Electrosurgical Facial Resurfacing

A Prospective Multicenter Study of Efficacy and Safety

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**Background:** A novel electrosurgical technology that uses a bipolar electrode-tipped stylet to deliver relatively low-radiofrequency energy through an electrically conductive medium has been developed.

**Objective:** To evaluate the efficacy and safety of the radiofrequency resurfacing system for the treatment of facial wrinkles.

**Design:** Multicenter, prospective, noncomparative study with longitudinal follow-up.

**Setting:** Four US academic dermatologic surgery clinics.

**Patients:** Ninety-five patients with mild to severe photodamage (Fitzpatrick classes I-III) involving periorbital (75 treatment sites) and perioral (50 sites) facial skin.

**Intervention:** Radiofrequency resurfacing with the use of 2 to 3 passes at 125 or 139 V.

**Main Outcome Measures:** Wrinkle and cosmetic improvements evaluated by patients, investigators, and, by means of photographs, an independent panel of 5 evaluators.

**Results:** All evaluators determined a positive mean improvement in wrinkles for both periorbital and perioral anatomic sites, with greater improvement for patients with more severe wrinkles at baseline. An increased number of passes and higher voltage settings had a positive impact on wrinkle improvement. Transient postinflammatory hyperpigmentation occurred in 26% of periorbital and 4% of perioral sites. Hypertrophic scars occurred in 3.8% of treatment sites, with all but 1 scar resolving by 6 months. For the most part, healing was rapid, pain was minimal, and erythema largely resolved within 2 months. Other untoward effects were relatively few and short-lived.

**Conclusions:** At the study settings used, radiofrequency resurfacing is an effective modality in the treatment of periorbital and perioral wrinkles in patients with Fitzpatrick class I, II, and III photodamage. There is less severe postoperative morbidity than seen with carbon dioxide or coagulating erbium:YAG lasers. The potential risks are similar to those seen with other resurfacing modalities.

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**STUDY**

SEVERAL TREATMENT modalities are available for facial resurfacing. Each of these treatments has specific tissue effects, some of which may be potentially disadvantageous. Dermabrasion produces aerosolized particles that remain airborne for hours after the procedure and may lead to transmission of live virus.1 Chemexfoliation may result in variable outcomes depending on the method of skin preparation, application technique, the chemical and concentration used, density of adnexal structures, and cumulative sun exposure of the treated skin.1-5 High-energy, short-pulsed resurfacing lasers are costly, create a potentially infectious laser plume, necessitate protection from beam hazards, and, as with other resurfacing modalities, may be associated with persistent erythema, hypopigmentation and hyperpigmentation, hypertrophic scarring, infection, and ectropion.5-10 A technique for facial resurfacing that is less costly and is associated with fewer complications would be advantageous.

Ablative resurfacing lasers produce mid- to far-infrared energy absorbed primarily by tissue water (carbon dioxide [CO2] and erbium [Er]:YAG) and peptide (Er:YAG) bonds.11 Tissue chromophore absorption of pulsed energy causes localized tissue heating and vaporization with resultant tissue ablation and residual thermal injury of resurfaced skin.12,13 Traditional electrosurgery uses high-radiofrequency (RF) energy that gener-
PATIENTS AND METHODS

The RF resurfacing treatment was conducted on 95 patients with Fitzpatrick skin phototypes I through III and mild to severe photodamage (Fitzpatrick classes I–III). Patients with active skin disease within the treatment areas (eg, psoriasis, cancer, or autoimmune disease) and patients with previous facial cosmetic procedures affecting the treatment areas (eg, botulinum toxin, dermabrasion, chemical peeling, laser surgery, or face-lift) within 2 years were excluded. The exclusion criteria also included use of oral isotretinoin within the previous year and current use of aspirin or noncorticosteroidal anti-inflammatory drugs. An investigational device exemption was obtained from the Food and Drug Administration for both the pilot and multicenter studies. Institutional review board approvals were obtained from all participating centers, and written informed consent was obtained from each patient.

