AILESBURY CLINIC REPORT PART 1

Randomised split face trial of two fractionalised laser resurfacing lasers for treatment of photoageing

Patrick J Treacy, Department of Skin Research, Ailesbury Clinic, Dublin, Ireland.

David J Goldberg Laser Research, Department of Dermatology, Mount Sinai School of Medicine, New York, NY, USA.

Objective: To compare the clinical effectiveness of two different fractionalised Co2 lasers in the treatment of photoageing
Design: Multicentre randomised split face study .
Setting: 2 practices in Dublin and New York
Participants: 25 patients aged 32 -58 years presenting with photoageing of skin.

Interventions: Lumenis ActiveFx CO_2 laser or Deka SmartXide DOT Co2 laser. All participants received regional anaesthesia 2% Lignocaine plus adrenaline, topical anaesthetic of AneStop® Valium 5mgs stat and Famvir 750 mg once daily for ten days if herpetic carrier. A post procedural advice sheet and Codeine with Paracetemol as required.

Main outcome measures: Participants' global assessment of improvement (five point scale) at two, four and twelve weeks. Reduction of rhytides, tactile roughness, pigmentation and blood vessels were recorded along with the re-ephithelialisation rate. The level of prolonged erythema and the presence of other side effects such as infection were also recorded.

Results: Over 7 months, 25 subjects were randomised into a split face study to compare the effect of 2 different fractionalised lasers on photoageing. There was little aesthetic difference noted by doctor or patient between the two lasers at 3 months. Histological results showed both lasers similar depth of penetration and consequential formation of new collagen. Greater thermal penetration effect was noted with the Lumenis ActiveFx than the SmartXide when the authors used it outside its 'soft' settings. 23 patients (92%) in the ActiveFx group felt their split face was completely better or improved compared with 21 (84%) in the SmartXide group ($P<0.001$) but the authors recorded no difference. 15 patients (60%) said they preferred the SmartXide experience compared to 10 patients (40%) in the ActiveFx group. Three patients received full facial herpes. Each of these had their neck treated with the ActiveFx, which raises the question of possible association.

Conclusions: There seems to be little difference in aesthetic outcome between the two lasers at 'soft' settings when examined at 3 months. The ActiveFx appears to have and a deeper dermal penetrative effect and possibly more herpetic infection when used in 'harder' setting but the authors recognise that both these effects is related to device settings. Both patients and physicians preferred the initial SmartXide effect.

Introduction

Fractionalised laser skin resurfacing (FLSR) has become an important component of facial rejuvenation surgery as patients continue the trend of seeking less invasive procedures with low downtime and low risks [1]. This behavioural change in attitude has also been prompted by a realisation of both doctors and patients that the recent much hyped non-ablative methods are not comparable with ablative skin resurfacing and were often subject to extravagant claims in terms of efficacy. [2–4]. Until this time, CO2 laser resurfacing was considered the 'gold standard' for the treatment of rhytids and photodamaged facial skin [5-10]. Many proceduralists went further and stated the ultrapulsed CO2 laser was the most effective modality for repairing years of skin exposure to harmful ultraviolet light and photodamaged skin [11–12]. This photoageing effect is demonstrated clinically as a gradual deterioration of cutaneous structure and function. It manifests itself in the epidermis and upper papillary dermis by giving skin a roughened surface texture as well as laxity, telangectasias, wrinkles and variable degrees of skin pigmentation [13–14]. Although, ultrapulsed CO2 laser skin resurfacing was largely considered the best option for treatment of this type of photoaged facial skin, it also had certain post- procedural problems. [15-17].These included prolonged postoperative recovery, pigmentary changes and a high incidence of infective adverse side effects, including acne flares, herpes simplex virus (HSV) infection [18-20]. Many patients also complained of oedema, burning, and erythema that sometimes lasted for many months. [21–22]. The delayed healing, the implied risks and long downtime made many patients reluctant to accept this method [23–24]. Although non sequential fractionalised technology is relatively new, its benefits of faster recovery time, more precise control of ablation depth, and reduced risk of post procedural problems are already clear [1]. These lasers also reduce the consistently high level of non-responders often seen with quite expensive non-ablative treatments that often required multiple painful sessions [25]. The obvious benefits of these lasers have led to many new fractional resurfacing lasers reaching the market at the same time [26].

The recent adoption of the newer fractionalised C02 lasers by many physicians also appears to have reduced the morbidity associated with this type of laser treatment [1]. Damage to the epithelium is less apparent because unlike in conventional ablation some the stratum corneum remains intact during treatment and acts as a natural bandage. This allows the skin to heal much faster than if the whole area was treated, as the 'healthy' untreated tissue surrounding the treated zones helps to fill in the damaged area with new cells. Downtime is also reduced and erythema is moderate, permitting patients to apply cosmetics five days after treatment. [27]

Fractionalised C02 lasers are extremely versatile, in that they can be used for the treatment of facial rhytides, acne scars, surgical scars, melasma and photodamaged skin. There are presently several high-energy, fractionalised carbon dioxide (CO2) lasers currently available for cutaneous resurfacing. Although each laser system adheres to the same basic principles there are significant differences between lasers with respect to tissue dwell time, energy output, and laser beam profile. These differences may result in variable clinical and histological tissue effects. The purpose of this study was to compare in vivo clinical and histopathologic effects of two novel fractionalised CO2 resurfacing lasers: the 30W SmartXide DOT (Deka: Calenzano, Firenze (Italy)) and the ActiveFx (Ultrapulse Encore, Lumenis Ltd, Santa Clara, CA, USA). The ActiveFx (although technically the name of a set of parameters) is an upgrade of the Ultrapulse Encore with smaller spot size and a new CPG giving a random pattern reducing the possibility of having several adjacent spots with resultant heat accumulation. The newer SmartXide DOT adopts lightweight titanium articulated arm in conjunction with a user friendly colour Touch-screen control panel to display the settings. The SmartXide DOT requires an external plume device.

Part of the study was hampered because of a lack of sufficient published data as yet relating to the specific comparative settings of each laser, particularly the number of passes required and whether each could be safely used onto the neck to further improve the superficial textural quality of the skin in this area.

