The Use of Hybrid Radiofrequency Device for the Treatment of Rhytides and Lax Skin

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BACKGROUND Recently, radiofrequency (RF) devices have been introduced and commercialized for nonablative procedures in dermatology and plastic surgery for the treatment of age-related rhytides and lax skin.

OBJECTIVE The objective was to assess the efficacy and safety of a novel RF device (Accent, Alma Lasers, Ltd, Caesarea, Israel) for the treatment of rhytides and lax skin.

METHODS AND MATERIALS Sixteen female patients (age range, 29–66 years; mean, 47 ± 6 years; skin phototypes II to IV) were treated with Accent system. Patients were treated on the chin ($n=5$), forehead ($n=8$), cheeks ($n=12$), jowl lines ($n=9$), periorbital area ($n=7$), marionette line ($n=3$), and nasolabial folds ($n=6$) for wrinkles ($n=27$ cases) and skin laxity ($n=23$ cases). Patients received two to six treatments (mean, 4.3 ± 1.1), with the time interval of 2 to 3 weeks. Photographs were assessed 1 month after the last treatment.

RESULTS For wrinkles and skin laxity, in 5 patients (42%), the cheeks ($n=12$) scored 51% to 75% (significant improvement), and 2 patients (17%), 76% to 100% (excellent improvement). For the jowl lines ($n=9$), 4 patients (44%) scored 51% to 75% (significant improvement), and 1 patient scored 76% to 100% (excellent improvement) for lax skin. For wrinkles on the periorbital ($n=7$) and forehead areas ($n=8$), three patients (37%) scored 51% to 75% (significant improvement).

CONCLUSION The Accent system is an effective and safe modality for the improvement of age-related rhytides and lax skin.

The radiofrequency device used in this study was loaned by Alma Lasers, Ltd.

One of the significant advances in facial cutaneous laser surgery in the past few years has been the proliferation of radiofrequency (RF) technology to provide nonsurgical, nonablative means for the improvement of age-related rhytides and lax skin and acne vulgaris.[1] Although proven effective, dermabrasion, chemical peels, and laser resurfacing (CO_2 and erbium) techniques waned significantly because of pain, substantial posttreatment "downtime," and prolonged recovery period. In fact, the potential risks associated with ablative laser therapy paved the way to the nonablative RF technologies.[2]

RF energy is a form of electromagnetic energy ranging from 300 MHz to 3 kHz. RF affects skin by emitting high-frequency radio waves that mimic the thermal effects of lasers and intense pulsed light sources. RF is similar to optical energy in that it interacts with the tissue to produce a thermal change. Unlike lasers, however, which induce heat by selectively targeting particular chromopheres, nonablative RF devices generate heat as a result of tissue resistance to the movement of electrons within the RF field.[3–5]

The delivery of RF energy is thought to induce dermal heating to the critical temperature of ~65°C, causing collagen to shrink and allowing wound healing with a subsequent contraction. In the skin, RF radiation provokes significant thermal effects at a particular depth based on the electrode configuration—monopolar (deep) and bipolar (superficial). With a controlled delivery of RF energy to the dermal and subdermal layers, the RF technology (monopolar and bipolar) has demonstrated an ability to stimulate

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collagen production and remodeling, resulting in softening wrinkles.[6] Most RF energy delivery devices, however, have slow coverage rates, need aggressive cooling, or require a lengthy patient preparation that includes local anesthesia due to significant pain.[7]

The Accent system (Alma Lasers, Ltd., Caesarea, Israel) is a new RF system that uses two RF configured handpieces on a single platform: unipolar, which permits volumetric (deep), and bipolar, superficial tissue heating with a predictable depth of penetration and without the need for an aggressive cooling or local anesthesia.

The purpose of this study is to report the clinical experience with the device in the treatment of facial rhytides and lax skin.

