

WHITE PAPER

SmartXide²

SMARTXIDE² DOT RF

IV Generation Resurfacing
Innovative, Combined Ablative/Non-ablative Method

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IV Generation Resurfacing
Innovative, Combined Ablative/Non-ablative Method

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Preface

"IV generation resurfacing" is a skin treatment procedure that exploits dual technology: a CO_2 Laser source and Bipolar Radio Frequency (RF). This device allows for coupling the emission of both sources to achieve, besides the well-known fractional CO_2 laser vaporization, an increase in controlled heat in the deeper skin layers with the RF emission.

Since RF is not affected by skin colour, it can be used on all skin types with no application limits for the different phototypes. This new device allows for balancing the total energy delivery between the RF (non-ablative) with the CO_2 (ablative) depending on the diagnosis and planned treatment. This exclusive characteristic of the new **SmartXide²** makes it possible, but still with the same results, to lower the ablative energy levels in favour of non-ablative energy that acts in-depth, meaning that high doses of total energy can be delivered while limiting thermal damage to the epidermis.

This method can also be used with phototype IV (Fitzpatrick skin type) patients which results in shorter recovery times and significantly superior results in terms of facial relaxation and glow.

Introduction

Today, skin resurfacing is still the gold standard for facial rejuvenation in patients with chronic diseases such as post-acne scars, chrono-aging, post-trauma scars, etc. (Table 1) that have a high incidence in the population.

This method evolved rapidly over recent years, undergoing three radical changes with the development of more and more sophisticated equipment. Dermabrasion, a "first generation" technique, was followed by "second generation" micro-ablative techniques with fractional CO_2 laser, and there are now devices that enable non-ablative resurfacing. This last method, called "third generation" has only ever given satisfactory results after an excessive number of sessions. Nonetheless,

Actinic Keratosis
Actinic Cheilitis
Seborrheic Keratosis
Post-acne Scars
Facial Wrinkles
Post-acne Scars
Photoaging and Chrono-aging

Table 1. CO_2 Resurfacing applications.

according to the American Society for Aesthetic Plastic Surgery (ASAPS) statistics, a positive trend can be observed for non-ablative methods. The percentage of non-ablative treatments rose from 85.9% in 2004 to 93.2% of all resurfacing procedures in 2006. So the question arises as to why patients decide to carry out treatments that could give disappointing results? Probably the answer lies in the fact that they prefer non-invasive procedures with fewer risks and shorter recovery times. Today, this is all guaranteed by a new system called SmartXide² with its innovative resurfacing that I would define as combined, that is, ablative and non-ablative (Fig. 1).

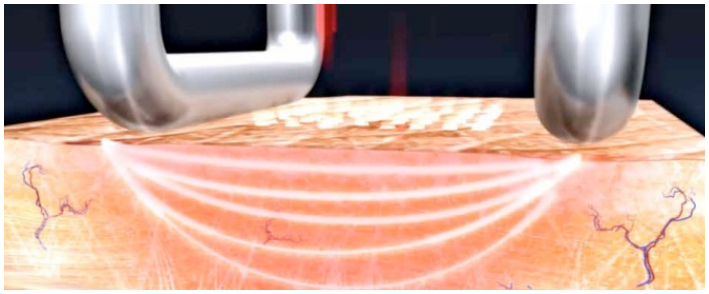


Figure 1. Combination of CO_2 and RF.

By combining a fractional CO_2 laser beam with RF bipolar emission, SmartXide² delivers a dose of total energy to the tissue that is the sum of the different energies supplied by these two sources: ablative (CO_2) and non-ablative (RF).

Microscopic columns of epidermis called MAZs, (micro-ablative zones) are removed by means of thermal ablation and photocoagulation, spaced apart from the healthy tissue and adjustable with the "Spacing" parameter (µm), thus allowing the operator to decide which fractions of tissue to vaporize. The intermediate healthy tissue acts as a cell reserve that undergoes biostimulation processes and favours the healing process of the micro wounds.

At the same time as the vaporization, the two strip-shaped electrodes resting on the skin generate a bipolar RF emission, causing volumetric skin heating and the desired "shrinkage" effect which is immediately visible and also at the 60-day follow-up.

By offering the ability of setting not only the power, but also the dwell time and DOT column spacing, the system allows to choose between various pulse modes such as **"S-Pulse"** or **"D-Pulse"** which direct the spreading of the heat produced by the vaporization on the surface and in-depth respectively. The RF can be also adjusted in terms of power (W) and duration (sec).