Abstract

A prospective randomised split face study using two different fractionalised CO2 resurfacing lasers (Lumenis ActiveFx, Deka SmartXide) was performed on twenty five patients to compare the clinical effectiveness of each device. The study evaluated post procedural aesthetic results, length of downtime and adverse side effects for the 'ActiveFx' and ‘SmartXide’ during the laser ablation treatment for photodamaged facial skin. Each patient was randomly assigned to receive treatment on one half of their face with one of the two CO2 lasers. The ActiveFx patients were treated at between (Energy) 100-125 mJ (Rate) 125 Hz CPG 3/6/1-3/6/3-3/6/5 Repeat Delay 1.0s. The SmartXide DOT patients were treated at (Power) 30W Dot Mode ON Spacing 300-500 μm Scanning Dwell Time 500 μS- 800 μS. These levels were relatively arbitrary and not based on specific conversion tables but the authors were hoping to achieve the ablation depth is about 80 mm and a depth of the residual thermal damage of 200 mm [28-30].

All of the patients underwent an 'active' single-session, single-pass and full-face ablative fractional treatment in the period from July 2007 to February 2008. Eighteen patients received a double-pass treatment of the periorbital region and twelve to the perioral area and in these cases the effect was repeated bilaterally. Significant differences (p<0.05) between baseline and 1 and 3 months post-treatment were observed for fine lines and wrinkles, although the best improvements were noted in the regions where the proceduralists considered the patient required a double-pass. The patients who received second overlapping passes in the periorbital and perioral areas received them for deeper rhytides. The authors went slightly above the recognised Lumenis ‘soft’ protocol for ActiveFx (Energy) 90-100 mJ (Rate) 100 Hz CPG 3/5/2-3/5/5 Repeat Delay 0.5s. as previous experience showed these parameters to be less preferable in aesthetic effect. The protocols for the SmartXide

DOT included treatments that required multiple passes (Fig 3) so the parameters above were agreed with the company to be comparatively similar.

A clinical assessment of each patient was made at 2 weeks, I month and 3 months postoperatively in the presence of two physicians. Scoring was based on the degree of re-epithelialization rate, reduction of rhytides, reduction of tactile roughness and loss of hyperpigmentation and telangectasias. The prolongation and severity of erythema as well as the presence of negative side effects (such as herpes were also recorded by both the patient and the doctor). The degree of photoageing and the efficacy of treatment were evaluated using a variation of the five-point scale (Fig I) originally suggested by Dover et al. (30). A total global score was recorded in each patient based on the addition of points obtained from six photodamage variables: fine lines, coarse wrinkles, hypo/hyper-pigmentation, sallow complexion, tactile roughness, and telangectasias. The authors felt that this method would allow individual photoageing parameter response to be recognised, while also allowing any differences in the laser effect to be exaggerated in the overall higher global totals. The positive results related to overall aesthetic outcome for treatment of photoaged skin while the negative ones (Fig 2) were more a reflection of patient satisfaction to the type of laser device that performed the treatment.

Parameter	0	1	2	3	4
Global Score	Area of Roughness x 0	Area of Roughness x 1	Area of Roughness X2	Area of Roughness X3	Area of Roughness X4
Fine lines	None	Rare	Several	Moderate	Many
Pigmentary Problems	None	Patchy	Moderate	Heavy	Marked
Touch Problems	Even	Rare	Mild	Moderate	Severe
Facial Veins	None	Rare	Several	Moderate	Severe
Coarse lines	None	Rare	Several	Moderate	Many
Complexion	Pink	Pale	Grey	Suggestion Yellow Grey	Distinct Yellow Grey

(Fig 1) Patient treatment (positive) scoring chart

A considerable number of patients (<12%) received full facial herpes (especially with the ActiveFx) requiring us to change our prophylactic anti-viral protocol to Famvir 70mgs for one week before and one week after when using this laser. This figure was still below the number of herpetic infections noted in other CO2 ablative laser studies [30]. Both lasers were considered comparatively similar in terms of downtime, erythema and overall aesthetic effect in this form of ‘soft’ resurfacing. However, histopathologic penetrative effect and adverse side effects, such as herpetic infection were considered higher with the ActiveFx than the SmartXide, although this may be due to non comparable device settings.

Parameter	0	1	2	3	4
Erythema Severity	None	Rare	Several	Moderate	Severe
Infective Outbreak (Herpes/Acne)	None	Rare	Several	Moderate	Severe
Crusting	None	Rare	Several	Moderate	Severe
Pain of Procedure	None	Mild	Tolerable	Moderate	Severe
Improvement	None	Minimal	Fair	Good	Excellent

(Fig 2) Patient treatment (negative) scoring chart

Materials and methods

The devices

1. **The 'ActiveFx'** is not so much a new laser but rather a particular protocol of settings applied in conjunction to an improved CPG (computer pattern generator) to the ultrapulsed CO2 laser (Ultrapulse Encore, Lumenis Ltd, Santa Clara, CA, USA). Technical differences exist between this upgraded nonsequential fractional device and the older ultrapulsed CO2. These include the device leaving intact tissue bridges between spots, which results in faster healing time and less thermal damage to the basal cell membrane. The device also has a smaller spot size (1300 mm instead of 2500 mm) resulting in less post procedure erythema due to reduced heat build up in these tissues. Lastly, the CPG lays down a random series of spots rather than a sequential sequence resulting in greater thermal relaxation time and less overheating of the treated tissue. The application of random rather than sequential beams is termed 'Cool Scan' and this feature was used with every patient in the study.

2. **The SmartXide DOT** laser is a 30W fractionalised CO_2 laser with computerized scanner which enables the user to deliver a customized scanned pattern with adjustable power, pattern density and dwell times. With DOT (Dermal Optical Thermolysis) technology the physician is able to deliver a superficial 'soft' treatment with no downtime, a moderate treatment requiring a few days of downtime, or a fully ablative traditional laser resurfacing treatment. We wished to see if there was also a single-one treatment schedule comparable to the ActiveFx settings. We decided to use the SmartXide DOT at these parameters:

a. **30W Dot Mode ON Spacing 300-500 µm Scan Dwell Time 500 µS- 800 µS**. We were aware that other parameters could achieve a preferable effect by increasing the dwell time at a lower energy setting. This would include

b. **20-25W Dot Mode ON Spacing 500-1000 µm Scan Dwell Time 1msec.** The energy per dot = power /dwell time so at 1msec dwell at 25 watts = 25millijoules per dot. Energy per dot with the previous parameters would be less 0.5 msec at 30 watts = 15millijoule per dot. The longer dwell time, albeit with reduced spacing could achieve deeper collagen stimulation to increase the rejuvenative effect. These parameters are for Fitzpatrick skin type 1-3

30 Watt Spacing 500 µm	Dwell Time	Passes	Down time
PHOTOTYPE I	1.0 ms	4	7 days
PHOTOTYPE II	0.5 ms	3	7 days
PHOTOTYPE III	0.2 ms	3	7 days

(Fig 2) Deka treatment protocols for SmartXide DOT

METHOD

Pre Laser Procedure

For full face resurfacing, we typically prescribed the following analgesic type medications to be started on the day of treatment: One hour before, the patient applies a thin layer of **Anestop® : (**Amethocaine; Propitocaine; Lignocaine) topical anaesthetic to the entire facial area. This is used with particular care in the periorbital areas and other lateral facial regions not easily covered by a regional block. A plastic wrap is not used during this procedure.