Four weeks before the treatment, standardized facial photographs were taken. Standardization in photography was achieved by following certain criteria: face washing to remove oil, no makeup or jewelry, placement of a black headband on the head to hold back hair, placement of a black drape around the shoulders to disguise clothing, neutral facial posture, and the use of a stereotactic device to hold the subject’s head at the proper vertical position and to ensure that the camera was always at the same distance and angle from the subject. One emulsion lot of film was used for all photography to decrease variability that may be caused by variation between film lots. Two rolls of film were taken at baseline. One roll was developed immediately and the other was frozen and subsequently developed in the same batch of developing fluid as the roll of film taken at month 6. This served to eliminate variability in processing. Patients then began using tretinoin cream (0.025% every night; Retin-A; Ortho Pharmaceutical, Raritan, NJ), hydroquinone cream (4% twice daily; Solaguin Forte; ICN Pharmaceuticals, Costa Mesa, Calif); and a broad-spectrum sunscreen with a sun protection factor of 15 or greater (daily). Periorbital and perioral wrinkles were scored by means of the 9-point Fitzpatrick Wrinkle Assessment Scale.18

Patients were prepared in a routine fashion and received nerve blocks and local infiltration anesthesia. Only periorbital or perioral areas were treated. The recommended power setting for the RF resurfacing system (Visage; ArthroCare Corp), which is composed of a controller, a handpiece, and a disposable stylet, was 125 V on the RF controller, with a higher output voltage (139 V) allowed when deemed necessary by the investigator. A maximum of 2 passes were allowed for patients with class I wrinkles and up to 3 passes in the treatment area for patients with class II or III wrinkles. The saline drip was adjusted to 1 drop per second, and traction was applied to the treatment area. The stylet was applied continuously and evenly across the treatment area with constant skin contact, at a rate of approximately 1.0 to 1.5 cm per second. After a stroke was completed, the next stroke was overlapped by about 30%. The electrodes had to be cleaned of denuded tissue every 2 to 3 strokes, especially during removal of the epidermis. Devitalized tissue was debrided with saline-soaked gauze after each complete pass over the treatment area. With the exception of feathering by applying sequentially fewer passes at the treatment site edges, the entirety of each treatment site was subjected to the same, uniform application of RF energy.

After treatment, the surgical site was covered with an occlusive dressing (Flexzan; Dow Hickam, Sugar Land, Tex). Systemic antibiotic treatment with cephalixin (250 mg orally 4 times daily; Keflex; Dura Pharmaceuticals, San Diego, Calif) was begun 1 to 2 days before surgery and continued for 7 days after surgery. Systemic antiviral treatment with acyclovir (200 mg orally 3 times daily; Zovirax; Burroughs Welcome, Research Triangle Park, NC) was also begun 1 to 2 days before surgery and continued for 10 days after surgery, or until healed.

Dressings were removed, the skin was cleansed, and dressings were replaced by the investigator at postoperative days 2 and 7. Subsequently, wound care was changed to an open technique with daily wound cleansing followed by bacitracin zinc ointment (and plastic wrap). Patients restarted using topical tretinoin cream (every night) when the investigator judged that the newly healed skin had reached adequate maturity or no later than 1 month after surgery. A broad-spectrum sunscreen (sun protection factor 15 or higher) was used after complete reepithelialization. Sunscreen was applied several times a day for at least 6 months postoperatively. Oral analgesics, topical corticosteroid ointments, or oral antihistamines were prescribed as needed for pain or itch. Hydroquinone cream (4% twice daily) was used as needed for hyperpigmentation until its resolution.