Methods and Materials

Study Design

The data for 16 volunteer women patients were analyzed retrospectively and are the subject of this report. The treatment was confined only to the facial area. The facial areas were defined as follows: upper face area—from the forehead to the periorbital and crow's feet borders; the middle face area—from the nasolabial folds to the preauricular area and mandibular angle; and the lower face—extending from the mandible to the middle of the neck. Patients received between 4 and 6 (mean, 4.3 ± 1.1) treatments, spaced every 2 to 3 weeks. Patients returned for a follow-up visit 1 month after the last treatment. Each treatment cycle consisted of two phases: a nontherapeutic phase (Phase I, two passes/20 seconds each) and a therapeutic phase (Phase II, three passes/20 seconds each). The total energy [energy (W) $\times$ time (seconds)] delivered during each pass was expressed in kilojoules.

Patients were photographed in a standardized method using high-resolution digital photography (D70, Nikon, Japan) at baseline, before each treatment, and 1 month after the last treatment. Replicate photographs were taken from 0°, 45° (right), and 45° (left) using a standardized ratio of f/16 for full facial photographs. Pre- and posttreatment photographs and specific anatomic landmarks were assessed and graded on a 5-point scale by two physicians blinded to the study and the patients: 0% change from the baseline was graded as no improvement; 1% to 25% change as a mild improvement; 26% to 50% change as a moderate improvement; 51% to 75% as a significant improvement; and 76% to 100% as most significant improvement. The patient satisfaction score was obtained at each visit and 1 month after the last treatment according to the following scoring system: 1 = not satisfied; 2 = somewhat satisfied; 3 = satisfied; 4 = very satisfied; 5 = excellent.

Patients

Sixteen women patients (age range, 29–66 years; mean, 47.6 ± 10.9; Fitzpatrick skin phototype II-IV; mean Fitzpatrick wrinkles score I-III) were treated in our dermatology clinic with the Accent system. Demographics, skin characteristics, and individual patient treatment areas are presented in Table 1. The patient volunteers are women who had visited the physician's office at least once in the 3 months before enrollment in the study. All patients were in good health and had undergone no surgical or nonsurgical facial procedure [i.e., laser skin resurfacing, dermabrasion, phenol peel, nonablative laser, or temporary filler (e.g., collagen, fat, hyaluronic acid injections)], nor did they have a history of pacemaker deployment or permanent fillers in the facial area at least 12 months before the enrollment. No topical anesthesia was used on any of the treatment areas. Patients were educated regarding the treatment regimen, result expectations, discomfort, and possible adverse side effects.

Device

The Accent system operation is based on the RF-heating technology. The RF generator operating frequency is 40.68 MHz. The device is designed for contact operation using two handpieces: a unipolar

TABLE 1. Demographics and Treatment Areas

Patient initials	*Age (years)*	*Skin type*	*FWC*	*Treatment areas/condition*
CA	63	III	III	CN,* CK,† NF,* JL,† PO*
SE	48	II	II	CK,† JL,† NF,* ML†
SA	29	III	I	CN,* CK†
AA	42	III	I	CK,* ML†
NA	58	IV	II	CK,† FH,* JL,* PO*
SB	30	III	I	CK,* FH,* JL*
MG	35	II	I	CN,† CK,* FH*
RH	54	IV	II	FH,* JL,† NF,† PO*
MZ	45	III	I	FH,* ML,† PO*
YT	48	III	II	CN,† CK,* NF†
YC	56	II	II	CK,* JL,† NF,† PO*
SL	42	II	II	CK,† FH,* JL†
TN	52	II	II	CK,* NF†
FS	40	III	II	CN,* FH,* JL†
LK	54	III	II	FH,* PO*
NBE	66	III	II	CK,* JL,† PO*

FWC, Fitzpatrick Wrinkles Classification; CN, chin; CK, cheeks; FH, forehead; JL, jowl line; ML, marionette line; NF, nasolabial folds; PO, periorbital.
*Wrinkling.
†Laxity.

and a bipolar, for volumetric and surface heating, respectively. Each handpiece contains an RF-resonant system, a thermoelectric cooler, and a trigger push-button (on the handle). Figure 1 shows the system's unipolar and bipolar handpieces. The output power is pulse-width-modulation controlled. This feature provides constant output RF-power amplitude and enables the mean