For anxiety and analgesia, we typically prescribe **Valium** (Diazepam5–10 mg po), **Tylex** (Paracetemol Codeine) to be given 45 minutes prior to the procedure.

If the patient has a strong history of HSV, we initially prescribed **Famvir** (Famciclovir) 750mgs daily for 10 days or **Valtrex** (valcyclovir) 500 mg bd for 10 days starting three days before surgery. This was adjusted during the study to commence one week before and to be used for one week after. If the patient has a strong history of acne, we prescribe an antibiotic **ByMycin** (Doxycycline 100mgs daily) **Augmentin Duo**, (Amoxil Clavulinic Acid) **Keflex** (Cephalexin 500 mg bd) for 7 days, starting the day of surgery). If the patient has a strong history of frequent yeast infections, we prescribe **Diflucan** (Fluconazole 150mgs), starting on the 4th post-operative day and taken once orally every other day. We do not routinely prescribe antibiotic and antifungal medication. We routinely prescribe **Famvir** (Famciclovir) 750mgs daily or **Valtrex** (valcyclovir) 500 mg bd for 7 days starting three days before surgery to every patient. (We found a 10% viral outbreak from over 450 patients before using strict anti-viral prophylaxis to every patient when using these fractionalised devices despite these protocols.)

No HSV recurrences were seen in 90% of patients receiving **Famciclovir** at this dose. Approximately fifteen percent of patients in the ActiveFx group with a positive history of oral herpes labials experienced HSV recurrence compared to eight percent of those in the SmartXide group. About 2% of those without a known HSV history succumbed to the infection. This was much lower than was experienced by other studies and may have been due to the skin bridge effect of fractionalised resurfacing. [31]

If just the periorbital or neck is to be treated, the only medications prescribed are **Valtrex** (valcyclovir) 500 mg bd for patients with frequent HSV outbreaks and **Valium** (Diazepam5–10 mg po), **Tylex** (Paracetemol 500mgs Codeine 30mgs po). Prior to resurfacing, the nurse wash the patient's entire face and neck to remove the topical anaesthetic.

Procedural Treatment

The patients were treated under a mixture of both topical and regional anaesthesia. As a dermasurgeon, I prefer a deeper form of anaesthesia for full-face ablative laser procedures and use regional nerve blockade and sometimes IV sedation to provide more complete anxiolysis, amnesia, and sedation. Since the advent of fractionalised CO2 lasers this is not presently required but I still feel more comfortable providing regional anaesthesia in the supraorbital, perioral and marionette areas. As previously mentioned, we found this was not usually necessary to administer in most patients but a high percentage of our patients had coarse wrinkles requiring multiple passes and we felt it was more appropriate to try and keep the procedures as standard as possible in respect of perceived bias at a later date. For the ActiveFx, the treatment parameters that we used were as follows: 100-125 mJ, Rate 125Hz. The CPG (computer pattern generator) was set to maximum size and an energy density of between 2-5 depending on the area of the face. We used the square-shaped pattern (number 3) with the largest spot size available for the pre-selected energy density setting used. For the SmartXide we use (Power) 30W Dot Mode Spacing 200-400 μm Scanning Dwell Time 500 Ms-1mS. These setting are much faster to use.

We usually treated the cheek area and perioral area (which are under regional anaesthesia) first in order to get the patient used to the laser. We treated the periorbital area next and finally then extended down onto the neck. When treating the neck area, the parameters were modified to use the lowest energy density possible (ActiveFx density 1). We always used the Cool Scan with a repeat delay of 1.0ms. Care was particularly taken in the inferior regions of the neck with a tendency to feather in the posterior border. The patients in general experienced no pain post procedurally and we placed them under a 633nm Omnilux Revive to try and biomodulate fibroblast activity, thereby leading to faster and more efficient collagen synthesis [32]

Topical Anaesthesia

Anestop® : (Amethocaine; Propitocaine; Lignocaine) as topical anaesthetic to the entire facial area for 45mins. Astra Zeneca

Regional Anaesthesia

Typically, we gave regional anaesthesia during the procedure including

1) **Supraorbital and Supratrochlear Nerve Block**
    a. Locate supraorbital foramen and insert needle
        i. Lateral to supraorbital foramen
        ii. Direct needle medially, parallel to brow, toward nose
    b. Infiltrate mid-two thirds of lower edge of eyebrow
        i. Use 1 cc of 1-2% Lidocaine
        ii. Inject just above bone level
2) **Infraorbital Nerve Block**
    a. Locate infraorbital foramen
    b. Insert needle
        i. Insert inferior to foramen by 1 cm (slightly medial)
        ii. Direct needle toward supraorbital foramen
        iii. Avoid approaching orbit
    c. Infiltrate at infraorbital foramen
        i. Use 1 cc of 1-2 % Lidocaine
        ii. Inject just above bone level
3) **Mental Nerve Block**
    a. Locate mental foramen
    b. Insert needle
        i. Insert 1.5 cm posterolateral to mental foramen
        ii. Direct needle toward mental foramen
        iii. Avoid approaching orbit
    c. Infiltrate at mental foramen
        i. Use 1 cc of 1-2% Lidocaine
        ii. Inject just above bone level

Post Laser Procedure Care

If the patient had pain we resolved this with ice packs. The patients face was then covered with Vaseline (petrolatum gel) using a tongue depressor and they were asked to continue doing this every few hours. On one patient CM we used dilute vinegar soaks (one teaspoon of distilled white vinegar to two cups water) applied over the layer of Vaseline petrolatum every few hours post-operatively but this was done because the patient requested multiple passes. We rarely ever use dilute vinegar soaks with the newer fractionalised devices now being trialled. The patients

were given demonstration photographs of other model patients that show that the treated facial areas will be pink-red for the first 2 days before turning a darker red to purple colour. They were also warned about the possibility of a herpetic outbreak on the third day and shown photographs of what this would appear like.
The patients were reviewed at 7–10 days post-operatively, during which time the treated areas of the face had mostly returned to normal, except the neck, which was still pink. Outbreaks of herpetic infection were reviewed on an almost daily basis and the patients were commenced on Famvir 750mgs tid during this period.