Patients were examined postoperatively on days 2, 7, 14, and 28, and at 2, 3, and 6 months. The degree of epidermal healing was evaluated only at weeks 1 through 4, but other signs and symptoms were evaluated at each visit. Pain was self-evaluated by patients at the first 3 postoperative examinations. Pain, erythema, hypopigmentation, hyperpigmentation, and scar formation were evaluated by means of a scale from 0 to 10 (0, none present; 10, most severe); edema was evaluated on a scale of none, mild, moderate, and severe; epidermal healing was evaluated as a percentage of reepithelialized tissue area within the total treatment area. At the 6-month examination, standardized photographs were taken, and both investigator and patient assessed wrinkle and cosmetic improvement (Table 1).

Wrinkle and cosmetic improvements were evaluated by patients, investigators, and an independent panel of dermatologists. Investigators and patients independently compared the baseline photographs with the 6-month clinical outcome. The 3 panel members scored both baseline and 6-month photographs by using the 9-point Fitzpatrick photodamage classification. An average of the 5 scores for each photograph was calculated. Improvement was defined as the difference between the average baseline and 6-month follow-up scores. Analyses were performed with PC SAS statistical software (version 6.12; SAS Institute Inc, Cary, NC), with a critical P value of .05.
method, the RF resurfacing device uses a bipolar multi-electrode-tipped stylet and an electrically conductive medium, usually isotonic sodium chloride solution.\textsuperscript{15} Multielectrode RF resurfacing is a low-heat process compared with traditional electrosurgery; hence, the term \textit{coblation} (cold+ablation) has been coined for this process. The device applies low-energy RF to a conductive medium, usually isotonic sodium chloride solution.\textsuperscript{15} Multiple electrode RF resurfacing is a low-heat process compared with traditional electrosurgery; hence, the term \textit{coblation} (cold+ablation) has been coined for this process. The device applies low-energy RF to a conductive medium, usually isotonic sodium chloride solution.\textsuperscript{15} These ionized particles have a very short range of travel and possess sufficient energy to dissociate organic molecular bonds within the tissue. In arthroscopic applications, the device has been shown to remove tissue in a controlled volumetric manner and with minimal collateral tissue necrosis (approximately 100 µm; data on file, ArthroCare Corp, Sunnyvale, Calif).

Tope\textsuperscript{16} investigated this RF resurfacing technology in an \textit{in vivo} human skin study. He found no apparent epidermal ablation, but an increasing amount of residual thermal damage with increased pass number. After 3 passes at 86, 108, and 139 V, the mean thickness of this layer of thermal damage was 97, 80, and 80 µm, respectively. The similarity of this pattern of tissue damage to that associated with short-pulsed CO\textsubscript{2} laser resurfacing indicated that this RF device should be effective in cutaneous resurfacing, with rapid postoperative wound healing. Burns et al\textsuperscript{17} evaluated this RF resurfacing technology in a scar resurfacing study involving 6 subjects. All of the patients showed improvement in scar appearance 6 months postoperatively, with minimal adverse effects.

An initial pilot study was undertaken at 3 sites in the United States to demonstrate the safety of RF facial skin resurfacing. Seventeen patients underwent RF skin resurfacing of the lateral canthal region ("crow’s feet"). Complications were minimal, with only transient dyspigmentation observed in 3 patients. Every patient volunteered for a different treatment site in the current study, suggesting a high level of patient satisfaction (R.C.G., W.D.T., D.J.L., C.B.Z., unpublished data, June 1998). The objective of the present study was to evaluate the efficacy and safety of the RF resurfacing system for the treatment of facial wrinkles in a prospective, multicenter study.

### RESULTS

Ninety-five patients were treated. Four of these patients did not meet the postprocedural examination schedule and were not included in this analysis. The mean age of the treated patient population was 52 years (SD, 9 years). All of the patients were white, and 89% (81/91) of the patients were women. A total of 75 periorbital and 50 perioral anatomic sites were available for assessment at the 6-month visit, and the majority (>90%) of these sites had class II and III wrinkle scores (Table 2).

