

Radiofrequency in Cosmetic Dermatology: A Review

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BACKGROUND Fine lines and rhytides are clinically evident signs of photodamage. Traditionally, ablative and nonablative lasers have been used for nonsurgical facial rejuvenation, but their side effects and downtime have limited their use.

OBJECTIVE Radiofrequency (RF) is novel nonablative technology originally used to target photodamage. It differs from lasers in that it uses an electric current rather than a light source. It is frequently used in dermatology to treat skin laxity, rhytides, acne vulgaris and scarring, and cellulite. The goal of this review is to summarize the various types of RF devices and their uses and to determine the evidence-based efficacy of these devices.

MATERIALS AND METHODS This article reviews the current literature on RF, its uses and clinical effectiveness, and a practical guide for application of the assorted RF devices.

RESULTS AND CONCLUSION Results have been favorable for the different clinical uses of RF, but many studies are nonrandomized, noncomparative trials that use subjective means of evaluation. Overall, nonablative RF is a safe, tolerable, and effective tool for skin rejuvenation and cellulite treatment that produces modest results. RF should serve as an alternative but not as an equivalent substitute to surgery.

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The hallmark of photodamaged skin is the accumulation of elastin-containing fibrils in the papillary dermis and mid-dermis, a process known as solar elastosis.¹ A decrease in collagen synthesis and architectural changes in the collagen fiber network accompany this process. The once-organized collagen fiber network evolves into one that is disorganized and laden with increased breakdown and reduced network formation.² Clinically, fine lines and rhytides, skin laxity, dyschromia, and telangiectasias characterize these changes.^{2,3}

Traditionally, aging has been treated with surgery, such as rhytidectomy, blepharoplasty, and brow lifts, but with the increasing demands of patients undergoing cosmetic surgery, minimally invasive procedures have gained popularity. The appeal behind these nonsurgical antiaging procedures is

that they are less invasive and require less downtime. Ablative and nonablative laser devices have conventionally been used to improve skin laxity, but novel technologies have emerged that use sources of energy other than light and laser to combat aging, such as radiofrequency (RF) and focused ultrasound. Although both technologies have gained popularity for the treatment of skin laxity of the face and jawline, their comparative clinical efficacy has yet to be determined.

Ablative laser resurfacing works by causing epidermal destruction and subsequent wound formation in the dermis.¹ Disadvantages of this modality include significant side effects and complications such as oozing, bleeding, and infection and considerable downtime to allow the epidermis to reepithelialize.¹ Therefore, nonablative lasers have been developed

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to address the limitations of ablative skin rejuvenation. These lasers have the disadvantage of being diffracted, absorbed, or scattered, which results in suboptimal energy penetration.⁴ RF is novel non-ablative technology that is different from lasers in that it uses an electric current rather than light for skin rejuvenation. RF may represent a promising alternative to ablative and nonablative laser- and light-based treatments.

RF devices produce focal thermal damage to the dermis. This focused energy preserves the epidermis and is associated with fewer complications and side effects and quicker recovery time.^{5,6} Three forms of RF delivery have been developed: monopolar, bipolar, and fractional. The goal of this review is to summarize the various types of RF and their uses in cosmetic dermatology and to evaluate the evidence-based efficacy of these devices.

History of RF

RF energy has many medical applications, ranging from joint capsular tightening to prostate and liver neoplasm eradication.⁷ It was initially developed in the 1920s for electrocautery⁸ but is now most widely used in dermatology for nonablative skin rejuvenation. In 2002, the U.S. Food and Drug Administration (FDA) approved the first RF device for facial wrinkle reduction.⁹ This device was a monopolar RF device (ThermaCool; Thermage, Hayward, CA) and it subsequently gained approval for off-face treatment in 2006.⁹ Since then, many other RF devices have been developed and combined with various laser and light sources.

Radiofrequency

RF devices produce electric current using electromagnetic radiation in the frequency range of 3 kHz to 300 MHz.^{4,9,10} A current is formed when charged particles flow through a closed tissue.¹⁰ When the current is applied to the tissue, it meets resistance, which is an inherent property of the type of tissue, also called impedance. This produces heat, and the electric

current is subsequently converted to thermal energy.^{7,10} The energy output is calculated using the formula³:

$$\text{Energy (J)} = I^2 \times z \times t,$$

where I = current, z = impedance, t = time (seconds). The amount of energy produced therefore depends on the amount of current and the impedance of the targeted tissue.¹⁰ High-impedance tissues, such as subcutaneous fat, generate a greater amount of energy and have deeper thermal effects.^{7,10} Laser light can be diffracted, absorbed, and scattered, which results in lower amounts of energy reaching the target. Unlike laser light, neither tissue diffraction nor chromophore absorption affects the energy that RF produces.⁴ Thus, these devices may be used on any skin type, and the depth of energy penetration is more controlled.