Topical steroids (1% Hydrocortisone) were applied to 2 patients for continual itch.

Variations on procedure

Five patients who received a variation on the prospective split face study were included. In each case a mini-split face was performed where the perioral or periorbital area alone was treated using the two different fractionalised CO2 resurfacing lasers (Lumenis ActiveFx, Deka SmartXide) on each side. Another two patients requested redo of the periorbital areas on three month evaluation and this requested was granted as the reviewing doctors agreed the aesthetic results were minimal. These result were not included.

Skin biopsies

Skin biopsies were obtained from five of the patients intraoperatively from each side, after one laser pass, and at 3 months postoperatively. Lesion penetrative dimensions were assessed histologically using haematoxylin & eosin. Blinded histological examination of laser-treated halves was performed to determine the amount of tissue ablation, residual thermal damage, inflammation, and new collagen synthesis.

Perioral split face study showing the different skin eschar results from the fractionalised lasers (Computer Pattern Generators) immediately after treatment.

CASE 1 *Patient EF: Each half of face was randomly assigned to receive treatment with one of the two CO2 lasers.*

ActiveFx *treated (Energy) 125 mJ 9.4J/cm2 (Rate) 125 Hz CPG 3/5/2/*

SmartXide *treated (Power) 30W Dot Mode Spacing 300 μm Scanning Dwell Time 500 μS*

B 

Patient EF


Patient EF

The patient was a 59yo Caucasian female who presented with normal level of photoageing. She had a previous history of herpes simplex and was commenced on Famvir 750mgs O.D three days before her procedure. The left side of her face was treated with the Lumenis ActiveFx with settings (Energy) 90-125 mJ (Rate) 125 Hz CPG 3/5/2, while the right side was treated with the Deka SmartXide with settings *(*Power) 30W Dot Mode Spacing 400 μm Scanning well Time 500 μS with 2 passes under eye. She also received ActiveFx with settings (Energy) 90mJ (Rate) 125 Hz CPG 3/5/1 in her neck area. The patient ranked the pain felt during the treatment was 2.0 and did not require any analgesia to take home. On the third day she developed full facial herpes and some truncal spots. She was commenced on Famvir 750mgs tid x 7/7. Her scoring for fine lines dropped from 3 to 1 for both lasers art Day 30. Her scoring for coarse lines dropped from 3 to 2 for both lasers art Day 30.

CASE 1 *Patient EF: Each half of face was randomly assigned to receive treatment with one of the two CO2 lasers. Patient on Day 5 with full facial herpes.*

Results

Patient demonstrated significant Global Score reduction in most of the parameters from 16 at Day 0 to 10 at Day 30. There was little aesthetic difference between the facial sides in Global Scoring either at Day 14 or Day 30.

Perioral Rhytides

CASE 2 *Patient FR: Each half of perioral area was randomly assigned to receive treatment with one of the two CO_2 lasers.*

ActiveFx *treated (Energy) 125 mJ 9.4J/cm2 (Rate) 125 Hz 18.8W CPG 3/5/3 Double Pass*

SmartXide *treated (Power) 30W Dot Mode Spacing 400 μm Scanning Dwell Time 1ms Double Pass*

A 

Patient FR: prior to treatment


Patient FR: 2 days post treatment

The patient was a 72yo Caucasian retired female physician who presented with moderately severe facial rhytids in the perioral area. The patient only wanted her perioral area treated and we decided to use her to compare the differences in the lasers.

The left side of her perioral area face was treated with the Lumenis ActiveFx with settings (Energy) 125 mJ (Rate) 125 Hz CPG 3/5/3, while the right side was treated with the Deka SmartXide with settings *(*Power) 30W Dot Mode Spacing 400 µm Scanning well Time 1ms with 2 passes over each side. Although her rhytides were equal initially the patient and physicians felt her ActiveFx side responded the most in reduction of coarse lines. Her scoring for fine lines dropped from 3 to 1 for both lasers art Day 30. Her scoring for coarse lines dropped from 4 to 2 for ActiveFx and 4 to 3 for SmartXide at Day 30.

Patient FR: 1 month post Rx

Results

Both devices gave acceptable results and the patient was extremely happy with effect. There were some coarse lines left on the left upper lip but it is unsure if the lasers were used at equivalent setting for deeper effect.

Periorbital Rythides

Case 3: *Comparison in removal of periorbital rhytides by differing CO2 fractionalised lasers.*

The patient was a 53yo Caucasian male who presented with bilateral periorbital rhytides for treatment. He had a previous poor response with fibroblast transplanting (Isolagen) into the area and he was an intermittent Botox user. It was decided to treat different areas with the two lasers. The right eye was randomly treated with the

Lumenis ActiveFx with settings (Energy) 100 mJ (Rate) 125 Hz CPG 3/5/2, while the left eye was treated with the Deka SmartXide with settings (Power) 30W Dot Mode Spacing 200 µm Scanning well Time 500 µS with 2 passes under eye

SmartXide RE before treatment

SmartXide RE on Day 4


SmartXide RE on Day 14


SmartXide RE on Day 30

Patient CM : Right Eye SmartXide treated (Power) 30W Dot Mode Spacing 200 μm Scanning well Time 500 μS 2 passes under R eye with obvious reduction in rhytides

The right eye was treated with the Lumenis ActiveFx with settings (Energy) 100 mJ (Rate) 125 Hz CPG 3/5/2.

ActiveFx before treatment

ActiveFx RE Day 4

ActiveFx RE Day 30

Results
Both lasers gave good effect at Day 30 with a global reduction of 13 at Day 0 to 9 at Day 30. The patient felt that the SmartXide gave a preferable aesthetic effect in the infraorbital area and marked this accordingly.