One pass with the coblation device results in epidermal whitening. The damaged epidermis is then gently wiped with saline-moistened gauze and can be removed. The epidermis does not come off as easily as residual epidermis after 1 pass with the CO\textsubscript{2} laser. Some epidermis may remain, especially in bearded areas in men or in badly sun-damaged solar elastotic skin. Epidermis in these areas will generally be removed with a second pass. The dermis appears as a pale, erythematous, dull surface. Bleeding is not seen unless excessive abrading occurs with the saline-moistened gauze. Subsequent passes produce a transient blanch lasting only about 10 to 15 seconds. Careful attention must be given to the path of the wand to ensure even treatment. No dermal contraction is seen during treatment.

All evaluators determined a positive mean improvement in Fitzpatrick wrinkle score for both periorbital and perioral anatomic sites (Table 3) (Figure 1). When all sites were considered, patients and investigators rated the improvement in wrinkles higher than did the panelists. In general, the magnitude of this improvement was greater for patients with more severe wrinkles at baseline. All evaluators also reported mean improvement in cosmetic appearance (Table 4). The order of magnitude in improvement was also similar to that of wrinkle improvement (judged greatest by patients, then investigators, then panelists).

Given the scoring difference between panelists and investigators or patients, we calculated an intraclass correlation coefficient for the panel members. An intraclass correlation coefficient measures the strength of the agreement among the participating members. For wrinkle improvement, the agreement between the panel members was 0.38 and 0.28 for periorbital and perioral areas, respectively. For cosmetic improvement, the correlation coefficient was even lower: 0.16 and 0.11, respectively. These low intraclass correlation coefficients indicate that the agreement among the panel members was low; for the

<table>
<thead>
<tr>
<th>Class</th>
<th>Wrinkling Score</th>
<th>Degree of Elastosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Fine wrinkles</td>
<td>1-3 Mild (fine textural changes with subtly accentuated skin lines)</td>
</tr>
<tr>
<td>II</td>
<td>Fine to moderate-depth wrinkles, moderate number of lines</td>
<td>4-6 Moderate (distinct papular elastosis [individual papules with yellow translucency under direct lighting] and dyschromia)</td>
</tr>
<tr>
<td>III</td>
<td>Fine to deep wrinkles, numerous lines with or without redundant skin folds</td>
<td>7-9 Severe (multipapular and confluent elastosis [thickened yellow and pallid] approaching or consistent with cutis rhomboidalis)</td>
</tr>
</tbody>
</table>

### Table 2. Wrinkle Classification by Anatomic Site as Assessed by Investigators

<table>
<thead>
<tr>
<th>Site</th>
<th>Class I</th>
<th>Classes II and III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periorbital</td>
<td>5 (7)</td>
<td>70 (93)</td>
</tr>
<tr>
<td>Perioral</td>
<td>5 (10)</td>
<td>45 (90)</td>
</tr>
</tbody>
</table>

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same patients, some panel members gave high scores and some gave low scores.

The number of passes and voltage settings for periorbital and perioral sites is presented in Table 5. The effect of number of passes (3 vs 2) and voltage settings (125 V vs 139 V for 1 or more passes) on wrinkle improvement scores for periorbital and perioral sites is given in Table 6 and Table 7, respectively. Both increased numbers of passes and higher voltage settings had a positive influence on the wrinkle score improvement. For periorbital skin, statistically significant improvement in wrinkle scores with 3 passes was noted by both the panel’s aggregate assessment and the investigators’ assessment. For periorbital skin, statistically significant improvement in wrinkle scores with a higher voltage setting was noted only by the panel’s aggregate assessment.