Monopolar RF

Mechanism of Action

Monopolar systems deliver current using one electrode that contacts the skin and another that acts as a grounding pad.⁷ The skin tightening effect is based on the principle of volumetric heating.³ The electrode contacting the skin delivers the electric current to the skin. A reverse thermal gradient is created by applying a cooling spray to the epidermis, which protects it from the heating effect of the device.¹¹ The dermis is then heated uniformly and volumetrically, sparing the epidermis. Partial collagen denaturation occurs as a result of this heating, which leads to collagen contraction and thickening.^{10,12} Some contraction of the collagen framework may occur immediately due to the fibril denaturation.¹¹ More tightening follows due to a natural inflammatory wound healing response that triggers neocollagenesis and further skin contraction.^{7,10,11} The collagen-based fibrous septa that separate fat lobules in the subcutaneous tissue are also preferentially heated, leading to further collagen denaturation and contraction of the subcutaneous tissue and accounting for the immediate tightening and lifting effect on the skin.^{7,11}

Device Properties

Some monopolar RF devices consist of three main components: a generator, a handheld tip, and a cryogen unit. Others do not use a cryogen cooling system. The generator creates a constantly changing electric field, which alternates up to 6 million times per second.^{3,10} The handheld tip, which varies in size, contains the electrode and a cooling apparatus that protects the epidermis with pre-, parallel, and postcooling.^{8,10} Sensors in the tip measure temperature and pressure continuously. The electrode meets resistance, and heat is created. The electrode is designed to disperse energy uniformly across the skin surface in a process termed capacitive coupling,⁵ which creates a zone of higher temperature at controlled depths of 3–6 mm.^{3,8,10} The depth of heating depends on the size and geometry of the treatment tip.¹⁰ Typically, the device heats the dermis from 65 to 75°C, the temperature at which collagen denatures.³ Again, the cooling apparatus protects the epidermis, keeping the epidermal temperature between 35–45°C.⁵

Applications and Effects

The FDA initially approved monopolar RF devices to treat periorbital wrinkles.^{8,10} Since then, they have been used to treat laxity of the forehead, cheeks, nasolabial folds, marionette lines, jawline, and neck. Aside from rhytid reduction, successful treatment of moderate to severe cystic acne, acne scarring, and cellulite have been reported.¹⁰

The histologic, ultrastructural, and molecular effects of RF have been studied. Zelickson and colleagues evaluated the effects of RF (ThermaCool) on two samples of human abdominal skin treated with energy ranging from 95 to 181 J. The treatment effect was evaluated using light and electron microscopy of punch biopsies taken immediately and up to 8 weeks after treatment. Immediately after treatment, a mild perivascular and perifollicular infiltrate was observed. At 0, 3, and 8 weeks after treatment, electron microscopy revealed collagen fibrils with greater diameter (shortening of

collagen fibers) compared to collagen fibers evaluated pretreatment, up to 5 mm deep in the skin. This was associated with an increase in collagen expression, as measured using Northern blot analysis.^{8,13}

El-Domyati and colleagues analyzed the effect of a monopolar RF device (Biorad, Shenzhen GSD Tech CO, Guangdong, China) on six individuals who underwent treatment on the face every 2 weeks for 3 months for a total of six sessions. Punch biopsies of the facial skin were performed at baseline, end of treatment, and 3 months after treatment. Histologic findings included an increase in epidermal thickness, increase in granular layer thickness, and development of rete ridges seen at the end of treatment and 3 months after treatment. There was also less total dermal elastin after treatment, which was more pronounced 3 months later. Lastly, significantly more collagen was observed after treatment, an yet more at 3 months after treatment.⁴

Evidence-Based Efficacy and Side Effects

The efficacy of monopolar RF has been widely studied for various applications. The results of these studies are discussed below (Table 1).

