel)

In this fashion the entire treatment area should be treated with a single pass when using the combined intense pulsed-light/RF unit and at least three to four passes when using the combined diode-RF unit for wrinkle reduction. With the diode-RF unit, deep folds and rhytides may require up to six passes to show the clinical endpoint of mild erythema and subtle edema, while fine rhytides in thin-skinned areas may require only two to three passes. Treatment of the nasal area and tissue inside the bony orbit should be avoided. Similarly, hair-bearing areas such as the eyebrows or beard area in men should be avoided as permanent hair loss can occur.

Optical and RF fluences may be increased by 10–15% in subsequent treatments if no adverse effects have occurred. Caution should be used in treating darker skin types or tanned skin because of the intense pulsed light component. Optical fluences should be lowered by at least 20% when treating darkly pigmented lesions or dense pigment irregularity, even in light-skinned patients.

HYBRID MONOPOLAR AND BIPOLAR RADIOFREQUENCY

The first step in treatment is to assess the treatment area and determine which hand piece is to be used in which

anatomic location, based on desired tissue effect. The monopolar hand piece will deliver a higher amount of energy since it theoretically is heating a greater tissue volume than the bipolar hand piece with this particular system (Accent RF, Alma Lasers Ltd., Caesarea, Israel). Typically the monopolar hand piece is used to treat the forehead, cheeks, jawline, and neck. The bipolar hand piece is used to treat the glabella, lateral periorbital area, upper lip, and chin.

After a treatment plan is established, each site should be marked with a 5 × 6-cm² grid using a washable pen or marker. This grid sets a 30-cm² treatment segment to be focused on one at a time and facilitates maintenance of therapeutic temperatures within a given area. A light coating of oil (i.e. baby oil or mineral oil) is then applied to the skin so that the hand piece will glide easily with continuous skin contact. No adjunctive anesthesia is needed as treatments are generally associated with only mild to moderate discomfort.

From this point the treatment protocol is divided into two phases. The first is a non-therapeutic phase designed to elevate the baseline temperature of the skin to approximately 39°C within 30–60 seconds using two successive passes. A laser thermometer can be used to monitor the epidermal skin temperature (Center, 350 series, Center Technology Corp., Korea); however, it is not absolutely necessary to use one as the patient's pain threshold can be used as a guide to optimal energy settings. The epidermal skin temperature is expected to be approximately 10°C lower than the dermal and subdermal temperatures, so that an epidermal temperature of 40°C would correspond to a dermal and subdermal temperature of approximately 50°C.

Either the monopolar or bipolar hand piece is applied to the skin and moved in a continuous fashion across the skin. The electrode should be kept perpendicular to the skin and in continuous contact. Passes are performed in a paint-brush fashion, beginning with horizontal strokes alternating with vertical strokes until the operator selected time limit expires. Time can be adjusted for up to 30 seconds at a time. Note that with this device a 'pass' is defined by the time limit set by the user and may consist of multiple swipes of the hand piece within the premarked 30-cm² grid during that amount of time. To reach the goal temperature, the energy may have to be increased by 15–20%. However, similar to the other RF devices, skin temperature alone should not be used as a sole criterion. Patient discomfort must be used as a feedback mechanism to turn down the overall energy in a particular case. Typical power settings on the face are 80–140 W for the monopolar hand piece and 60–80 W for the bipolar hand piece.

After the skin has been warmed to an effective temperature, the second, therapeutic phase of treatment can begin. In this phase, the goal is to maintain the temperature of the skin between 39°C and 43°C for at least 60 seconds with three passes of 20 seconds each. The first two passes are applied in perpendicular directions, while

the third pass is performed using rotational movements. To avoid overheating, the energy will normally have to be turned down by 10–20% from the peak energies of the warm-up phase.

When treatment with one hand piece is complete, treatment with the alternate hand piece should be performed in the same fashion where indicated. After the treatment is complete, the face should be cleansed to remove excess oil and any remaining grid. Patients are expected to have post-treatment erythema that resolves within 1–2 hours.

Treatments are performed in a series of two to six treatments spaced 2–3 weeks apart for optimal results.

VACUUM-ASSISTED BIPOLAR RADIOFREQUENCY

Before treatment begins, the area should be cleansed and a conductive lotion is applied to the skin surface. The conductive lotion helps maintain conductivity through the stratum corneum, allowing the RF energy to pass through the epidermis into the targeted dermis and subcutaneous tissue.