Clinically significant adverse events were unusual. Intraoperative pain was well controlled by the anesthetic techniques described above. The incidence and severity of pain were assessed at the first 3 posttreatment follow-up examinations. (Because not all patients attended every follow-up visit, patient numbers do not always equal the total number of patients treated per site.) The incidence of recorded pain was the highest at the day

Table 3. Wrinkle Score Improvement Assessment at 6 Months*

<table>
<thead>
<tr>
<th>Site</th>
<th>Assessor</th>
<th>Mean (SD)</th>
<th>No. of Sites†</th>
<th>P</th>
<th>Mean (SD)</th>
<th>No. of Sites†</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class I</td>
<td>Classes II and III</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periorbital</td>
<td>Investigator</td>
<td>0.4 (1.1)</td>
<td>5</td>
<td>.48</td>
<td>3.0 (1.3)</td>
<td>70</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Subject</td>
<td>1.0 (0.7)</td>
<td>10</td>
<td>.001</td>
<td>2.6 (1.2)</td>
<td>64</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Panel</td>
<td>0.7 (0.7)</td>
<td>10</td>
<td>.01</td>
<td>1.7 (0.8)</td>
<td>60</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Perioral</td>
<td>Investigator</td>
<td>1.8 (0.5)</td>
<td>5</td>
<td>&lt;.001</td>
<td>2.2 (1.3)</td>
<td>45</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Subject</td>
<td>2.0 (0.0)</td>
<td>2</td>
<td>NA</td>
<td>2.7 (1.2)</td>
<td>47</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Panel</td>
<td>0.7 (0.3)</td>
<td>10</td>
<td>&lt;.001</td>
<td>1.8 (0.7)</td>
<td>32</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*Fitzpatrick Wrinkle Assessment Scale19; score, 1 to 9. Mean represents average preoperative mean score minus average postoperative mean score. NA indicates not applicable.
†One subject did not provide a self-assessment. The panel assessment was done before all patients finished the study. Only 40 patients in each class were required for statistical significance.

Figure 1. A, Patient 1 before treatment of perioral rhytids. Preoperative wrinkle assessment score was 7. Treatment was performed at 125 V with 3 passes. B, Patient 1 six months after treatment. Postoperative wrinkle assessment score was 5. C, Patient 2 before treatment of periorbital rhytids. Preoperative wrinkle assessment score was 6. Treatment was performed at 125 V with 2 passes. D, Patient 2 six months after treatment. Postoperative wrinkle assessment score was 3.
Perioral, No. of Sites

By postoperative day 14, erythema was still almost uniformly present at each site. Erythema was highest during the first week of follow-up examinations, but the severity was at most mild, with a mean severity score of 1.5 or less on an 11-point scale (0, none; 10, most severe). The severity of erythema was highest during the first week of follow-up examinations, but the severity was at most mild, with a mean severity score of 1.5 or less on an 11-point scale (0, none; 10, most severe). The severity score was greater than 8 at any time point.

**Table 4. Cosmetic Score Improvement at 6 Months**

<table>
<thead>
<tr>
<th>Site</th>
<th>Assessor</th>
<th>Mean (SD)</th>
<th>No. of Sites†</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periorbital</td>
<td>Investigator</td>
<td>4.4 (1.9)</td>
<td>75</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Subject</td>
<td>6.0 (2.3)</td>
<td>74</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Panel</td>
<td>2.8 (1.3)</td>
<td>70</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Perioral</td>
<td>Investigator</td>
<td>5.1 (2.0)</td>
<td>50</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Subject</td>
<td>5.9 (1.8)</td>
<td>49</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Panel</td>
<td>2.8 (1.1)</td>
<td>42</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*Cosmetic improvement scale; score, 0 to 10. Mean represents average preoperative mean score minus average postoperative mean score.
†One subject did not provide a self-assessment. The panel assessment was done before all patients finished the study. Only 40 patients were required in each site for statistical significance.

**Table 5. Distribution of Treatment Sites by Number of Passes and Voltage Settings**

<table>
<thead>
<tr>
<th>Periorbital, No. of Sites</th>
<th>Perioral, No. of Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>125 V</td>
<td>&gt;125 V†</td>
</tr>
<tr>
<td>2 Passes</td>
<td>45</td>
</tr>
<tr>
<td>3 Passes</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>52</td>
</tr>
</tbody>
</table>

*Sites treated with 1 or more passes at 139 V.