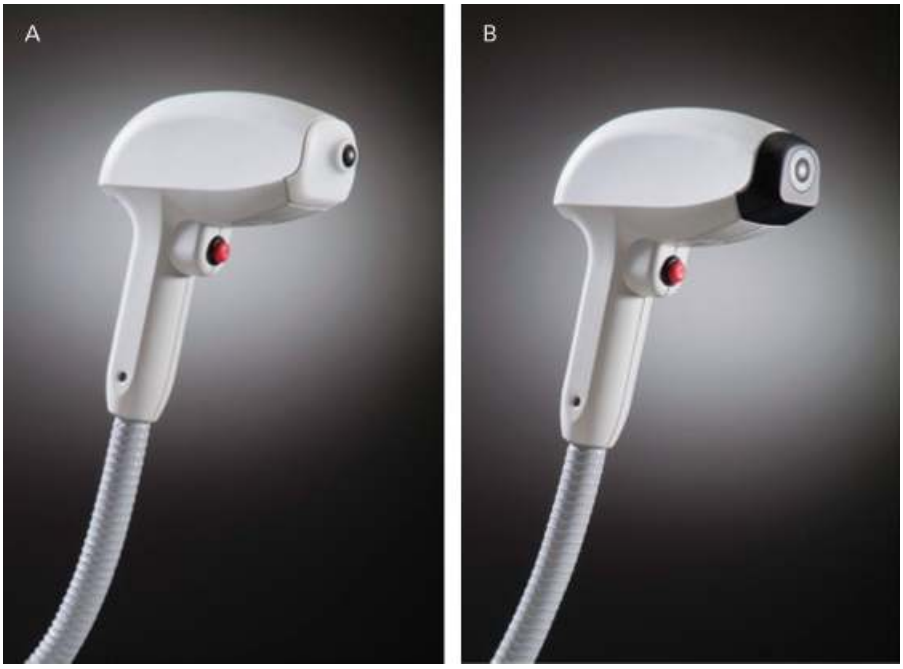

Figure 1. The Accent unipolar (A) and bipolar (B) handpieces.

RF power to be altered with changes in the duty cycle. The unipolar handpiece radiates the RF energy into the contacting tissue from the extremity of the coupling tip. The bipolar handpiece concentrates the energy in the medium area of the contacting tissue due to the presence of coaxial grounding structure (electrode) surrounding the RF-coupling tip. The time (seconds) and the intensity (power level) of the RF emission is operator-controlled and may vary by up to 30 seconds at a given pass. When applied on the skin, each handpiece is moved in continuous ("free-hand") sweeping ("paint-brush") motion: beginning with horizontal strokes followed by vertical strokes—alternating until the set time expires. Therapeutic power output settings on the facial area are typically between 80 and 140 W (unipolar) and 60 to 80 W (bipolar), and the handpiece selection is based on the treatment area anatomic location (Table 2). The unipolar handpiece utilizes a higher energy level, since it heats a greater tissue volume compared to the bipolar handpiece. To ease the handpiece movement, on the skin, a light coating of oil (e.g., baby oil) is applied just before treatment.

The Accent technology allows two mechanisms of RF-induced heating of biological tissues: (1) rotational movement of water (dipole) molecules in the alternating electromagnetic fields (unipolar) and (2) tissue resistance to the RF-conductive current (bipolar). The resistance and level of the heat production depends on several factors, including the impedance of the treated tissue, the volume of targeted tissue, and the cooling applied.

Treatment Procedure

Before the treatment, each patient's treatment area was examined for skin firmness (firm vs. lax), fragility (normal vs. fragile), and oiliness (oily, normal, dry). Examination of the areas was done when the patient was seated on the medical bed. After the treatment sites were identified, each area was marked by a 5×6-cm (30 cm^2) grid with a washable marker. The treatment protocol was divided into two phases: (1) Phase I, a nontherapeutic; and (2) Phase II, a therapeutic phase. In Phase I, the goal was to elevate the baseline tissue temperature to the therapeutic level of 39°C within 30 to 60 seconds by employing two successive passes. To reach that goal and depending on the epidermal temperature and patient discomfort, the energy was increased by 15% to 20%. After reaching the therapeutic temperature of 39°C, Phase II (therapeutic) began. The goal of Phase II was to maintain the temperature of the treatment area between 39 and 43°C for at least 60 seconds (i.e., three passes $\times$ 20 seconds). In Phase II, the first and second passes were applied perpendicular to one another, and the third pass

