# Analysis of Histologic and Clinical Changes Associated With Polaris WR Treatment of Facial Wrinkles

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Background: The Polaris WR is a device that combines laser energy with radiofrequency (RF) treatment to provide more focused RF energy on the skin to reduce wrinkles and/or tighten skin. Clinical results have varied from highly visible to no obvious reduction in wrinkles.

Objective: This prospective study investigated whether there was any corollary between clinical results, standardized VISIA (Canfield Imaging Systems, Fairfield, NJ) and digital photographs, and skin biopsy analysis after the treatment of facial wrinkles with the Polaris WR device.

Methods: Fifteen patients received four full-face treatments. Biopsy of the treated skin was performed before and 1 and 3 months after their last treatment. A VISIA computer analysis of facial wrinkle density and depth was performed before any treatment and then 3 months after the last treatment. Digital photographs were reviewed by four surgeons to evaluate wrinkle reduction at 3 and 6 months after the four treatments.

Results: Physicians' ratings of these digital images revealed that 58% of the patients were improved at 3 months after treatment, and 42% were still improved at 6 months. The patient questionnaire responses revealed that 75% of patients felt that they looked better at 3 months, and 67% felt that they remained improved 6 months after their last treatment. VISIA photographic analysis demonstrated that 67% of the patients had fewer and/or shallower wrinkles at their 3-month visit. The average degree of improvement with VISIA analysis was 30%. Biopsy specimens in the group of patients that were defined as improved by VISIA assessment showed a greater dermal thickness and interfibrillar spacing ( P < .024). Two patients received superficial second-degree burns that did not require corrective treatment.

Conclusions: Improvement in skin wrinkling after Polaris WR therapy was confirmed in patients at 3 months after treatment by physician assessment, VISIA analysis, and patient assessment, with a lower rate of improvement at 6 months after treatment. VISIA analysis tended to confirm patient assessments. Physician assessments of improvement tended to be lower. (Aesthetic Surg I 2007;27:32–46.)

adiofrequency (RF) treatment of the skin has been demonstrated to reduce wrinkles and/or tighten skin.<sup>1-\overline{5}</sup> The Polaris WR (Syneron, Toronto, Ontario, Canada) is a device that combines radiofrequency and laser energy (900 nm) with the goal of focusing RF energy into the dermis and perhaps the fat layer without damaging the epidermis. Clinical results vary considerably from highly visible to no obvious reduction in wrinkles. Possible explanations for this range include the treatment parameters, protocol, patient selection/response, operator experience, methods of evaluation, and, perhaps, device variance. This study was

designed to determine whether a corollary exists between posttreatment histologic study, clinical results, and a form of standardized photography.

#### Methods

Fifteen patients were enrolled in this study. Exclusion criteria included a history of diabetes, recent aesthetic facial surgery, hypersensitivity to sunlight, recent Accutane or anticoagulant use (warfarin [Coumadin], aspirin, nonsteroidal antiinflammatory agent), patients taking medications associated with photosensitivity, and presence of an internal pacemaker or defibrillator. In

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addition, study participants could not have received any type of skin treatment (chemical peel, dermabrasion, etc) or injection of a paralytic agent (ie, botulinum toxin) within 6 months of the study initiation and refrained from such treatments for at least 6 months after their last Polaris WR treatment. The study was approved by the Essex Institutional Review Board. Subjects were given a diary to record treatment satisfaction and any adverse reactions. Before treatment, patients received a 1% Xylocaine mental nerve block at the supraorbital, infraorbital, and mental nerve regions, as well as subcutaneous infiltration. Coated, external metal shields covered the eyes, and a rubber guard protected the teeth. To maximize the lower eyelid skin exposure to the treatment device head, the cheek was pulled in a caudal direction before treatment without displacement of the eye shield.

Patients received a total of four full-face Polaris WR treatments from the primary investigator (M.I.K.) with a 1- to 3-week interval between sessions. A thin coat of gel was applied to the skin, and each quadrant of the face was treated with sequential passes until the desired end point, a light pink skin color, was obtained. During each facial treatment, there was no overlap of the immediate, adjacent treated site. The number of passes administered in each session to achieve the treatment end point ranged from 3 to 4. Sequential passes were perpendicular to the previous direction. Treatments remained outside the bony orbit. The laser energy was turned off before the vermilion border of the lip was crossed.