**Table 6. Effect of Number of Passes on Wrinkle Score Improvement**

<table>
<thead>
<tr>
<th>Site</th>
<th>Assessor</th>
<th>No. of Passes</th>
<th>Score</th>
<th>Mean (SD)</th>
<th>No. of Sites†</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periorbital</td>
<td>Investigator</td>
<td>2</td>
<td>1.7 (1.3)</td>
<td>49</td>
<td>.09</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>2</td>
<td>2.3 (1.3)</td>
<td>26</td>
<td>.46</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Panel</td>
<td>2</td>
<td>1.3 (0.8)</td>
<td>45</td>
<td>.001†</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>2.0 (0.8)</td>
<td>25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perioral</td>
<td>Investigator</td>
<td>2</td>
<td>1.5 (1.0)</td>
<td>27</td>
<td>&lt;.001†</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>2</td>
<td>2.7 (1.2)</td>
<td>23</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Panel</td>
<td>2</td>
<td>1.3 (0.7)</td>
<td>18</td>
<td>.04†</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>1.8 (0.8)</td>
<td>24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Fitzpatrick Wrinkle Assessment Scale**: score, 1 to 9. Mean represents average preoperative mean score minus average postoperative mean score.
†One subject did not provide a self-assessment. The panel assessment was done before all patients finished the study. Only 40 patients were required in each site for statistical significance.
‡One subject did not provide a self-assessment. The panel assessment was done before all patients finished the study. Only 40 patients were required in each site for statistical significance.
§P <.05.

2 examination: 53% (40/75) of periorbital and 60% (30/50) of perioral sites manifested pain. Of these patients, the severity of pain was judged as very mild, averaging 1.4 and 1.3 on an 11-point scale (0, none; 10, most severe) for periorbital and perioral sites, respectively (Figure 2). At day 7, only 15% (11/75) and 14% (7/50) of patients experienced pain, and the pain severity score averaged 1.0 for both periorbital and perioral sites. Only 2 patients reported periorbital pain and 1 patient reported perioral pain (severity score, 1.0) at the day 14 examination. On day 28, there was only 1 patient who manifested periorbital pain (severity score, 1.0).

Erythema was uniformly present at the first follow-up week and progressively resolved in each subsequent examination up to the 6-month follow-up examination (Figure 3). The severity of erythema was highest during the first week of follow-up examinations, but the severity was at most mild, with a mean severity score of 1.5 or less on an 11-point scale (0, none; 10, most severe). By postoperative day 14, erythema was still almost uni-
During the first postoperative week, 63% to 67% of treated areas exhibited edema, while edema was present in approximately 30% of the treatment sites. The edema severity of the 6 remaining sites (4.6%) at the 6-month examination was rated a mean score of 1.0. This very mild erythema was still observed 3 months after treatment (mean score, 1.0-1.1), but only in approximately 30% of the treatment sites. The erythema severity of the 6 remaining sites (4.6%) at the 6-month examination was rated a mean score of 1.0.

Complete epithelialization was achieved in approximately half of the treated areas (49% [37/75] for periorbital and 52% [26/50] for perioral treatment sites) at the day 7 examination (Figure 4). For sites in which epithelialization was not complete at day 7, 93% and 92% of the treatment areas were epithelialized for the periorbital and perioral areas, respectively (Figure 4). In other words, all treatment sites were more than 90% epithelialized at day 7. Most of the treated areas (91% [67/74] for periorbital sites and 82% [41/50] for perioral sites) were completely epithelialized at the day 14 examination. For those sites in which epithelialization was not complete at day 14, 97% of the treated areas were epithelialized for both periorbital and perioral sites. In other words, all treatment sites were greater than 97% epithelialized at day 14. All of the treated areas were completely epithelialized at the day 28 examination.