Periorbital Rhytides

Fitzpatrick and colleagues¹⁴ demonstrated the efficacy of a monopolar RF device (ThermaCool) on 86 patients in a blinded, multicenter clinical trial. Subjects received a single treatment (52–220 J) on the lateral canthal and forehead areas. Three blinded physicians evaluated treatment efficacy using the Fitzpatrick Wrinkle Classification System (FWCS) by comparing photographs taken at 2, 4, and 6 months. Eyebrow lift was also measured by comparing baseline and 4- and 6-month photographs using an objective technique. Eighty-three percent of patients had improvement of at least one point on the FWCS, and 50% of subjects reported satisfaction with periorbital wrinkle reduction. Brow lift of at least 0.5 mm was reported in approximately 62% of patients. The authors of this study concluded an objective and subjective reduction of periorbital wrinkles and changes in brow

TABLE 1. Studies Evaluating the Effects of Monopolar Radiofrequency RF

<i>Authors</i>	<i>Type of Study</i>	<i>Results</i>
Fitzpatrick et al. ¹⁴	Multicenter nonrandomized blinded clinical trial	Objective and subjective improvement in periorbital wrinkles and brow elevation
Bassichis et al. ⁵	Comparative nonrandomized nonblinded	Objective improvement in brow elevation, brow asymmetry observed in many patients, and the majority of patients did not perceive a cosmetic benefit
Nahm et al. ¹⁵	Comparative non randomized nonblinded split face	Objective brow elevation observed in all patients by 3 months
El-Domyati et al. ⁴	Nonrandomized nonblinded	Subjective notable improvement in skin tightening and wrinkles in periorbital and forehead regions that was more pronounced 3 months after treatment; objective increase in collagen synthesis
Jacobsen et al. ¹⁷	Nonrandomized nonblinded clinical trial	Subjective improvement in lower face skin tightening
Alster and Tanzi ¹⁸	Nonrandomized nonblinded clinical trial	Subjective improvement in moderate cheek laxity and nasolabial folds
Weiss et al. ¹⁹	Retrospective chart review	Greater rate of unexpected adverse side effects with single-pass high-energy treatment than using a lower-energy multiple-pass technique
Ruiz-Esparza et al. ²⁰	Nonblinded nonrandomized case study	Objective reduction in active acne lesions and subjective improvement in scarring
Javate et al. ¹⁶	Nonblinded, nonrandomized	Objective clinical improvement in wrinkles with electron microscopic correlation

position.¹⁴ Side effects included low rates of edema and erythema and an overall incidence of 0.36% of second-degree burns. Most patients rated their pain as mild to moderate.¹⁴

Bassichis and colleagues⁵ also evaluated the use of a monopolar RF device (ThermaCool) on rejuvenation of the upper third of the face as evidenced by brow elevation. Twenty-four patients received a single-pass treatment over the mid- and lateral forehead and temporal regions. Pretreatment and follow-up photographs were taken, and brow elevation was measured 1, 2, and 3 months after treatment. The authors concluded that the amount of energy delivered did not appear to affect the amount of brow elevation; treatment resulted in statistically significant brow elevation of at least 0.5 mm or greater in 87.5% of patients, with progressive improvement over time; brow asymmetry was observed in many patients; and 64% of patients did not perceive a cosmetic benefit. No complications were reported, but pain was not included as a possible complication.

Nahm and colleagues reported more-positive results with a monopolar RF device (ThermaCool). Ten patients were treated with a single pass ranging in fluence from 97 to 134 J/cm² on one side of their face.¹⁵ Changes in brow position were measured using standardized photographic images taken 1, 2, and 3 months after treatment. Brow elevation was observed in all patients by 3 months, with a statistically significant average elevation of 4.3 mm of the midbrow and 2.4 mm of the lateral brow and a 1.9-mm increase in the level of the palpebral crease. No adverse reactions, such as blistering, dysesthesia, or scarring were noted.

In a recent study by El-Domyati and colleagues,⁴ six individuals with mild to moderate wrinkles underwent 3 months of treatment (six sessions at 2-week intervals) using a monopolar RF device (Biorad, Guangdong, China). Two initial passes of 150 J each were performed over the entire face and three to six passes of 200 J were performed to targeted treatment regions. The effects were evaluated using standard photographs at baseline and 3 and 6 months. All six

volunteers showed notable improvement in skin tightening and wrinkles in the periorbital and forehead regions at the end of treatment, with continued improvement 3 months after treatment. Skin tightening improved from 35% to 40% at the end of treatment to 70% to 75% at 3 months after treatment. Appearance of facial wrinkles improved from 40% to 45% to 90% to 95% at 3 months after treatment. These results were associated with an increase in collagen synthesis and a decrease in elastin content. Transient erythema and hyperpigmentation developed in one volunteer.