Energy parameters were as follow: laser energy settings were 18 to 25 J/cm<sup>2</sup> in patients with Fitzpatrick skin types II and III. Patients with Fitzpatrick skin types IV or greater received laser energy between 12 to 16 I/cm<sup>2</sup>. RF energy settings were based on the pretreatment wrinkle depth. Patients with predominantly fine to moderate wrinkles received 80 to 90 J/cm<sup>2</sup>, whereas those with moderate to severe wrinkles received 90 to 100 J/cm<sup>2</sup>. RF energy settings were reduced by 20% when treating the skin over the forehead, nose, and malar regions. In addition to the face, the submental region (area of skin biopsy specimens, see below) was treated with the same parameters/passes as the face. After the treatment, patients were asked to wear sun protection and take acetaminophen for any posttreatment discomfort. They were given a diary to record treatment satisfaction and any adverse reactions.

## Physician analysis

For physician analysis, digital photographs were obtained before and 3 months and 6 months after treat-

ment by the primary investigator. Photographs were analyzed for changes in skin wrinkling by the principle investigator and 3 other plastic surgeons who were unaware of the treatment provided. Evaluators were asked to rate any skin wrinkle/texture improvement in the posttreatment pictures as follows: no change = 0, minimal improvement = 1 (analogous to the effect seen with Retin-A), slight to moderate improvement = 2 (similar to erbium laser resurfacing tissue effect), moderate to significant improvement = 3 (similar to a deep chemical peel or CO2 laser resurfacing result). The scores of the four evaluators were then averaged for each patient and time period. A final average score greater than 1.0 was required for a patient to be considered improved after treatment. Evaluations were to focus only on skin texture, not the other signs of photoaging, such as hypervascularity or dyschromia.

## **Photographic assessment**

Two types of photographs were obtained for picture analysis. A "standardized" set of right and left oblique pictures was obtained with the VISIA camera system (Canfield Imaging Systems, Fairfield, NJ) before treatment and then 3 months after the last session for all patients. In addition, six patients had VISIA pictures analyzed at the 6-month follow-up visit.

This VISIA camera system detects both the number of wrinkles and the depth of wrinkles within the analytical area. This system has a reproducible head positioning apparatus, standardized lighting, and performs a self-contained, computer analysis of the digital images, defining wrinkles as long features that meet specific area-to-perimeter ratios. The "mask" area chosen for wrinkle analysis was large and incorporated most of the cheek, nasolabial fold, lower eyelid, and upper lip regions. It did not incorporate the lateral eye area, because this region was overexposed in many pictures. The system allows minor adjustments of mask positioning to optimize symmetry of the analytical region in subsequent photographs.

For data examination, the "absolute scores" (fractional areas) were used as they were intended for comparative analysis. The computer-generated wrinkle value for the mask area was automatically determined at each photographic session. A lower score in the posttreatment picture analysis would represent an improvement in facial wrinkling. Because of the variability of the computer analysis algorithms (± variance of 5% to 8%, version 1.2.0 of the software), a posttreatment improvement greater than 9% was required to consider a patient to

have a benefit via VISIA analysis. The software version used for picture analysis in this study was 2.4.0, which may have a better variance reading of wrinkle scores.

# **Biopsy**

Five-millimeter punch biopsy specimens were obtained from the submental region before the initial treatment and then at 1 and 3 months after the last treatment. Biopsy specimens were randomly color coded at their base and placed in formalin. Specimens were sectioned and stained with hematoxylin and eosin (H & E), trichrome, and Elastic van Gieson stains. The dermatopathologist performing the analysis was "blind" with regard to the type of treatment the patients received and the date of harvest but did know that two of the three specimens were obtained from each patient after the skin treatments.

Slides were reviewed to determine the timing of the sample harvest (pretreatment versus 1 or 3 months after the last treatment) and then further analyzed for changes in the epidermis, dermal elastin, collagen, and the superficial fat-dermal junction. After the initial assessment of the harvest date, the code was revealed, and any changes in the epidermis, dermis, and superficial fat were graded at the 1- and 3-month posttreatment periods with a scale of 1 to 3, where 1 had the least change and 3 had the most change. This grading system was somewhat subjective, given the natural differences and variation of the subcutaneous interface histologically. For example, the subcutaneous adipose tissue is arranged in lobules, thereby slightly varying the depth of the fat-dermal interface in some of the specimens.6 Reporting was based on the combined differences observed within the 1- and 3month biopsy specimens compared with the pretreatment biopsy specimens for each patient.