During the first postoperative week, 63% to 67% of treated areas exhibited edema, while edema was present in 7% (5/74) and 2% (1/48) of treated areas at the day 28 follow-up examination (Figure 5). On the following visits, there were 2 cases of periorbital edema at month 2 and 1 periorbital case at month 3, with a mild intensity. The intensity of the edema was mild in the majority of the cases throughout the study.

Hyperpigmentation was first reported starting at day 28 in 26% (19/74) of the periorbital sites and 4% (2/48) of the perioral sites, with a mean severity score of no greater than 2.0 on an 11-point scale (0, none; 10, most severe). The incidence of hyperpigmentation decreased to 15% (11/73) and 2% (1/47) for periorbital and perioral areas, respectively, with a mean severity score of 1.0 at month 2. Whereas no hyperpigmentation was observed in perioral areas at month 3 or month 6, 7 periorbital sites (9.6%) at month 3 and 2 periorbital cases (3%) at month 6 manifested hyperpigmentation. As would be expected from experience with laser resurfacing, hyperpigmentation was seen mostly in patients with skin type III. Hypopigmentation occurred at 2 treatment sites. Each was judged mild (score, 1.0) and each had resolved by month 6 without any treatment.

Small (<5 mm) focal hypertrophic scars occurred in 4 periorbital and 1 perioral treatment sites. All 4 periorbital scars resolved by the 6-month evaluation with appropriate use of topical or intralesional corticosteroid treatment. One case of perioral scarring (severity score, 1.0) remained at month 6. This patient had refused any treatment because she was pleased with the final treatment outcome.

Other adverse events were rare. Pruritus and irritant dermatitis each occurred in 2 anatomic sites (1.6% [2/125]). One patient reported ocular irritation during the procedure, which then led to a brief period of anxiety for the patient; however, the patient completed the procedure without further complications. All other adverse events were reported only for 1 treatment site each (0.8%); they included milia, petechiae, scale or desquamation, eczema, papule of granulation tissue, Pseudomonas infection, allergic contact dermatitis, conjunctivitis, blepharitis, herpes labialis, adenovirus infection of the left eye, and cephalosporin-induced drug rash.

In this prospective multicenter study, a novel RF resurfacing system proved to have an acceptable safety profile and was found to be effective in reducing facial wrinkles as determined by investigators, patients, and an independent panel of dermatology experts. Statistically significant improvement in investigator-assessed wrinkle scores was achieved, as was statistically significant patient satisfaction with wrinkle and overall cosmetic improvement. While efficacy was also noted by the panelists, the magnitude was lower than that judged by both patients and investigators. More importantly, within the panel, there was great variability and poor interreviewer consistency. Although photographs were standardized, they were imperfect because of variations in lighting, oiliness or dryness of skin, ability to relax the face, open vs closed eyes, and placement of the subject in the stereotactic device (eg, chin compression leading to perioral compression). Thus, while it was initially thought that independent panelists would provide an unbiased evaluation, the variability between photography and reviewers might overshadow the benefits of this type of study design. Additional variability might have been introduced by differences in surgical techniques, including varying sizes of treatment areas, and different speed and pressure during passes. Because of the size of the study

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population, these factors were unlikely to affect overall results.

Pain was assessed differently at each investigational site, resulting in site-to-site variability. At one site, patients were asked to provide an overall rating of pain since their last follow-up visit. At another site, patients were asked to rate pain before removal of the occlusive dressings, while at a third site, patients were assessed after removal of the dressings and rinsing of the treated area. We believe the discrepancy created variation in the data, yet the overall results were not affected by this variation.

A more aggressive treatment, as determined by higher power settings as well as an increased number of passes, resulted in greater beneficial effect. In general, there was more improvement in class II and III wrinkles as compared with class I wrinkles. However, this finding was confounded because investigators were limited to 2 passes for class I wrinkles, and the improvement in class I wrinkles can only be improved by 2 levels at the most. Nevertheless, when all patients were analyzed, there was strong statistical evidence that wrinkle improvement correlated positively with the severity of baseline wrinkle score.