Javate, using a 4-MHz monopolar RF system, also treated periorbital rhytides. Subjects were evaluated 1, 3, and 6 months after treatment with a RF device (Ellman International, Oceanside, NY). A 9-point rating scale was used, and statistically significant changes were noted clinically and according to electron microscopic evaluation.¹⁶

Lower Face and Neck

Jacobsen et al. treated 24 patients with laxity of the neck, nasolabial folds, marionette lines, and jawline using the ThermoCool system.¹⁷ Each patient received one to three monthly treatments that consisted of two passes on the forehead, three on the cheek, and one on the neck using 106–144 J. Two physicians assessed results 1 and 2 months after treatment by evaluating photographs. Seventeen of the 24 patients showed notable improvement by 1 month after treatment that was more pronounced at 3 months after treatment. All patients experienced discomfort during the procedure, described as transient burning. Patients who underwent multiple treatments and passes had greater results. Alster and Tanzi¹⁸ reported similar findings with the ThermoCool system, with improvement in moderate cheek laxity and nasolabial folds in 30 patients treated with monopolar RF. Fifty-six percent of patients were sore from the procedure.

Weiss et al.¹⁹ published a retrospective chart review to establish the rate and degree of side effects. More than 600 patients were treated using the ThermoCool

device for mild laxity. Patients were treated with multiple passes with fluences of 74 to 130 J/cm² using a 1-, 1.5-, or 3-cm² tip. The most common side effects were self-limited erythema and edema. Ninety percent of patients experienced transient erythema that resolved within 5–20 minutes, but 5% reported erythema lasting up to 72 hours. Thirty percent of patients experienced edema lasting <24 hours. The most significant side effects occurred with the 1-cm² tip and included one case of superficial crusting that resolved in 1 week, one case of a slight depression on the cheek that lasted for 3.5 months, three cases of subcutaneous erythematous papules, and three cases of neck tenderness lasting 1–4 weeks. The overall rate of unexpected adverse side effects was 2.7%, none of which were seen with the multiple-pass lower-energy treatment algorithm.

Acne Vulgaris and Atrophic Scarring

Monopolar RF has also been used to treat active cystic scarring acne. Other physical modalities such as laser ablation and chemical peeling are used more to treat the scarring effect of acne than the active disease. The rationale behind using nonablative monopolar RF is to inhibit sebaceous activity and promote dermal contouring. One study conducted on 22 patients with moderate to severe active cystic scarring acne reported favorable results with the use of the ThermoCool monopolar RF device.²⁰ Patients were treated in one to three sessions using 65–103 J/cm². A 75% reduction in active acne lesion count was seen in 92% of patients, and 25% to 50% reduction occurred in 9% of patients. The other 9% of treated patients had no response, defined as less than 25% reduction in active acne lesion count. Results were visible after 1 month of treatment while some flared up up to the fourth month, at which time the full effect of a single treatment was seen. In some patients, a dual effect was observed consisting of a decrease in active lesions and improvement of underlying scarring.

Limitations

The major limitations to monopolar RF devices are the associated pain and the modest effects observed.

When this technology was first introduced, treatment protocols focused on providing the maximum amount of energy ($\leq 144 \text{ J/cm}^2$) in a single-pass treatment over the 1-cm^2 area of the treatment tip. This technique was associated with notable patient discomfort.¹¹ With time, techniques evolved to optimize results and minimize side effects, and studies demonstrated that using multiple passes with lower energy levels was associated with the same or greater amount of collagen denaturation and skin tightening.¹³ Larger treatment tips have been developed to treat larger areas in less time. The use of larger, faster tips; lower energy levels; and multiple passes has diminished associated pain but not eliminated it.

Most published studies report better outcomes in all clinical endpoints evaluated. Of these studies, only one, that of Bassichis and colleagues,⁵ reported patient dissatisfaction. Because most studies have reported more-modest results than with more-invasive techniques, it is important to discuss patient expectations before treatment, informing them that results may be gradual and subtle. Equally important is choosing optimal candidates. The best results are seen in patients with mild to moderate wrinkling with early signs of aging.¹¹ Patients who have prominent skin folds and laxity would probably benefit from more-invasive procedures. Contraindications include implantable medical devices such as pacemakers and defibrillators and active dermatologic conditions such as collagen vascular disease and autoimmune diseases. Device companies recommend avoiding treatment over areas of skin marked with tattoos. Caution should be exercised in patients with radiated skin and those who are prone to herpetic outbreaks.^{11,21} A topical anesthetic cream over the treated areas may be used to minimize pain, and device companies recommend oral anxiety medications for pain control.