Materials and Methods: Description of the Device

SmartXide² (DEKA M.E.L.A., Calenzano, Italy) is a CO_2 laser with a wavelength of 10,600 nm and a beam produced by a stimulated radiofrequency source that is absorbed by the water in the tissues. The laser beam is delivered to the tissues through a jointed arm which has various handpieces attached to the end.

Its power varies from 0.1 to 40, 60 or 80W, depending on the model. A whole range of handpieces is available for the different surgical sectors.

The handpieces used in dermatology to treat skin lesions exploit a multi-function scanner called HiScan DOT/RF for combined resurfacing that emits a fractional laser beam with a scanning area of 15×15 mm, inside which dermal-epidermal vaporization columns are formed.

The geometric shapes and surfaces of this area can be adjusted directly from the handpiece. The device's new software allows the operator to vary several parameters including the scanning mode **(Normal, Interlaced or SmartTrack)**, and downtime from 100 to 2000µs, while the **"SmartStack"** function makes it possible to vary the repeated pulse emission from 1 to 5 on the same point (DOT), ensuring gradual penetration into the tissues. The spacing of the DOTs may vary between 0 and 2000 µm.

Two strip-shaped electrodes adapt to the skin surface, further delimiting the action area of each single emission. Via use of a "bipolar transmission-reception" system, the two electrodes emit radiofrequency outputs of up to 50 W.

The controlled and selective heating of the deep tissues, which amplifies and conveys the post-CO_2 vaporization thermal effect, causes "shrinkage" of the tissues.

The combination of this wide range of appropriately set parameters has excellent clinical results on the tissues with negligible thermal damage, significantly reducing the post-op recovery times.

	0	1	2	3	4
Fine lines	No evidence	Rare, widely spaced	Several, fine	Moderate in close proximity	Many, densely packed
Tactile roughness	Smooth skin	Smooth skin with occasional rough areas	Mild roughness	Mild roughness	Severe roughness
Coarse wrinkles	No evidence	Superficial in one area	Superficial on more than one area or moderate on one	Moderate on more than one area or deep in one	Deep on more than one area

Table 2 Modified Dover et al. scale.

Purpose of the Study

The purpose of this clinical study is to describe the use of a device with a dual CO_2 and RF laser emission source that performs combined ablative and non-ablative fractioned resurfacing, defined by the author as "IV generation" resurfacing.

The study also analyses the preliminary results obtained from a cohort of 24 patients, of which 50% suffered from atrophic post-acne scars and 50% from facial wrinkles due to chrono-aging.

Finally, it investigates the technical aspects for ensuring correct, simple, and safe application.

Study Plan

From March 2011 until May 2011, 24 patients (23 females and 1 male) participated in this study. 12 patients suffered from atrophic post-acne scars (11 females and 1 male), and 12 patients, all females, suffered from facial wrinkles due to chrono-aging. The age range varied from 21 to 74 years with a mean of 48.5 years, the phototypes varied from II to IV according to Fitzpatrick.

A five-point scale formulated by Dover et al. (adapted in this study) was used to assess the degree of chrono-aging and the results of patients suffering from facial wrinkles (Table 2). Three skin aging variables were assessed: fine lines, tactile roughness and coarse wrinkles (Fig.2).

The patients with post-acne scars were selected depending on the presence of "atrophic" lesions on the cheeks and side of the chin, simultaneously present in the various ranking subgroups: Ice pick, Box car and Rolling scar (Fig. 3).

All patients signed an informed consent agreement before being included in the protocol.

The type of procedure was addressed in-depth during the anamnesis to ensure patients had realistic expectations regarding the results, and potential side effects such as hyperpigmentation, hypopigmentation, transitory or permanent changes of skin texture, and scarring.

The exclusion criteria for the study were also defined and differentiated in absolute or relative: topical treatments with retinoic acids, steroids, azelaic acid, isotretinoin, six months before the operation; local injection local therapies such as fillers with hyaluronic