## Results

#### Patient data

All patients were female, with an average age of 63 years. Three patients did not appear for their scheduled visits and were excluded in the final analysis. Three quarters of the patients believed that the final pass required to achieve the treatment end point was "warm to hot." Compared with our initial study where only topical anesthetic was used, nerve blocks significantly decreased discomfort during treatment. In general, the intensity of feeling warmth increased with an increase in the number of passes regardless of the RF or laser energy settings. This finding correlates well with our understanding of the

relationship of RF energy and tissue temperature—the higher the tissue temperature created by the antecedent pass, the greater the effect of RF energy. Seventy-five percent of the patients (9 of 12 patients) believed they had fewer skin wrinkles at 3 months, and 67% felt they remained improved 6 months after the last treatment. Skin redness resolved within 24 hours. Two of these 12 patients received superficial skin injury caused by electrode arch that did not require corrective treatment.

# **Physician assessment**

Analysis revealed that seven of 12 patients (58%) were improved at 3 months after treatment (average score = 2.0), and five of 12 patients (42%) remained improved at 6 months after treatment (average score = 1.73) (Figures 1 and 2). Three patients who received a score  $\geq$ 2.0 at the 3-month evaluation had a score of at least 2.0 at 6 months. Patients with the greatest degree of pretreatment wrinkling were found to be the most difficult to assess in terms of improvement.

## **VISIA** analysis

Comparison of the pretreatment and posttreatment absolute scores revealed that 67% of the patients (8 of 12) were improved 3 months after their last treatment (Figures 3 to 6). The average improvement at 3 months was 30% (range 10%-74%). Four of these eight "improved" patients had a VISIA analysis at 6 months after their last treatment. The average improvement in these four patients was 21%, (range 15%-35%). VISIA analysis provided support for a patient's indication of improvement despite physician assessments of no improvement. Figure 6 illustrates a 30% VISIA analysis improvement at 3 months after treatment for patient results categorized by physician evaluators as showing no improvement (average improvement score less than 1.0). VISIA analysis also demonstrated a worsening of skin wrinkling after treatment (Figure 7).

#### Histologic analysis

The dermatopathologist was able to differentiate the specimens with regard to the date of harvest in eight of the 12 specimens. Three of the four that had the 1- and 3-month posttreatment dates transposed belonged to patients who were determined to have "no improvement" by the VISIA system analysis. Posttreatment biopsy specimens from all patients demonstrated no change in the epidermis (Figure 8).

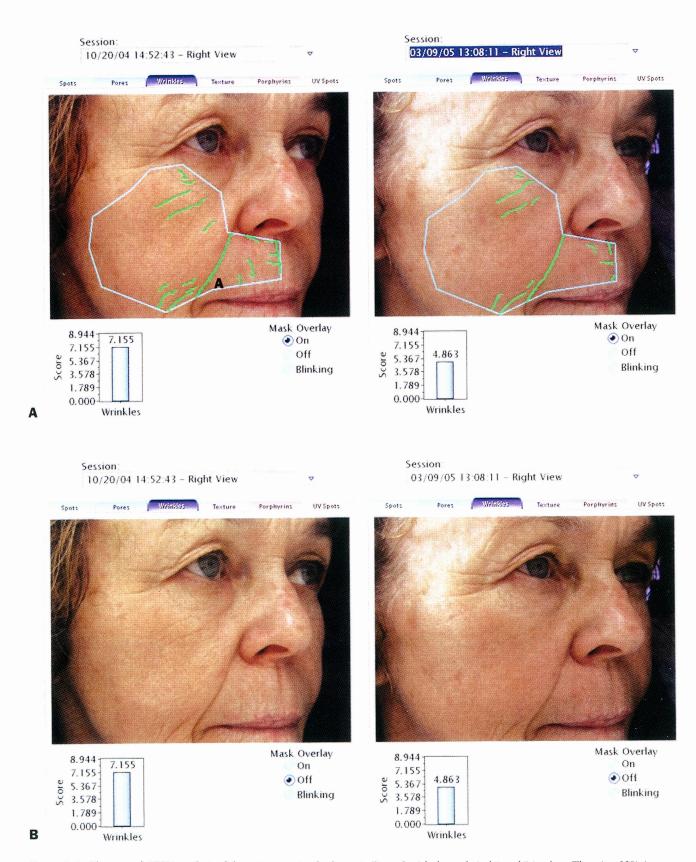
Use of the VISIA analysis performed at 3 months to segregate patients into treatment "responders versus non-