Unipolar RF

Unipolar RF differs from monopolar RF in that it does not deliver an electric current to the skin.

Instead, it uses high-frequency electromagnetic radiation at 40 MHz to induce rotational oscillations in water molecules and ultimately produce heat. This heat is dissipated to surrounding tissues and can reach a depth of 15–20 mm. The deeply penetrating technology has been used to treat conditions caused by irregularities of the fibrous septa in the dermis, specifically cellulite.

Goldberg and colleagues²² evaluated the efficacy of a unipolar device (Accent RF System; Alma Lasers, Buffalo Grove, IL) on 30 patients with grade III or IV cellulite on the upper thigh. Patients underwent six treatments at 2-week intervals. Twenty-seven of 30 patients treated experienced clinical improvement 6 months after treatment, with a mean decrease of 2.45 cm in thigh circumference. Minimal side effects were reported. Histologic evidence of dermal fibrosis was reported, but there was no magnetic resonance imaging evidence of changes in the pannicular layer. The authors propose that RF-induced contraction between the dermis and Camper's fascia may explain the initial skin tightening effect but that its longer-lasting effect is due to dermal fibrosis.²³ Del Pino and colleagues²³ reported 20% contraction between the stratum corneum and Camper's fascia in 68% of patients 15 days after treatment using a unipolar RF device (Accent RF System). Goldberg and colleagues²² did not report this effect 6 months after treatment, indicating that it may be a transient response. A randomized, blinded, split-design, controlled study on 10 individuals with grade II to IV cellulite similarly reported favorable results of clinically visible and quantifiable improvement of cellulite 3 months after treatment using a unipolar RF device.²⁴

Bipolar RF

The main difference between bipolar and monopolar RF is the configuration. The monopolar RF devices have one active electrode placed on the skin and a grounding electrode. The bipolar configuration consists of two active electrodes placed a short distance apart overlying the intended treatment area. The

current flows between the two electrodes. The depth of penetration is approximately half the distance between the two electrodes.¹⁰ The major limitation of this configuration is the depth of penetration.¹⁰ The monopolar device achieves high penetration of the emitted current, which serves as its main advantage and also its major drawback, which is associated pain.^{10,25} The bipolar configuration is not as penetrating but provides more-controlled distribution of energy and less pain.²⁵ Bipolar RF devices are frequently combined with light-based technologies, termed electro-optical synergy (ELOS).^{1,7} Functional aspiration controlled electrothermal stimulation (FACES) is another system used with the bipolar device that uses a vacuum to maximize and control penetration of the electric current.

Mechanism of Action

The mechanism of action for simple bipolar RF devices is similar to that of monopolar RF devices. The electric current generates heat as it travels through the skin and meets resistance from the tissue. This heat causes collagen shrinkage, an inflammatory response, and fibrous septa contraction in the dermis.

The ELOS system uses the synergistic effects of light- and RF-based devices. The light energy is used to preheat the target tissue through photothermolysis, which lowers the tissue's impedance. The lower impedance makes the tissue more susceptible to the RF component so that it is selectively targeted.^{1,10} Therefore, lower levels of energy of the light and RF component are needed to produce the desired effect with fewer side effects.¹⁰ The optical component also targets fibroblasts, blood vessels, and dyschromias.¹

The FACES system uses a vacuum system in combination with bipolar RF. The vacuum is used to fold the skin to a predetermined depth, which allows for closer alignment and deeper penetration with the RF energy than with traditional monopolar and bipolar devices. The volume of treated tissue is limited to that located between the electrodes in the special vacuum

tip, so lower energy levels can be used to meet the energy density needed to reach and affect the chosen skin layers, leading to greater efficacy, less pain, and lower incidence of side effects.