Periorbital Rhytides (cont'd)

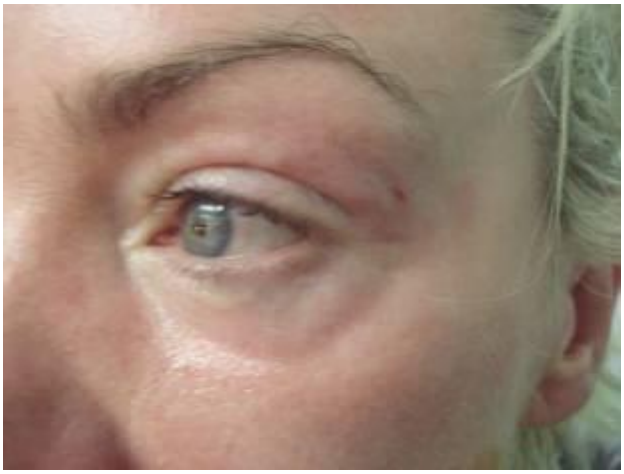
Case4: *Comparison in removal of periorbital rhytides by differing CO2 fractionalised lasers.*

The patient was a 39yo Caucasian female who presented with bilateral periorbital rhytides for treatment. She had a previous treatment with Dysport 35u bilaterally. It was decided to treat different areas with the two lasers. The right eye area was treated with the Lumenis ActiveFx with settings (Energy) 100 mJ (Rate) 125 Hz CPG 3/5/2, while the left eye area was treated with the Deka SmartXide with settings *(*Power) 30W Dot Mode Spacing 400 µm Scanning well Time 500 µS with 2 passes under eye

Patient AT *: Each periorbital area was randomly assigned to receive treatment with one of the two CO2 lasers.*

(L side) SmartXide *treated (Power) 30W Dot Mode Spacing 400 µm Scanning Dwell Time 500 Ms*

L eye SmartXide Day 1


L eye SmartXide Day 4


*L eye SmartXide Day **30***

***Patient AT** : Each periorbital area was randomly assigned to receive treatment with one of the two CO2 lasers.*

***(R side) ActiveFx** treated (Energy) 100 mJ (Rate) 125 Hz CPG 3/5/2*


R eye ActiveFx Day 1


R eye ActiveFx treated Day 3


R eye ActiveFx Day 30


Comparison RE/LE Day 2


Comparison RE/LE Day 30

Results

This patient received good effect from each laser at Day 30 with a global reduction of 10 at Day 0 to 6 at Day 30. The patient achieved the same Global Score reduction bilaterally for both the ActiveFx and SmartXide at Day 30. The patient also felt both devices gave similar effects in terms of perceived, erythema, pain and desired aesthetic effect.

HISTOLOGY

Image A is PN S14306/07 A immediate post procedure

***SmartXide** treated (Power) 30W Dot Mode Spacing 400 µm Scanning Dwell Time 500 Ms*

Laser penetration depth 113 mm

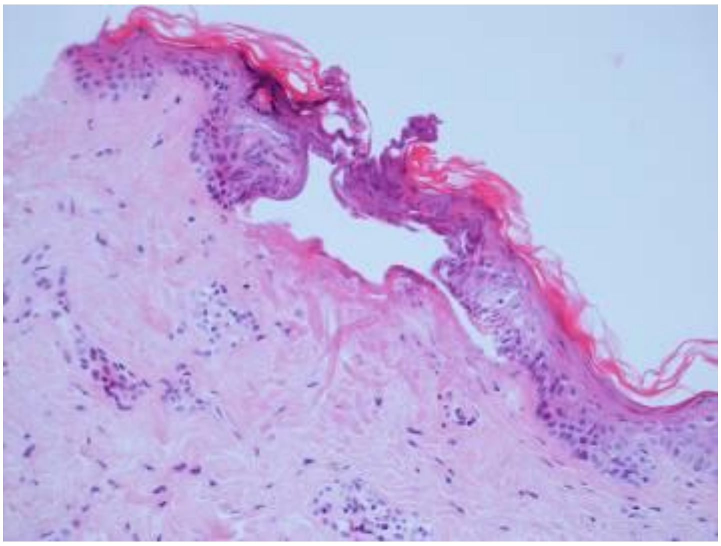


Image B - is NMcG S479/08 B immediate post procedure

***ActiveFx** treated (Energy) 100 mJ 9.4J/cm2 (Rate) 125 Hz 18.8W CPG 3/5/2/*

Laser penetration depth 85 mm

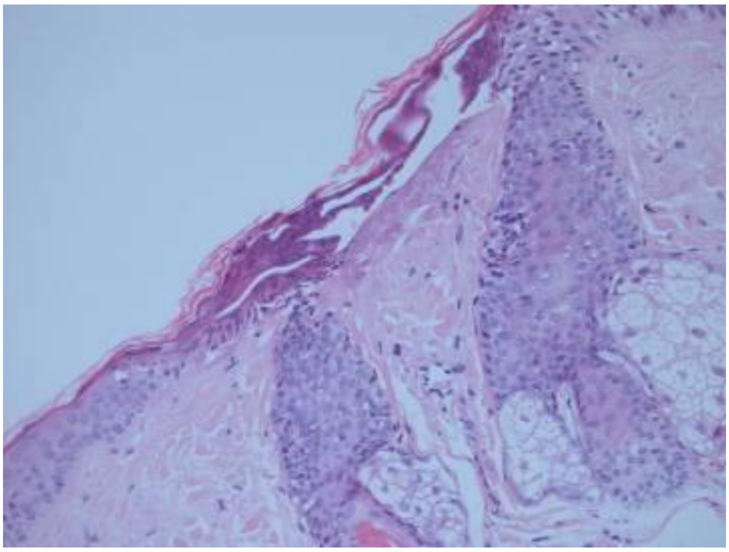


Image C is NMcG S479/08 B Three months post procedure

***ActiveFx** treated (Energy) 15-30W 125 mJ 9.4J/cm2 (Rate) 125 Hz 18.8W CPG 3/5/2/*

Laser penetration depth reported as 700 mm ? new collagen formation seen at this level