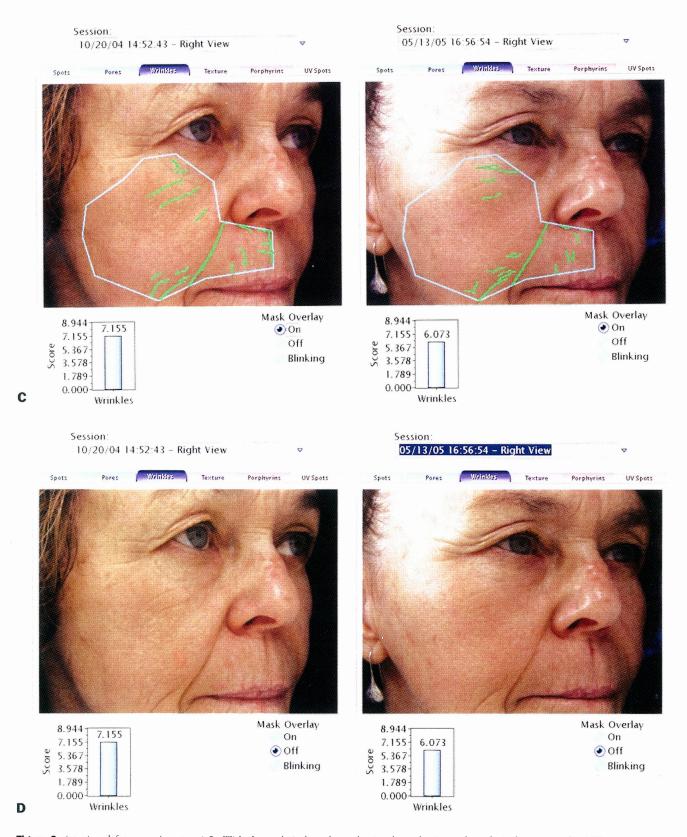
Figure 1. A, Pretreatment right oblique view of 51-year-old woman, Fitzpatrick III. B, Posttreatment view 3 months after her last Polaris WR session. C, Posttreatment view 6 months after her last session. D, Pretreatment close-up view of the right eye region. E, Posttreatment close-up view 3 months after her last session. F, Posttreatment close-up view 6 months after her last session. The patient and all evaluators felt that she had a significant improvement at both posttreatment periods without a change in her skin color. VISIA analysis demonstrated a 74% improvement at 3 months after her last session (see Figure 5).



**Figure 2. A,** Pretreatment close-up of the mouth of a 65-year-old woman. **B,** Posttreatment view 3 months after the last Polaris WR session. **C,** Posttreatment view 6 months after the last session. There were mixed ratings of her full-face views but all evaluators agreed that she had an improvement in her perioral wrinkles at 3 and 6 months after her last session.



**Figure 3. A,** Three-month VISIA analysis of the patient previously shown in Figure 2 with the analytical "mask" in place. There is a 32% improvement via VISIA analysis 3 months after the last Polaris WR treatment. **B,** Without the analytical mask overlay, improvement in the cheek and upper lip skin can be seen. (Figure 3 continued on next page)



**Figure 3.** (continued from previous page) **C,** With the analytical mask overlay in place, the 6-month analysis demonstrated a 15% improvement. **D,** Without the mask, the 15% improvement is difficult to quantify by gross inspection. The VISIA system did not allow for focused analysis of the front views of the skin surrounding the upper and lower lips, which showed the greatest improvement in this patient via standard digital photographs (Figure 2).