Device Properties

The bipolar configuration consists of two electrodes placed a short distance apart perpendicularly over the treatment area. The electric current passes between the electrodes, and the depth of penetration of the current is equal to half the distance between the electrodes.¹⁰ This results in enhanced control of energy distribution and ultimately less pain,²⁵ but the depth of penetration of the current is less than that of monopolar devices.²⁵

The most widely used ELOS systems are those that use intense pulsed light (IPL), a diode laser, or infrared light. One system (Aurora SR; Syneron Medical Ltd, Yokneam, Israel) uses IPL as its optical energy source with wavelengths between 400 and 980, 580 and 980, and 680 and 980 for different targets or chromophores.¹⁰ RF energies up to 25 J/cm³ can be generated with dermal penetration of 4 mm.⁷ Another system (Polaris WR; Syneron Medical Ltd) is a combined 900-nm diode laser with RF energy. Optical and RF energies are delivered simultaneously through the bipolar electrode tip. Optical energy fluences range from 10 to 50 J/cm² and RF energies from 10 to 100 J/cm³.¹⁰ The diode laser targets superficial structures, and the RF targets collagen.⁷ Another ELOS device (Vela-Smooth; Syneron Medical Ltd) uses a combination of infrared light (700–2,000 nm), RF energy, and suction with mechanical massage for the treatment of cellulite.²⁶

FACES-based devices (e.g., Aluma System Lumenis, Inc., Santa Clara, CA) are composed of an RF generator, a handpiece, and a tip with two parallel electrodes. When the handpiece with the tip is placed perpendicular to the surface of the skin, the system produces a vacuum, which suctions a flap of skin.²⁵ This flap of skin is positioned between the two electrodes so that the energy emitted reaches the

middle and deep dermis. The vacuum pump provides 5–28 inches of mercury vacuum.¹²

Applications

Bipolar devices, combined RF and optical energy systems, and FACES are used for the treatment of facial laxity, rhytid reduction, vascular and pigmented lesions, acne, acne scarring, hair removal, and cellulite.

Evidence-Based Efficacy and Side Effects

Skin Rejuvenation

Combined bipolar RF and IPL devices are frequently used for skin rejuvenation. A recent study by El-Domyati and colleagues² evaluated the histologic changes and corresponding clinical outcomes after use of the Aurora system for skin rejuvenation. Six volunteers were treated over the periorbital region for a total of six sessions at 2-week intervals. The outcomes were assessed using photographs and punch biopsies taken at the end of the treatment and 3 months after treatment. Two dermatologists, two independent observers, and patients evaluated wrinkle improvement, skin tightening and texture, and overall satisfaction on a 5-point scale. Improvements in skin tightening, skin texture, wrinkles, and overall satisfaction at 3 months were 75% to 80%, 70% to 75%, 95% to 100%, and 95% to 100%, respectively. Histologic analysis revealed an increase in epidermal thickness, a 53% reduction in elastin content 3 months after treatment, and a 28% increase in newly synthesized collagen fibers.² Sadick and colleagues²⁷ reported similar results in 108 consecutive patients treated using the Aurora system. Each patient received five full-face treatment every 3 weeks and were assessed according to double-blind physician photographic evaluation and patient satisfaction. Overall skin improvement was 75.3%, and overall average wrinkle improvement was 41.2%. Skin laxity improved 62.9% and skin texture 74.1%. Additional features measured were pore size, pigmentation, and vascular concerns, all of which improved between 65% and

79.3%. Overall patient satisfaction was rated at 92% at 15 weeks after treatment.²⁷

The Polaris system, a combined 900-nm diode laser with RF energy device, has been used to treat deep wrinkles and superficial signs of photoaging. The first study to evaluate the Polaris system was conducted on 24 patients who underwent three treatment sessions at 3-week intervals. Modest improvements of wrinkles in the majority of patients treated were reported 6 months after treatment, with greater improvement in periorbital than perioral wrinkles.²⁸ A study on eight patients who received three full-face treatments reported average wrinkle reduction of 30% and improvement in dyschromia.²⁹ No significant side effects aside from discomfort were noted. Hammes and colleagues³⁰ reported a notable improvement in 58% (14/24) of patients treated with six treatments over 3 months. Mild to moderate edema and erythema were reported side effects.

The combination bipolar RF with vacuum device (Aluma) based on the FACES technology has reduced facial wrinkles and elastosis. One study treated 46 patients with eight facial treatments every 1–2 weeks.¹² The evaluators found statistically significant improvement in facial wrinkles using the Fitzpatrick-Goldman Classification of Wrinkling and Degree of Elastosis (ES), which continued at 6 months. Using a visual analog scale, mean improvement at 6 months was twice as high as the corresponding observation at the fifth treatment. Erythema, burning and blistering, edema, and crusting were reported as adverse events.¹² Another study reported clinical improvement in 30 patients treated with six to eight cycles of the Aluma system. Patients were treated for periocular and glabellar wrinkles, slackness of cheeks, striae distensae, and acne scars. Clinical improvement was observed in 90% of patients with periorbital wrinkles and in all patients with glabellar wrinkles. The wrinkles appeared less deep and less evident than before the cycle of treatment session, and these clinical findings were confirmed by biopsy. Treated skin revealed less

collagen atrophy and greater interstitial edema, while untreated skin showed atrophic and intensely elastotic dermal collagen. All patients with striae distensae on the abdomen achieved 50% improvement.²⁵