TABLE 2. Power Output (Range) and Treatment Areas

Treatment area	*UP (W)*	*BP (W)*
1 = CK	100–140	—
2 = FH	80–100	50–60
3 = JL	100–140	—
4 = ML	100–120	—
5 = PO	—	50–70
6 = CN	110–120	50–70
7 = NF	100–120	—

CK, cheeks; FH, forehead; JL, jowl lines; ML, marionette lines; PO, periorbital; CN, chin; NF, nasolabial folds; UP, unipolar; BP, bipolar; gray, unipolar; yellow, bipolar.

was performed with rotational movements. To prevent overheating the epidermal–dermal interface, the energy level was down-scaled by 10% to 15% from Phase I most recent pass. The mean treatment time for each patient was 15 to 30 minutes per visit, depending on the number of areas that were treated. Phase I treatment parameters averaged 120 W × 20 seconds (1.6 kJ) per pass for the unipolar and 60 W20 seconds (1.0 kJ) per pass for the bipolar handpieces, respectively. Phase II treatment parameters averaged 100 W × 20 seconds (2.4 kJ) per pass for the unipolar and 50 W × 20 seconds (1.2 kJ) per pass for the bipolar, respectively. The total energy (W × seconds) expressed in kilojoules was recorded at each pass.

The energy deposition delivered over 20 seconds in 30-cm^2 area with power output of 120 W (unipolar handpiece) and 60 W (bipolar handpiece) was 80 and 40 J/cm^3 (single pass), respectively. The speed of the handpiece movement was metronomed at a pace of approximately 10 cm/seconds; the area was covered within 5 seconds × 4 times for 20 seconds (one pass). Skin temperature was measured immediately after each pass, until end points were reached. Before and after each pass, the epidermal skin temperature was monitored and recorded with a laser thermometer (Center, 350 series, Center Technology Corp., Korea). Therapeutic temperatures were considered as greater than 39°C and less than 44°C (mean, 42°C).

The patient discomfort level was monitored (1 = cold; 2 = natural; 3 = nice warm; 4 = getting too warm; 5 = too hot) during each pass. Acute clinical response was recorded after each session to assess skin changes (edema, erythema, and blistering). For moisturized skin or sensitive skin types, the power level was reduced by 10 to 20 W, while increased by 10 W for oily skin.

Statistical Analysis

Mean and standard deviation were calculated for each category. Differences between age groups were compared using an independent-sample Student's *t* test. Statistical significance was considered when *p* values were less than .05.

Results

All 16 patients completed the course of the treatment protocol. A total of 50 areas were treated: chin ($n = 5$), forehead ($n = 8$), cheeks ($n = 12$), jowl lines ($n = 9$), periorbital ($n = 7$), marionette line ($n = 3$), and nasolabial folds ($n = 6$; Table 1). The mean energy level set-up for the unipolar handpiece was 120 ± 22 and 60 ± 13 W for the bipolar handpiece. No statistically significant differences were found between the age groups and the energy delivered by each handpiece in the various facial areas (Table 3). In all 50 areas, the therapeutic temperature level (mean epidermal skin temperature, approx. 42°C) was reached within two to three passes. No unexpected adverse side effects were detected or reported. As expected, the discomfort level during the treatment was associated with the energy level and the time of exposure. In all patients, posttreatment erythema (hyperemia) was detected which was resolved within 1 to 2 hours. No patients experienced burns, skin breakdown, or scarring.

One month after the last treatment, the improvement score in 2 patients was "excellent," in 9 patients between "satisfied/very satisfied," in 9 patients "somewhat satisfied/satisfied," and in 3 patients "not satisfied/somewhat satisfied.". Eleven patients (69%) scored between "satisfied/excellent."