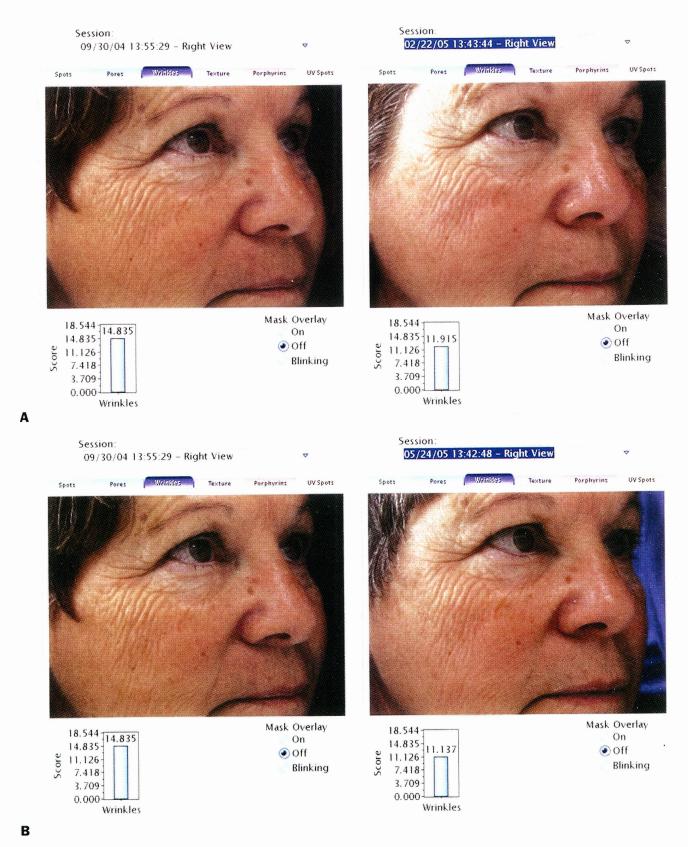


Figure 4. A, VISIA 3-month analysis of results in a 62-year-old woman demonstrates a 20% improvement. B, Six-month analysis shows a 25% improvement. Physician evaluators found it difficult to rate this patient as improved because of the depth and concentration of wrinkles around the eyes and cheek.

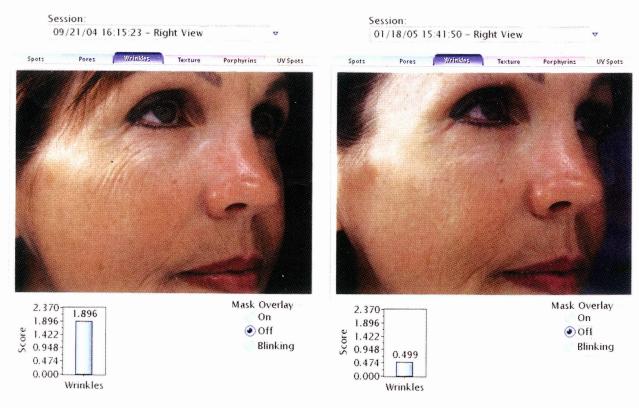


Figure 5. VISIA analysis of the patient shown in Figure 1 demonstrates a 74% improvement at 3 months after her last Polaris WR treatment.



**Figure 6.** This 53-year-old woman was felt to have no improvement, according to physician analysis on the basis of standard digital photograph review. The patient felt she was improved after her four Polaris WR treatments. VISIA analysis demonstrated a 30% improvement at 3 months post-treatment. There is a reduction in depth and concentration of wrinkles around the lower eyelid and cheek.

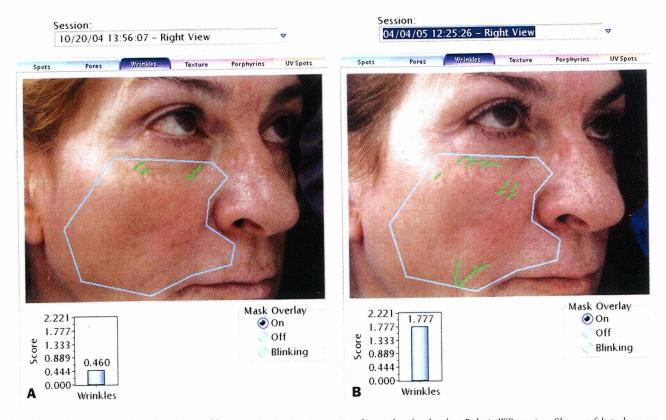


Figure 7. A, Pretreatment view of a 60-year-old woman. B, Posttreatment view 3 months after her last Polaris WR session. She was felt to have no improvement via patient and physician analysis. Histologic analysis of her biopsy specimens did not show a thickening of the dermis or significant neocollagen deposition. VISIA analysis demonstrated a worsening of the wrinkles—an increase in the absolute score of 1.32. The green lines reflect the wrinkles within the "masked" area (blue outline) that the computer used for analysis of wrinkle presence and depth.