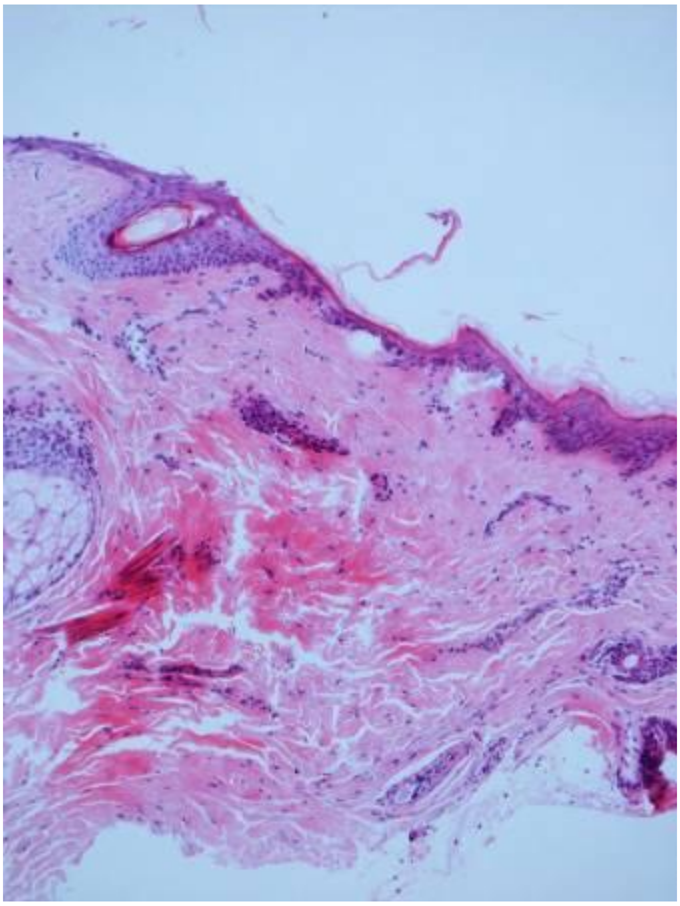


Image D1 is EK S14304/07 immediate post procedure
***SmartXide** treated (Power) 30W Dot Mode Spacing 300 µm Scanning Dwell Time 500 µS*

Laser penetration depth 113 nm

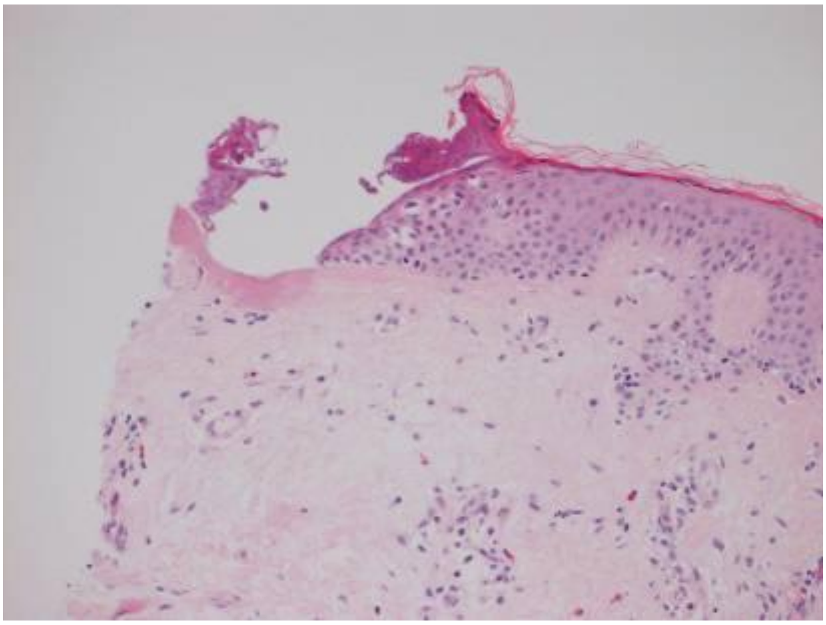
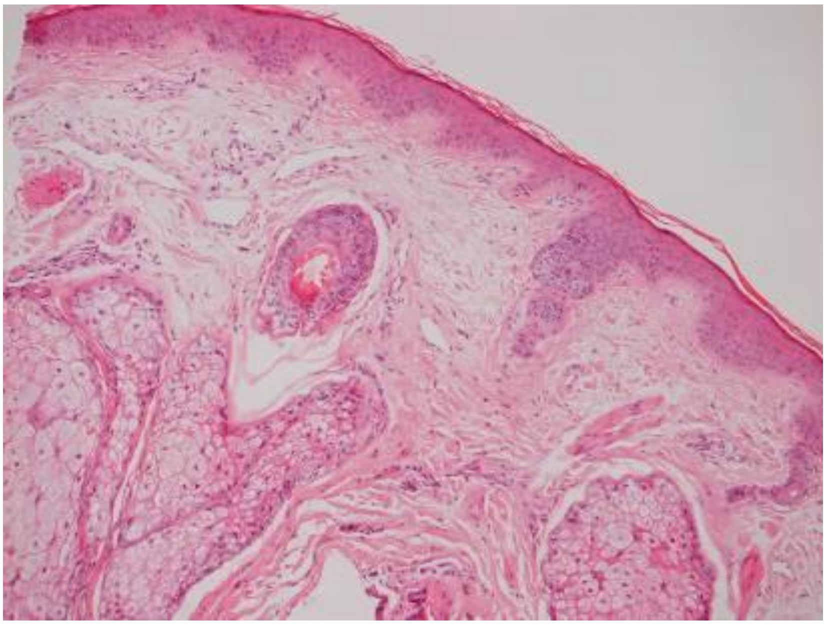


Image D2 is EK S14304/07 B Three months post procedure
***SmartXide** treated (Power) 30W Dot Mode Spacing 300 µm Scanning Dwell Time 500 µS*

Laser penetration depth 113 nm



All skin biopsies in this study show effect of thermal treatment with thermal coagulation of epidermis and superficial dermis in a depth ranging from 85 to 113 microns. Many studies show the zone of residual thermal (coagulative) damage can extend a further 20 to 120 µm, depending on the particular laser variables used.[14-16] This was particularly evident in Patient C where the thermal effect appears to be more diffuse than focal and the evidence of effect was still measured at 700 microns, although this reflected a vague diffuse thermal effect as compared with the more localized usual effect. Because the various CO2 lasers currently available differ in their biophysical properties, their documented depth of histological ablation and thermal effects vary.[15-16] Indeed, some studies, show a progressively increasing zone of thermal damage with each subsequent laser pass, whereas others do not consistently find this to be true.

RESULTS:

The two CO2 lasers (Lumenis ActiveFx Deka SmartXide) appeared to produce equivalent clinical improvement of lesions and rhytides. Re-epithelialization occurred in all laser treated areas by both devices by day 7and this appeared to be similar for both lasers. Mean duration of reepithelialization was 6.9 days after resurfacing (range, 4-10 days). This appeared to be in keeping with previous studies [11]. All patients reported having no crusting effect remaining on their face after 6 days. Residual erythema remained for a period of 14 days but this was minimal (mean decreased from 4.1 on day 3 to 0.9 at day 14). Postoperative erythema was most intense in the areas treated by SmartXide whenever the dwell time was increased up to 1ms. This effect was also noted with the ActiveFx at the energy level above 125Mj. While postoperative erythema intensity differed slightly between laser systems, (ActiveFx 0.9 at Day 14 SmartXide 0.7 at Day 14) little research benefit could be drawn from this at this time as we did not know comparative settings and total duration of erythema was equivalent. Of more interest was the result mean erythema was slightly higher for the ActiveFx at day 4. (ActiveFx 4.2 at Day 14 SmartXide 3.6 at Day 14) giving better patient satisfaction with the SmartXide device at that time.