TABLE 3. Energy Output per Treatment for the Unipolar and Bipolar Handpieces by Age Group

Age group (years)	*Unipolar (kJ)*	*Bipolar (kJ)*
25–35 ($n = 3$)	11.3 ± 1.8	5.7 ± 0.4
36–45 ($n = 4$)	12.1 ± 1.3	5.4 ± 0.3
46–55 ($n = 5$)	10.8 ± 1.6	5.4 ± 0.6
56–70 ($n = 4$)	10.9 ± 1.2	5.3 ± 0.9

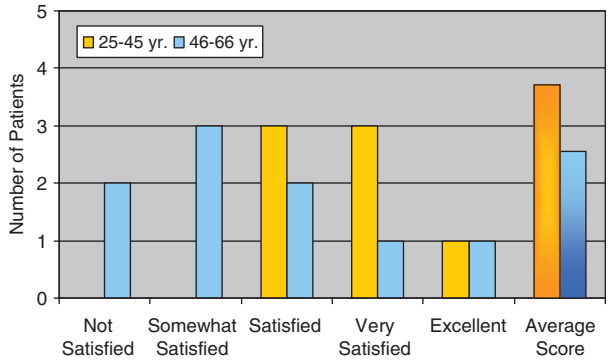

Figure 2. Patients' evaluation of treatment outcome 1 month after the last treatment by age group.

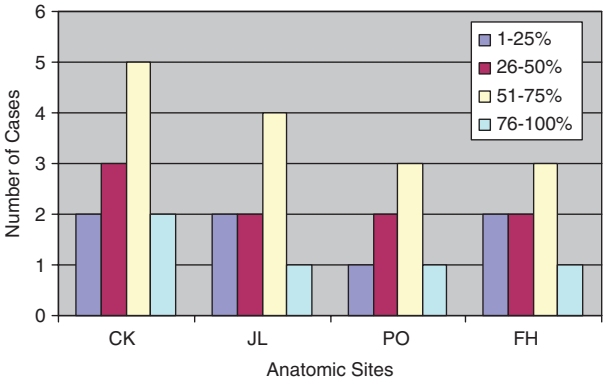

Figure 3. Photography assessment of laxity (CK, cheeks; JL, jowl lines) and wrinkling (PO, periorbital; FH, forehead) before and 1 month after the last treatment. 1%–25%, mild improvement; 26%–50%, moderate improvement; 51%–75%, significant improvement; 76%–100% marked improvement.

The mean patient satisfaction score was 3.06 ± 1.2 (satisfied/very satisfied), representing 9 of the 16 patients (57%). When divided into two age groups, the younger group reported statistically significantly ($p < .01$) higher satisfaction scores (3.71 ± 0.75) when compared to the older group (2.55 ± 1.3; Figure 2).

Photographic analysis of pre- and posttreatment digital images showed moderate-significant improvement in 11 of the 16 patients (69%) and marked improvement (>75%) in 3 patients (19%). For wrinkles and skin laxity, in 5 patients (42%), the cheeks ($n = 12$) scored 51% to 75% (significant improvement) and 2 patients (17%) scored 76% to 100% (excellent improvement). For the jowl lines ($n = 9$), 4 patients (44%) scored 51% to 75% (significant improvement) and 1 patient scored 76% to 100% (excellent improvement) for lax skin. For wrinkles in the periorbital ($n = 7$) and forehead areas ($n = 8$), 3 patients (37%) scored 51% to 75% (significant improvement; Figure 3). Figures 4 and 5 show before and after photos of 2 patients (SE and NBE) 1 month after the last treatment.

Discussion

Nonablative skin resurfacing technologies share a common method of inducing thermal dermal injury while preserving epidermal integrity. The prime consideration during the past decade for the physicians and scientists regarding procedures for the improvement of aged skin is to ensure an effective treatment while sparing damage to the epidermis and adjoining upper dermal layer. The data reported in our study demonstrate that this RF device offers a safe and effective noninvasive technique to improve the appearance of age-related rhytides and lax skin in women.

Numerous studies have documented that thermally modified tissue undergoes a remodeling process characterized by fibroplasia and increased collagen deposition.[8,9] The two main mechanisms for heat flow inside the tissue is conduction (heat gradient) and convection (blood perfusion). During our treatment regimen, we have documented baseline epidermal temperature of approximately 31 to 33°C and after Phase II temperatures of 40 to 42°C. We assume that the surrounding tissue is 10°C cooler than the dermal and subdermal temperature (~50–55°C). Although the changes that were seen clinically were detected 1 month after the last treatment, it is not known whether the thermally altered collagen persists indefinitely in its new form or acts as a matrix for new collagen formation that recapitulates its shortened overall structure.