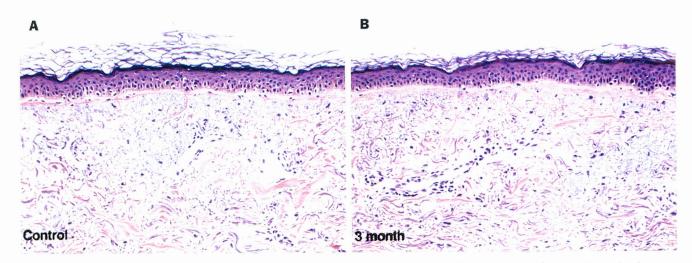


Figure 8. A, H & E stain of a pretreatment biopsy specimen. B, Biopsy specimen from a patient in the VISIA improved group at 3 months after treatment. There is no significant change in the epidermis. In this specimen, there is little change in the papillary dermal, interfibrillar collagen spacing and collagen stain uptake, which was true for all posttreatment sections reviewed.

responders" (greater than 10% improvement in the absolute score difference), allowed a comparison of changes observed in the posttreatment biopsy specimens in these two groups. Examination of the orientation and thickness of the collagen fibers and thickness of the dermis revealed that patients who were considered improved by VISIA analysis had a significantly greater increase in dermal thickness score than the VISIA non-improved

patients (P < .024, Student t test). The VISIA "improved" group also had a greater increase in interfibrillar spacing and an increase in thickness of the neo-collagen fibers in the reticular dermis (Figure 9). Most of the 3-month specimens in the VISIA "improved" group had changes at the dermal-fat junction, within the fat lobules. Changes in the dermis at this depth were also observed by others who evaluated the effect of multiple RF passes on the skin.<sup>7</sup>

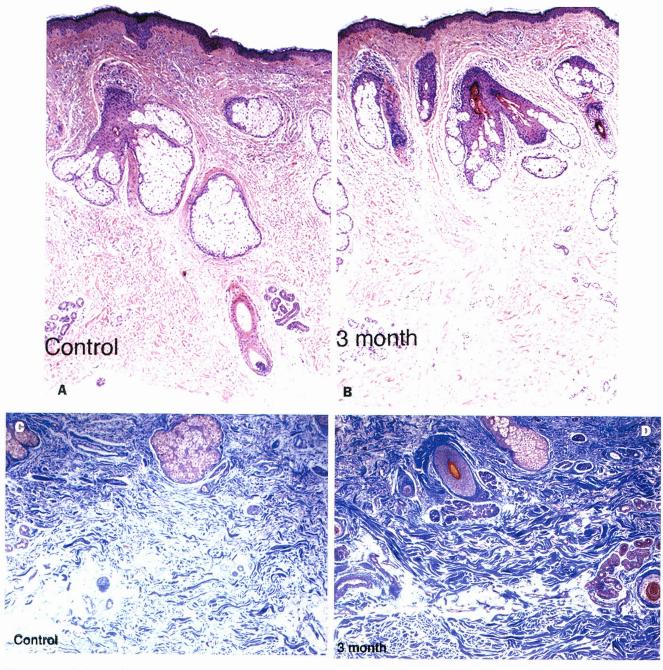


Figure 9. A, Thickness of a typical pretreatment skin biopsy specimen. B, Three months after the patient's last Polaris WR treatment, the dermis is much thicker. Both slides are taken at original magnification ×20. Because of the increased dermal thickness, the entire post:reatment specimen could not fit on the field of view. C, This is a trichrome stain of a pretreatment specimen. D, This trichrome stain of the 3-month posttreatment biopsy specimen shows a greater intensity of stain with thicker collagen fibers.