Acne Vulgaris

RF pulsed light devices with ELOS technology have been used to treat acne vulgaris. A study of the Aurora system on 32 patients with moderate inflammatory acne revealed clinical improvement as evidenced by a reduction in lesion count, decrease in size of the sebaceous glands, and reduction in perifollicular lymphocytic infiltrates. Side effects included temporary erythema, tingling, and burning.³¹ Another study using the Aurora system for acne scars on three patients noted improvement, one with greater 50% improvement and the others with 25–50% improvement.²⁵

Cellulite

Nonablative RF devices have recently been used to treat cellulite. One device that is gaining more acceptance and popularity is based on ELOS technology (VelaSmooth; Syneron Medical Ltd). This device is a combination of bipolar RF, infrared light (700–2,000 nm), and mechanical manipulation of the skin and fat layer. Heat causes thermal damage to surrounding adipose tissue and connective tissue septa, penetrating up to 3 mm deep. A two-center study investigated the effectiveness of the system on 35 patients who received eight to 16 treatments twice weekly. The circumference of the right and left medial thighs was measured at baseline and 4 weeks after the last treatment. The level of improvement was graded based on skin smoothing and cellulite improvement using pre- and post-treatment photographs. All patients showed reduction in thigh circumference after 8 weeks of treatment, and 70% of patients noted a reduction after 4 weeks of treatment. All patients showed some improvement in skin texture and cellulite. Although the mean decrease in circumference was 0.8 inches, some patients demonstrated reductions of more than 2 inches. The mechanism is thought to occur by

infrared light- and RF energy-induced increase in dissociation of oxygen from oxyhemoglobin and diffusion to adipose tissue and by disruption of fat cell clusters and stretching of fibrous bands by the mechanical device.³² Another study of VelaSmooth found a statistically significant decrease in thigh circumference at 4 weeks but no persistent decrease 8 weeks after treatment. The majority of patients had less than 50% visual improvement in cellulite, and 31% of patients experience bruising.²⁶ Tanzi and Alster also studied the effects of VelaSmooth on 20 patients who underwent eight biweekly treatments on one thigh, with the contralateral thigh serving as a control. Ninety percent of patients noticed overall clinical improvement, with an average decrease in thigh circumference of 0.8 cm and an average 50% clinical improvement. Erythema was the most common side effect, and bruising occurred in two of the 20 patients treated.³³

Limitations

The major limitations of the bipolar RF devices seem to be depth of penetration. Combination with light devices has been used to overcome this limitation. Although most studies report efficacy with these devices for skin rejuvenation, more clinical studies are needed. Overall, these devices seem to be tolerated better than monopolar RF systems, but the comparative efficacy of these devices has not been established. Although the combination systems are better tolerated than the monopolar RF systems, topical anesthetic creams may be used at the physician's discretion to alleviate any associated pain.

Modest results have been reported regarding the efficacy of the ELOS systems for cellulite. More investigations are needed to confirm the role of bipolar RF in the treatment of acne and cellulite.

Fractional RF

Fractional RF is a newer nonablative approach. There are two ways to deliver fractional RF. Whereas some devices (Matrix RF device; Syneron

Medical Ltd) use electrodes, others use an array of microneedles arranged in pairs between which bipolar RF energy is delivered (ePrime system; Syneron Medical Ltd).³⁴ Thermal wounds are created in a nonhomogenous fractional form directly to the reticular dermis. The area directly in contact with and below the array of microneedles or electrodes is selectively heated while the areas between the targeted areas are left intact.³⁵

Mechanism of Action

The fractionally delivered energy creates zones of affected skin adjacent to unaffected areas. The treated areas have resulting thermal damage in the deep dermal collagen, which stimulates wound healing, dermal remodeling and new collagen, elastin, and hyaluronic acid formation.³⁴ The unaffected areas located in between affected areas initially maintain skin integrity but, in the long term, serve as a reservoir of cells that promote and accelerate wound healing.³⁵