Most patients said they could use camouflage make up (Glo Minerals® Medium Honey with Bismuth and Zinc Oxide) to cover up the erythema on Day 4-5. No significant sex differences in the duration of reepithelialization, erythema or in the histopathologic changes were noted. Because the patient re-evaluations obtained one week later did not reveal much epidermal healing regarding the Global Score, this data was not discussed in detail with the patient as it might tend to influence the outcome of the study. One patient complained about the overall SmartXide effect and was asked to present for more treatment.

The mean pain sensation felt during the treatment was 3.4, surprisingly higher than other studies, despite the deliberate use of regional anaesthesia to cover most of the facial area. [1]. It was felt this occurred in the topical areas due to the slightly higher laser parameters used. We noted most patients do not really feel pain with the ActiveFx until the proceduralists crosses 100mj. Some patients required ice-packs after experiencing a mild ‘burning’ effect after the procedure but none required analgesia to take home. It was also felt that more experience with the SmartXide laser could allow more advantage to be taken of longer dwell times to achieve deeper papillary dermal effect and thereby increase neocollagenesis.

All patients received generally only one pass with both laser devices. This physician felt the setting of the Dot Mode Spacing 200-300 μm appeared to give preferable epithelial coverage compared to the ActiveFx. However, in some cases two or more passes were performed if deemed necessary to allow overlap and fill in missed edges. In each case the erythematous effect appeared similar at Day 3 and Day 5 for both devices. I am aware that the adoption of the single-pass technique by many physicians related to earlier non-fractionalised devices in order to reduce the morbidity associated with CO_2 laser treatment. [15-16]. Limiting the depth of penetration also decreases the risk of scarring and permanent pigmentary alteration. However, during the period of the study, the author became quite comfortable using the SmartXide with longer dwell time, reduced spacing and selective use of double passes, particularly in the upper lip and lateral periorbital areas of some patients outside the study to achieve better aesthetic effect. In general, thinner periorbital skin normally requires fewer laser passes but the authors also felt comfortable enough to double pass patients with the SmartXide in this area.

Postinflammatory hyperpigmentation was not noted in any of the patients. Fifteen patients were classified as Fitzpatrick skin type I and other ten as Fitzpatrick skin type I1. Three patients sustained a global facial herpetic infection. From the authors wider experience in a yet unpublished paper, more people (10%) appeared to have suffered herpetic infections with the ActiveFx than the SmartXide although this could be considered to be due to the number of patients treated rather than for other reasons. It is also of interest, that nearly all of the patients who sustained these herpetic infections in this study had their necks treated with the ActiveFx. We had not performed this procedure on SmartXide patients as we unsure of the settings for this region. With the Lumenis ActiveFx device, the neck was also treated to further blend in the treated area with non-treated, adjacent photodamaged skin as well as improve the superficial textural quality of the neck skin. We thought it preferable not to treat any of the SmartXide patients until we got proper setting for this part of the anatomy.

No patient experienced any adverse reaction to laser skin resurfacing outside herpetic infection and 92% of patients were satisfied with their final aesthetic outcome. Mean patient age was 53 years (range, 43-74 years).

Previous histological studies3-9 demonstrated that 50 to 150 µm of skin may be ablated with a single pass of a CO_2 laser.[11-13] All skin biopsies in this study show effect of thermal treatment with thermal coagulation of epidermis and superficial dermis in a depth ranging from 85 to 113 microns. This was similar in both lasers with the SmartXide consistently getting below 100 µm. Many studies show the zone of residual thermal (coagulative) damage can extend a further 20 to 120 µm, depending on the particular laser variables used.[14-16] This was particularly evident in Patient C where the thermal effect appears to be more diffuse than focal and the evidence of effect was still measured at 700 microns, although this reflected a vague diffuse thermal effect as compared with the more localized usual effect. Because the various CO_2 lasers currently available differ in their biophysical properties, their documented depth of histological ablation and thermal effects vary.[15-16] Indeed, some studies, show a progressively increasing zone of thermal damage with each subsequent laser pass, whereas others do not consistently find this to be true. [11]

The global score for photoageing for both devices improved from 13.8 at baseline to 9.6 at Day 30. The score for fine lines was the most significant reduction dropping form 3.6 at baseline to 1.4 at Day 30. The score for sallowness was the most difficult to interpret at Day 30 as the patients still had some mild erythematous effect. Scores for reduction of coarse wrinkles (3.2 at baseline to 2.2 at Day 30) was also difficult to interpret in this heterogeneous age grouping with older patients requiring the deeper penetrating 'harder' MaxFx rather than the 'softer' ActiveFx and it is apparent that Lumenis are presently working on a combination therapy to solve this problem.

Both authors and patients felt the SmartXide appeared to work faster, covered a greater area and have a more sophisticated CPG effect. This is probably because it is a dedicated skin laser rather than a development of a previous device as is the ActiveFx. However, the lack of an internal exhaust device to remove the laser plume is a distinct disadvantage. The authors know from another unpublished paper that the Lumenis Encore ActiveFx was the recent preferred option to satisfactorily treat a giant congenital nevus at higher settings. If fractionalised laser skin resurfacing (FLSR) with minimal downtime is now considered the new method of softly treating patients for minor skin conditions such photoageing then the SmartXide DOT has cost advantages to the operator. It has yet to be established whether this will be in multiple sessions or not. If the physician requires to treat patients with deeper facial rhytides or other pathology in a one off session then the ActiveFx appears to have these advantages.

.