While cross-study comparisons of efficacy are difficult to make on the basis of this study alone, the objective efficacy observed with the RF resurfacing system in this study is comparable with that previously reported to result from resurfacing with short-pulsed CO2 and Er:YAG lasers.19,20 Such lasers cause a substantial degree of thermal injury to treated tissue. In general, traditional Er:YAG laser energy is far better absorbed by tissue water and by peptide bonds than energy from CO2 lasers; therefore, more of its energy is applied to tissue ablation and less is used in tissue heating. This results in less collateral thermal damage and more effective tissue removal. Never “coagulating” Er:YAG lasers may produce a thermal signature similar to that of a CO2 laser. It is possible that the less severe postoperative course noted is a result of the lower tissue temperatures generated.

The RF resurfacing system uses plasma-mediated molecular dissociation to produce controlled tissue ablation with controlled thermal injury to surrounding tissue. To date, the mechanism of action of the RF resurfacing system on skin tissue is not fully characterized. Developers of this electrosurgical resurfacing technology attribute tissue effects to 2 potential mechanisms: plasma-mediated molecular dissociation and/or dielectric breakdown of tissue. The combined effects of an RF-induced electrical field associated with low-pressure cavitation bubbles at electrode asperities contribute to the formation of a gaseous plasma sheet between the electrodes and the tissue surface. The ionized species present within the plasma bombard the tissue, leading to impact ionization and dissociation of molecular bonds. Ionized tissue particles could then also participate in the plasma sheet such that the plasma extends into the tissue itself. Dissipation of ion energy in tissue would lead to heating and thermal denaturation of collagen. Plasmas associated with pulsed laser irradiation are generally hot and associated with an acoustic wave, causing tissue ejection. Plasma generation can occur at much lower temperatures depending on the atmospheric pressure, irri-

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RF wounding, and few had not completed epithelialization by day 14. Although this study did not directly compare wound healing after RF with that after laser resurfacing, RF resurfacing was followed in these patients by more rapid healing and markedly less pain and erythema than seen after CO₂ laser, but comparable with that after short-pulsed Er:YAG laser. The apparent delay in epithelialization can be attributed to the use of an adherent dressing, which occasionally avulsed small portions of the newly regenerated epithelium. Erythema was clearly less severe and less prolonged than that we have seen after laser resurfacing. We attribute the apparently prolonged residual erythema to use of tretinoin beginning 1 month after resurfacing. Small hypertrophic scars did occur in 5 of 125 treatment sites, a number slightly in excess of that one might expect after laser resurfacing. Each scar that was treated did resolve completely. This somewhat higher rate of hypertrophic scarring may reflect the novelty of this technique for most of those performing the procedures. As was observed in the development of laser resurfacing, we predict that this adverse sequela of RF resurfacing will decrease with time and experience.

Other differences are seen between the RF resurfacing modality and laser. There is absolute hemostasis with RF resurfacing, as no or very minimal dermal tissue is ablated. Overly aggressive manual debridement can stimulate bleeding in patients with marked telangiectasia. Bleeding is a distinct problem with noncoagulating Er:YAG lasers and can occur in patients with marked telangiectasia with the CO₂ laser. No plume or debris is generated with RF resurfacing and therefore no smoke evacuator or assistant to use it is needed. As there is no light beam, no eye protection is required, eliminating the need for expensive and potentially irritating intraocular shields. The equipment is small, about the size of a video cassette recorder; highly portable; and relatively inexpensive compared with lasers. It is a solid-state technology requiring no service contract.

In summary, compared with laser resurfacing, RF resurfacing was found to be effective and safe in the treatment of periorbital and perioral wrinkles in patients with skin types I, II, and III. For the most part, healing was rapid, pain was minimal, erythema resolved within 2 months, and untoward effects were relatively few and short-lived.

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