The treatment operator is able to vary both the power and the pulse duration to achieve the ideal clinical endpoint of trace erythema with a mild heat sensation. The different tip aperture sizes control the volume of tissue treated. Increasing the vacuum level enables delivery of RF energy to deeper layers of the skin and subcutaneous tissue. Higher vacuum levels are useful in the treatment of areas with thick or coarse skin such as the arms or thighs, or in cases where skin laxity is an issue since it will enable deeper levels of tissue to be drawn into the field. Low vacuum levels will confine heating to more superficial layers and should be used for the treatment of rhytides in areas of delicate skin such as the periorbital or perioral regions. Similarly, the large tip is more useful in areas of thick skin and where tightening is an issue because more tissue can be brought into the treatment field. The small tip should be used for delicate or thin-skinned areas.

Test spots are performed to determine the maximum energy level that the patient can tolerate without anesthesia. Again, the goal is to get a mild heating sensation with some degree of skin tingling or minimal discomfort without significant pain. In the initial pilot study on facial skin, the protocol used 2–8-W power settings delivered for 2 seconds per pulse.

When treating the skin, the treatment tip should be placed perpendicular to the skin surface. One to three passes should be administered over each treatment area using the full vacuum range. After treatment, patients commonly have transient erythema lasting for 1–2 hours.

Treatments are performed in a series of eight treatments spaced 1–2 weeks apart.

TROUBLESHOOTING

• Adverse effects, complications, and alternative approaches

MONOPOLAR RADIOFREQUENCY

The most common potential problems with RF skin tightening are pain during the procedure, temporary postoperative surface irregularities, postoperative changes in sensation, and unrealistic patient expectations. Patient pain may be mitigated by topical, oral, or intramuscular analgesics as discussed herein; however, it is best to keep sensation as intact as possible so that the pain feedback calibration system for temperature settings is secure. If in doubt, it is safest to use the lowest possible treatment settings. The incidence of both postoperative surface irregularities and changes in sensation has decreased dramatically with the introduction of the newer fast tips. Surface irregularities are often described as small nodules or lumps that patients feel but rarely see on casual inspection. They are most common over thin-skinned areas such as the neck and self-resolve within a few weeks. Changes in sensation may include itching or numbness and occur most commonly along the preauricular area, jawline, temples, and forehead. Symptoms are usually mild and resolve completely in days to weeks.

Rarely, patients may experience adverse effects related to overly aggressive treatment approaches such as burns, indentations, scars, or changes in pigmentation. The overall incidence of such problems is 0.15% of patients treated. Indentations are thought to occur when high-energy settings overheat fat lobules and fibrous septa. This is extremely unlikely to happen with the use of the newer tips and the low-energy, multiple pass protocol. Of depressions, 30% have occurred in patients using topical anesthesia with the original 1-cm³ tips and may be related to the incomplete removal of the product before the procedure. There also appears to be a higher incidence of adverse effects in patients using local infiltrative anesthesia, nerve blocks, or general anesthesia. Again, this is likely due to overly aggressive treatments as the patient feedback loop is cut off.

COMBINED ELECTRICAL AND OPTICAL ENERGY

Adverse effects associated with combined electrical-optical energy are minimal. This may be because the synergistic effects of the two forms of energy allow lower levels of each to be used than when using either component alone. The most common occurrence appears to be mild transient erythema after the procedure, usually resolving in several hours. In one study using combined broadband IR light and bipolar RF for facial skin laxity in an Asian population, 7% of treatment sessions resulted in isolated small superficial crusting over the forehead. All episodes resolved without sequelae. Patients tolerate the procedure well without need for analgesics. Crusting, blisters, pigmentary change, and scarring are uncommon.

HYBRID MONOPOLAR AND BIPOLAR RADIOFREQUENCY

As with the other RF devices, adverse effects are rare but may include burns, skin breakdown, or scarring with the use of inappropriately high energies. Patient discomfort increases with the energy level and should be used as a feedback mechanism that energies are too high in a particular case, regardless of temperature readings on the laser thermometer. It is also important to keep the hand piece in constant motion when in contact with the skin to avoid localized overheating and possible skin breakdown. No instances of subcutaneous fat atrophy have yet been reported to the author's knowledge.

VACUUM-ASSISTED BIPOLAR RADIOFREQUENCY

Adverse effects reported with vacuum-assisted bipolar RF procedures include erythema, burns, blistering, edema, purpura, crusting, and transient hyperpigmentation. Most of these occurred in the first few treatment sessions in the initial pilot study when treatment protocols were just being established. Subcutaneous fat atrophy or indentations have not been reported to the author's knowledge.

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