References

1. Matteo Tretti Clementoni [a]; Patrizia Gilardino [a]; Gabriele F. Muti [a]; Daniela Beretta [b]; Rossana Schianch. Non sequential fractional ultrapulsed C02 resurfacing of photoaged skin. Journal of Cosmetic and Laser Therapy, Volume 9, Issue 4 2007 , pages 218 – 225

2. Sadick NS. Update on non-ablative light therapy for rejuvenation: A review. Lasers Surg Med. 2003;32:120–8.
3. Williams EF III, Dahiya R. Review of nonablative laser resurfacing modalities. Facial Plast Surg Clin North Am. 2004;12:305–10.
4. Grema H, Greve B, Raulin C. Facial rhytides – subsurfacing or resurfacing? A review. Lasers Surg Med. 2003;32:405–12.
5. Manuskiatti W, Fitzpatrick RE, Goldman MP. Long-term effectiveness and side effects of carbon dioxide laser resurfacing for photoaged facial skin. J Am Acad Dermatol. 1999;40:401–11.
6. Fitzpatrick RE, Goldman MP, Satur NM, Tope WD. Pulsed carbon dioxide laser resurfacing of photo-aged facial skin. Arch Dermatol 1996;132:395–402.
7. Hamilton MM. Carbon dioxide laser resurfacing. Facial Plast Surg Clin North Am. 2004;12:289–95.
8. Fitzpatrick RE. CO2 laser resurfacing. Dermatol Clin.2001;19:443–51.
9. Fitzpatrick RE. Maximizing benefits and minimizing risk with CO2 laser resurfacing. Dermatol Clin. 2002;20:77–86.

10. Hruza GJ, Dover JS. Laser skin resurfacing. Arch Dermatol 1996;132:451–455.
11. Lowe NJ, Lask G, Griffin ME, Maxwell A, Lowe P, Quilada F. Skin resurfacing with the Ultrapulse carbon dioxide laser. Observations on 100 patients. Dermatol Surg 1995;21:1025–1029.
12. Lask G, Keller G, Lowe N, Gormley D. Laser skin resurfacing with the SilkTouch flashscanner for facial rhytides. Dermatol Surg 1995;21:1021–1024.

13. Taylor CR et al: Photoaging/photodamage and photoprotection. *J Am Acad Dermatol* **22**:1, 1990
14. Lavker RM: Cutaneous aging: Chronological versus photoaging, in *Photodamage*, edited by Gilchrest BA. Cambridge, MA, Blackwell Science, 1995, p 123
15. Nanni CA, Alster TS. Complications of carbon dioxide laser resurfacing. An evaluation of 500 patients. Dermatol Surg 1998;24:315–320.
16. Bernstein L, Kauvar A, Grossman M, Geronemus R. The short and long term side effects of carbon dioxide laser resurfacing. Dermatol Surg 1997;23:519–525.
17. Alster T, Hirsch R. Single-pass CO2 laser skin resurfacing of light and dark skin: Extended experience with 52 patients.J Cosmet Laser Ther 2003;5:39–42.
18. Alster TS. Cutaneous resurfacing with CO2 and erbium: YAG lasers: preoperative, intraoperative, and postoperative considerations. *Plast Reconstr Surg*. Feb 1999;103(2):619-32; discussion 633-4
19. Alster TS. Side effects and complications of laser surgery. *In Alster TS: Manual of Cutaneous Laser Techniques, ed 2. Philadelphia, Lippinco*. 2000;pp 175-187.
20. Alster TS, Lupton JR. Treatment of complications of laser skin resurfacing. *Arch Facial Plast Surg*. Oct-Dec 2000;2(4):279-84.
21. Sullivan SA, Dailey RA. Complications of laser resurfacing and their management. Ophthal Plast Reconstr Surg.2000;16:417–26.
22. Berwald C, Levy JL, Magalon G. Complications of the resurfacing laser: Retrospective study of 749 patients. Ann Chir Plast Esthet. 2004;49:360–5.
23. Trelles MA, Mordon S, Svaasand LQ, et al. The origin and role of erythema after carbon dioxide laser resurfacing: a clinical and histologic study. *Dermatol Surg.* 1998;24:25-30.

24. Burkhardt BR, Maw R. Are more passes better? safety versus efficacy with the pulsed CO_2 laser. *Plast Reconstr Surg.* 1997;99:1531-1534.

25. Bjerring P. Photorejuvenation – an overview. Med LaserAppl. 2004;19:186–95.
26. Treacy PJ. Article on fractionalised lasers Jan 2008 Health & Living Magazine www.hlaw.ie
27. David Goldberg, MD: Reduced Down-time Associated with Novel Fractional UltraPulse CO2 Treatment (Active FX) as Compared to Traditional Resurfacing P3115 -65th Annual American Academy of Dermatology Meeting
28. Smith KJ, Skelton HG, Graham JS, et al. Depth of morphologic skin damage and viability after one, two and three passes of a high-energy, short-pulse CO_2 laser in pig skin. *J Am Acad Dermatol.* 1997;27:204-210.

29. Fitzpatrick R, Ruiz-Esparaza J, Goldman M. The depth of thermal necrosis using the CO_2laser. *J Dermatol Surg Oncol.* 1991;17:340-344.

30. Dover JS, Bhatia AC, Stewart B, Arndt KA. Topical 5-aminolevulinic acid combined with intense pulsed light in thetreatment of photoaging. Arch Dermatol. 2005;141:1247–52.

31. Tina S. Alster MD & Christopher A. Nanni MD Famciclovir Prophylaxis of Herpes Simplex Virus Reactivation After Laser Skin Resurfacing *Dermatol Surg* Volume 25 Issue 3 Page 242-246, March 1999

32. *Mario A. Trelles; Inés Allones* Red light-emitting diode (LED) therapy accelerates wound healing post-blepharoplasty and periocular laser ablative resurfacing *Journal of Cosmetic and Laser Therapy: formerly Journal of Cutaneous Laser Therapy*, Volume 8, Issue 1, 2006, Pages 39 – 42

33. Kauvar ANB, Waldorf HA, Geronemus R. A histopathologic comparison of char-free lasers. *Dermatol Surg.* 1996;22:343-348.

34. Cotton J, Hood A, Gonin R, Beeson W, Hanke C. Histologic evaluation of preauricular and postauricular skin after high-energy, short-pulse carbon dioxide laser. *Arch Dermatol.* 1996;132:425-428.

35. Rubach BW, Schoenrock LD. Histological and clinical evaluation of facial resurfacing using a carbon dioxide laser with the computer pattern generator. *Arch Otolaryngol Head Neck Surg.* 1997;123:929-934.

36. Fitzpatrick RE, Tope WD, Goldman MP, Satur NM. Pulsed carbon dioxide laser, trichloroacetic acid, baker-gordon phenol, and dermabrasion: a comparative clinical and histologic study of cutaneous resurfacing in a porcine model. *Arch Dermatol.* 1996;132:469-471.