An interesting finding in four of the posttreatment biopsy specimens was the presence of calcification associated with the elastin fibers in the deep dermis, a finding consistent with a diagnosis of pseudoxanthoma elasticum (Figure 10). Given the low incidence of this primarily inherited clinical condition in the general population (0.001% to 0.004%),8 the finding that one third of our patients had such an occurrence may be related to the postinflammatory changes that occurred in the deeper dermis after treatment. Three of the four patients with this finding were in the VISIA "improved" group. The inflammatory process may have either altered the existing elastin fibers or the new elastin fibers may have had the associated calcium deposited at the time of formation.

#### Discussion

This study also confirmed a variable response to Polaris WR skin treatment. While there was a correlation between the histologic changes and clinical efficacy, an unequivocal explanation as to why all patients did not show obvious improvement or why the improvement was not uniform, was not possible, for several reasons.

The effect of electro-optical synergy (ELOS) technology on differing thicknesses of dermal and subcutaneous tissue and the predictability of the impact of the underlying osseous support has not been fully evaluated. The 20% reduction of RF energy over bony prominences was an arbitrary number that was chosen to optimize patient safety. Patients with a greater degree of skin wrinkling may require more than four treatments to show obvious clinical improvement.

Patient age may also play a role in tissue reaction to thermal energy. The response to the trauma/healing process is not the same in young versus older individuals, secondary to changes in the immune system, nutrition, hormone levels, etc. 9-14 The best response was observed in the younger patients. Increased efficacy in younger patients was also observed with a monopolar RF device. 15 Patients with a greater degree of wrinkling were, in general, older. Our sample size prevented any type of statistical comparison of age as a response factor.

Although no corrective measures were required in the two patients that had superficial burns, the inflexible metal electrodes of the Polaris WR device require the physician to be cautious when treating curved surfaces, such as the malar region and lateral forehead. Arching can lead to superficial skin burns; reducing the speed of treatment can minimize such complications with this treatment head design. Another option may be to reduce the light and RF settings and perform more treatment sessions.

# Physician analysis

Physician analysis provided the lowest percentage of improvement at 3 months after treatment. Discussion after the analysis revealed that all surgeons felt that patients with greater pretreatment wrinkling were the most difficult to assess. Evaluators had a relatively short time to evaluate multiple pictures and, if the difference was not striking, a lower score may have been given. Evaluators also judged results based on the overall improvement or lack thereof. Thus, if a patient did not

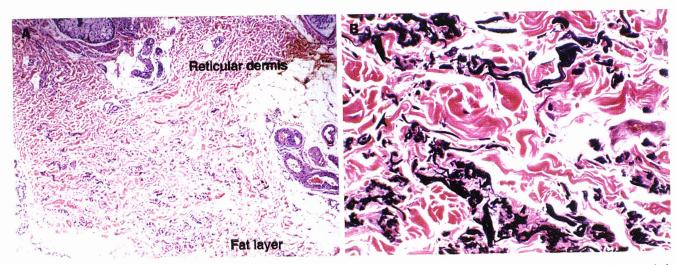
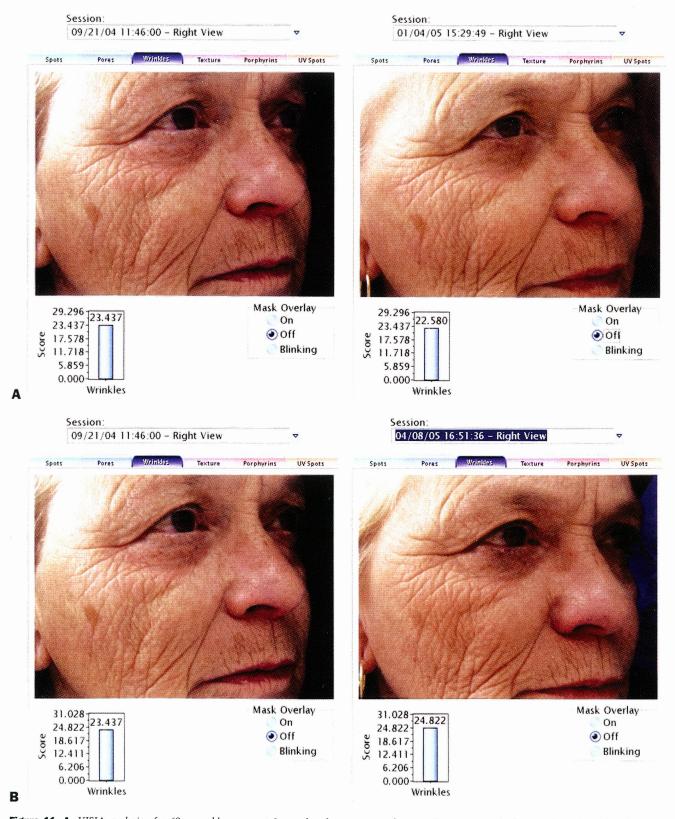