Device Properties

Fractional RF devices consist of a handheld applicator with a disposable tip. The tip contains parallel rows of microneedles or electrodes arranged in a bipolar array. The RF energy flows between each pair of positively and negatively charge electrodes or needles so that each pair forms a closed circuit of bipolar RF current.³⁵ The geometry of the electrode pairs defines the volume of each lesion.³⁴

Evidence-Based Efficacy and Side Effects

Fractional RF (FRF) has been used mainly for skin rejuvenation. A prospective multicenter study was conducted on 35 subjects who received three treatments on their entire face with a fractional device (Matrix RF; Syneron Medical Ltd). Clinical improvement was assessed 4 weeks after the last treatment using photographic analysis. Eighty-three percent of patients show improvement in skin brightness, 87% in skin tightness, and 90% in smoothness and wrinkling. There was a trend

toward less wrinkling and elastosis, but this difference was not statistically significant. Eighty percent of patients were satisfied with their treatment. Side effects included minimal, moderate, and severe pain in 87%, 11%, and 3% of patients, respectively. Only 3% of patients experienced prolonged edema and temporary erythema.³⁵

In a randomized blinded trial, 15 patients with facial skin laxity completed one FRF treatment with the Miratone FRF system (Primaeva Medical, Inc., Pleasanton, CA) using a microneedle electrode array. Five independent, blinded evaluators graded randomized (not paired in sequence) digital baseline and 3- to 6-month follow-up photographs. Improvement from baseline in facial laxity was 16%. Side effects included transient erythema, mild edema, and mild to moderate purpura that resolved in 5–10 days.³⁴ Patients who underwent FRF were compared with six patients who underwent a surgical face lift. Patients who underwent a surgical face lift demonstrated 49% improvement in skin laxity over baseline, compared with 16% of patients treated with FRF.³⁴

A recent study evaluated the relationship between subjective clinical improvement scores and objective measures of mechanical properties of the skin in 44 patients treated using the Miratone FRF device.³⁶ Three independent clinicians graded clinical improvement in skin laxity and wrinkles using a standard scoring system 3 and 6 months after treatment. Objective evaluation consisted of elasticity measurement using a skin probe. Three months after treatment, statistically significant improvement in elastometry measurements was observed that correlated to a 2.6-year improvement in skin property. Subjective clinical improvement in skin laxity and wrinkles was subjectively observed, which corresponded to a statistically significant improvement of 1.42 grades on the Fitzpatrick Wrinkle Scale and 0.66 grades on the Alexiades laxity scale.³⁶

A new device has been developed that combines fractionated optical energy with a 915-nm diode

combined with a fractionated bipolar RF. This integrated system targets the epidermis and superficial dermis. By using the RF component synergistically, less energy is used to heat the collagen in the deep dermis and stimulate new collagen formation and contraction (Matrix eLaser; Syneron, Irvine, CA). This device has been associated with significant improvement in acne scarring, texture, and pigmentation.³⁷

Limitations

It appears that FRF devices are a safe, tolerable, and effective modality for wrinkle and facial laxity reduction. The most common side effects are erythema and edema, which are transient, and patient discomfort does not seem to be a major disadvantage. A topical anesthetic cream may be used before treatment to minimize pain. Studies suggest that this nonablative method is inferior to the criterion standard for rhytid reduction, the surgical facelift, but is associated with less downtime and fewer side effects.

Conclusions

Nonablative RF devices have broad applications in the field of dermatology. They are used for the treatment of skin laxity, rhytides, acne vulgaris and scarring, and cellulite. Results have overall been favorable, but many studies are nonrandomized, noncomparative trials that use subjective means of evaluation. The few studies that have used objective means of evaluation report improvement, sometimes statistically significant, and overall patient satisfaction. The side-effect profile of these devices is more benign than that of invasive and ablative modalities and include transient erythema, edema, and patient discomfort.

Overall, nonablative RF is a safe, tolerable, effective tool for skin rejuvenation and cellulite treatment. It produces modest results that should serve as an alternative but not as an equivalent substitute to surgery. The major advantage of this modality over

ablative and surgical treatments is the lower rate of side effects and less downtime required after treatment.

Questions remain regarding the ideal treatment parameters, specifically energy levels and number of passes that should be employed for optimal results. More controlled randomized comparative clinical trials are necessary to elucidate the most-effective way to use these devices for their various clinical applications. Furthermore, the comparative safety and efficacy of the monopolar, bipolar, and fractional RF devices has not been established.

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