The clinical results of nonablative RF tissue tightening were first reported in the periorbital areas.[6] In this multicenter study, Fitzpatrick and his col-

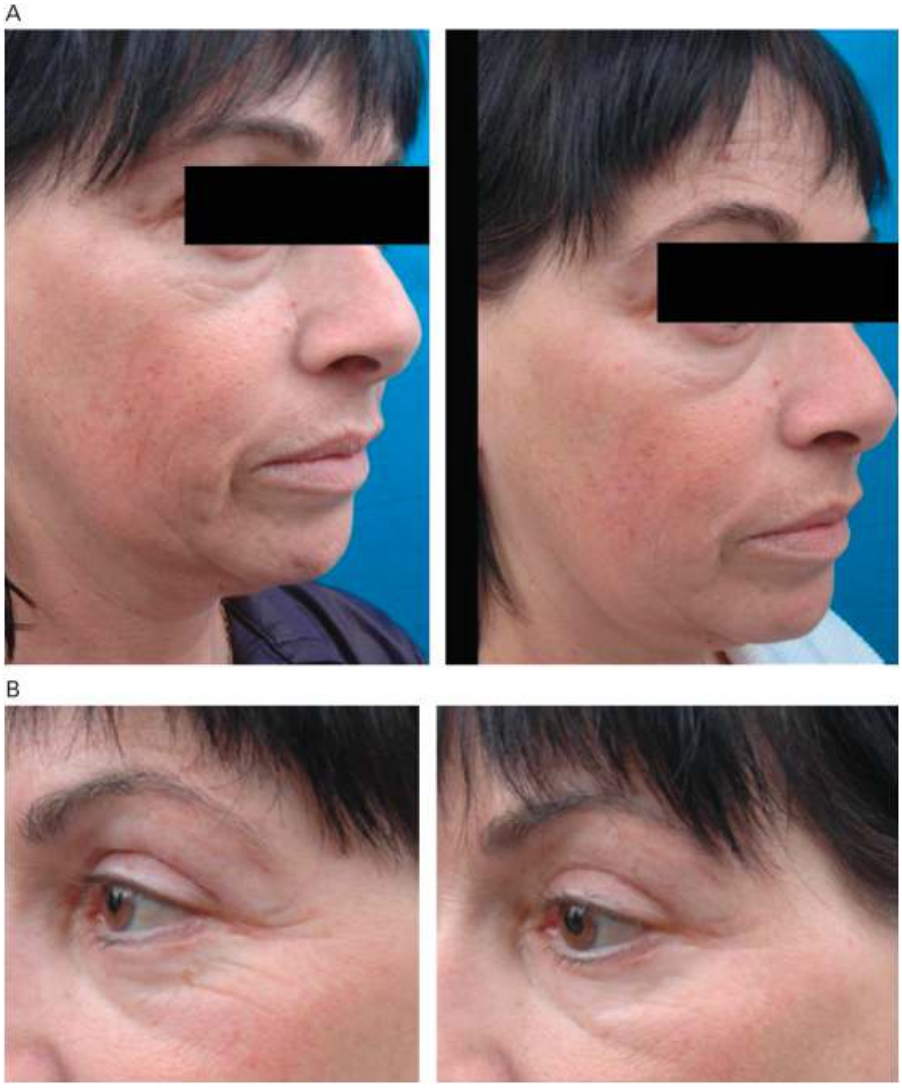

Figure 4. (A) Patient SE: Before (left) and 1 month after (right) four treatments. Marionette line (laxity), improvement by photography 51% to 75%; patient satisfaction, satisfied. (B) Patient SE: before (left) and 1 month after (right) four treatments. Periorbital (wrinkles), improvement by photography 76% to 100%; patient satisfaction, excellent.