Figure 10. A, Low-power view shows the dark speckled elastin fibers at the dermal-fat junction. B, The EVG stain shows the elastin fibers as a dark black color and associated calcium deposits that also stain dark black. A defining characteristic for a diagnosis of PXE is the "crinkled" elastin fibers that have calcium deposits on them.



**Figure 11. A,** VISIA analysis of a 69-year-old woman at 3 months after treatment shows no improvement. **B,** Six-month analysis also shows no improvement. (Figure 11 continued on next page)



Figure 11. (Figure 11 continued from previous page) **C**, Standard digital right oblique views before treatment. **D**, Standard digital right oblique views 3 months after the last treatment. There appears to be some improvement, but the change was not significant enough for this patient's score to reflect an improvement (>1.0). **E**, Six months after treatment, the patient still has many wrinkles. **F**, High magnification of the cheek view before treatment. **G**, Three-month posttreatment view shows some improvement in skin texture. **H**, The improvement in texture is maintained at 6 months after the last treatment.

have a consistent improvement in all views, a lower score would have been assigned. In contrast, a better rating may have been given in the other two methods of evaluation because patients may have focused on areas that they were most concerned with, whereas the VISIA analysis evaluated only the skin within the masked region.

# VISIA analysis

Photographs are a "moment in time," static images that may incorporate subtle, unintentional changes in facial animation or positioning that the VISIA system or physician review cannot account for. The limitations of clinical photography have been pointed out by Niamtu. 16

The VISIA camera system provided valuable information but was limited by the lack of 3-point fixation system for VISIA head positioning, which would be helpful to optimize reproducibility.

Other limits were camera resolution, and the logarithms that determine wrinkle presence/depth. The latter problem was somewhat alleviated by use of the absolute score versus comparative percentile values when evaluating improvement after treatment and with a minimum improvement value of 9% for a patient to be considered "improved."

Figure 11 illustrates how inspection of high-magnification photographs can demonstrate changes that are not evident on full-face views. This patient was deemed to be a "nonresponder" by patient self-assessment, VISIA, and physician analysis, as well as histologic examination of the biopsy specimens. Close-up views of the cheek digital image shows an improvement in the skin texture at 3 and 6 months after treatment. Thus there was some "response," but not sufficient to rate her as improved by use of this study's standards.

# Histologic analysis

Histologic analysis provided an anatomic basis for a possible explanation of why patients classified as improved clinically looked better. Dermal thickening, an increase in the fiber size of neocollagen and increased interfibrillar spacing, has been shown to be a basis for improvement with other wrinkle-reducing methods. 17-19

Histologic study also supported the claim that RF and laser diode energy can improve wrinkles without changes in the epidermis. This finding indicates that this technology may be useful in treating patients with darker skin and those who want to avoid the morbidity associated with ablative technologies for wrinkle reduction. The multiple passes used and the synergistic effect of laser and RF energy, ELOS technology, may explain the deep versus superficial dermal changes and the greater improvement rate versus other types of RF devices. <sup>15,20</sup>

The biopsy specimens did not show a change in the epidermis associated with the reduction in skin wrinkles. However, clinical photographs did show some improvement in facial dyschromia. This may be explained by the fact that the biopsy specimens were taken from the submental region, which had little if any sun damage in comparison to the face. Although the RF energy has no affinity to pigment, the 900-nm laser energy does; this most likely contributed to the reduction in undesirable brown spots. Thus, when using the Polaris WR for treating patients with darker skin, the laser energy settings should be

reduced, because the laser light energy will be attracted to the pigment and affect the impact of the RF energy.

## Conclusion

Our study confirmed improvement in skin wrinkling after Polaris WR therapy in most patients at 3 months after treatment, as determined by physician assessment, VISIA analysis, and patient assessment, with a lower rate of improvement at 6 months after treatment. VISIA analysis tended to confirm patient assessments, whereas physician assessments of improvement tended to be lower.

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