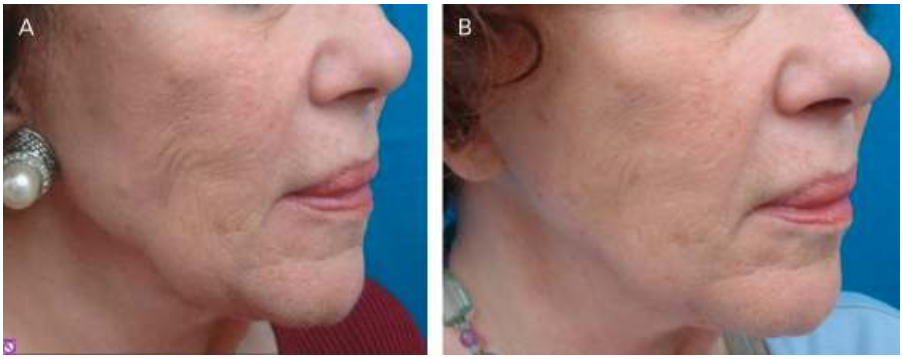

Figure 5. Patient NBE: Before (A) and 1 month after (B) four treatments. Cheek area (laxity): improvement by photography, 51% to 75%; patient satisfaction, very satisfied.

leagues demonstrated clinical improvement in periorbital rhytides in 80% of subjects. In contrast, in 24 patients who underwent a single RF treatment to improve the upper third of the face, only 36% of the patients' self-assessment reported improvement.[10] In our study, the improvement in the appearance of rhytides and lax skin was reported in 56% of the patients. Our results, however, are in agreement with other studies performed in other facial areas.[11,12] Although the temperature to which the tissue rises cannot be established precisely, the histopathologic findings suggest that the temperature of 55 to 65°C is most likely achieved and that heat fibroblasts may be stimulating fibroblasts to the produced collagen. The proposed mechanism of RF tissue tightening through thermally induced immediate collagen reorganization followed by remodeling is supported by clinical observation and ultrastructural analysis. The skin treated with the RF monopolar device has demonstrated epidermal preservation, thermal changes in collagen fibrils, and increased Type I collagen messenger RNA steady-state expression.[13] It has been suggested that in near-infrared lasers, which exclusively target the water, these thermal-induced changes can help to improve the appearance of the ryhtides.[3] Interestingly, Oringer and colleagues[14] studied connective tissue remodeling induced by carbon dioxide (CO_2) laser resurfacing of photodamaged human skin. In this study, it has been proposed that at least some of the clinical benefit seen after the CO_2 skin resurfacing may be based on increased elastin levels.[14] We have speculated that displacement of the disorganized elastotic material, which is the hallmark of photodamaged skin deeper into the dermis after RF induced heating of the tissue, may partially be responsible for the cosmetic changes in some of the patients in our study.

In our study, the patients received successive multiple treatments (four to six treatments) spaced 2 to 3 weeks apart. Ruiz-Esparza and Gomez[15] reported clinically evident skin tightening in 14 of 15 patients treated with a single RF treatment on the lower third of the face. In a recent study, Fritz and coworkers[16] compared the effectiveness of single and double RF treatments done with a monopolar device. Two RF treatments yielded in the nasolabial folds a significantly better improvement than a single treatment. Although overall improvements were modest in both groups, patient satisfaction was relatively high. Iyer and colleagues[17] demonstrated that approximately 70% of patients noticed a significant improvement in the skin laxity 3 months after a single RF treatment with a greater improvement noted after multiple treatments.

The mean energy settings for the unipolar handpiece in our study were found to be similar to those reported in other studies done with comparative RF technologies.[13,15–17] Hsu and Kaminer[11] reported an association between the energy levels and improved clinical results. Overall, the younger patients were reported to respond better compared to the older group. It has been suggested that heat-labile collagen bonds are progressively replaced by irreducible multivalent cross-links as the tissue ages, thus rendering older skin less amenable to heat-induced tissue tightening.[11] Our observations support this since we found that the older group (>46 years old) reported less favorable results.

In a similar device, it has been reported that the use of a RF device was associated with significant pain, and in a small but significant number of cases subcutaneous fat atrophy developed.[7] No subcutaneous fat atrophy was noted in our patients. In our study, the procedures with both unipolar and bipolar handpieces were performed without any anesthesia and yet were regarded by all patients as pain-free and associated with only moderate discomfort. In fact, no patients considered the procedure intolerable at any session.

In conclusion, the data reported in this study support the effectiveness of the Accent system in the treatment of facial rhytides and skin laxity in women.

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