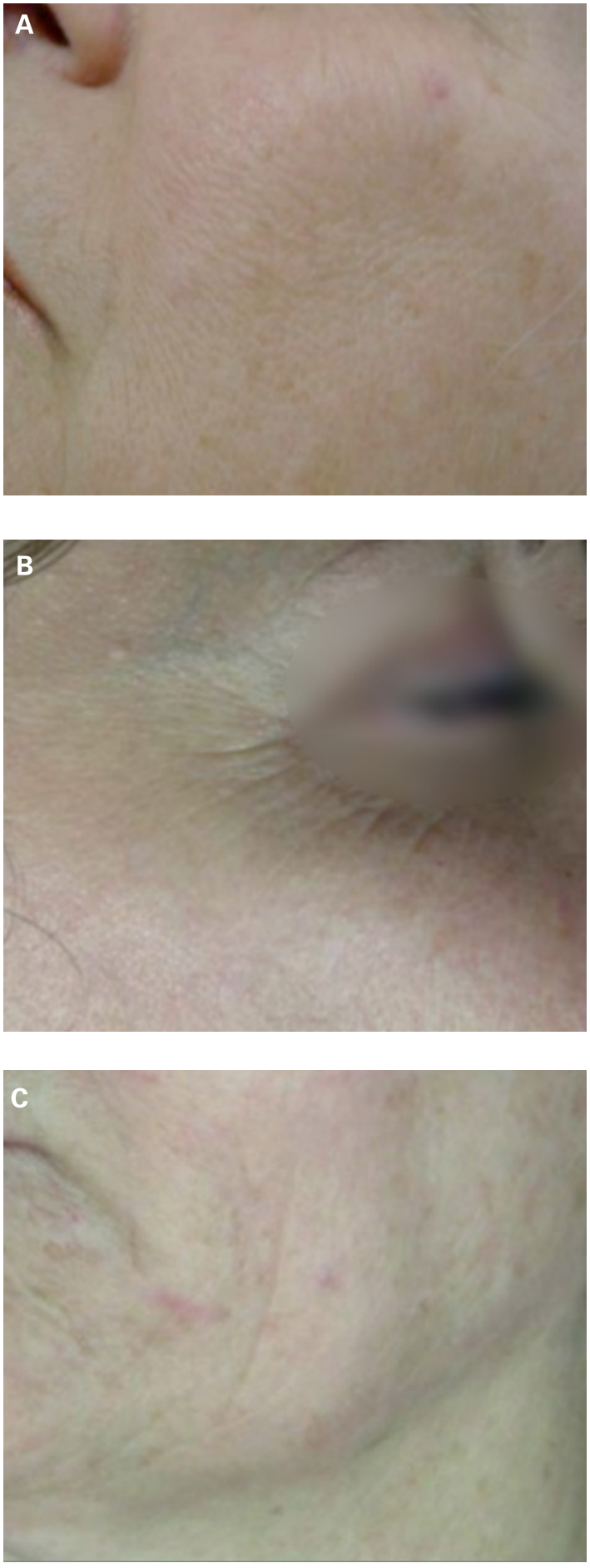


Figure 2. **(A)** Fine lines; **(B)** Tactile roughness; **(C)** Coarse wrinkles.



Figure 3. **(A)** Box car, Rolling scar; **(B)** Ice pick.

Absolute	Relative
Topical Retinoics	Vitiligo
Topical Steroids	Scleroderma
Depigmentation	Recent Radiotherapy
Pregnancy, Dysmetabolic Syndromes	
Recent Peelings	
History of Keloids	
Recent Infection from Herpes Virus	
Infective Diseases	
Anti-coagulative Therapies	
Autoimmune Illnesses	
Thyroid Diseases	
Neoplasia	
Pacemaker	

Table 3. CO_2 Resurfacing Applications.

acid, botulinic toxins and biostimulants, twelve months beforehand. Patients treated with a photo-rejuvenating Laser or IPL procedures twelve months beforehand were excluded as they would have distorted the significances of the entire study (Table 3).

patients were photographed before (T0) and after the treatment (T1). The photographic follow-up continued

T0	Before treatment
T1	After one treatment
T2	Three-day follow-up
T3	Seven-day follow-up
T4	Thirty-day follow-up

Table 4.

for three days (T2), seven days (T3) and thirty days (T4) afterwards.

It is generally accepted that in case of skin lesions, the microbial load should be kept as low as possible since bacteria inhibit the healing processes. For this reason, all patients were treated with a systemic antibiotic prophylaxis with the administration of one 1-g tablet of Amoxicillin/Clavulanic Acid every 12 hours for 5 days, starting two days before treatment.

The antiviral prophylaxis for Herpes Simplex (HSV1) which in re-infections has a 3-9-day incubation, consisted of the administration of one 400-mg tablet of Acyclovir every 8 hours for 5 days also starting two days before treatment.

Only one patient with an anamnesis of recurrent retronuchal mycosis was treated with Fluconazole for seven days starting three days after treatment.

In all cases we preferred to carry out a double prophylaxis since clinical findings have demonstrated that this is useful for the patient's safety as well as for medical-legal reasons.





Figure 4. (A) Before surgery; **(B)** After surgery.

In order to calm any pre-treatment anxiety and sedate severe post surgery pain, the study also envisaged the administration of Diazepam 10 mg orally 30 min. beforehand and one vial of Toradol 30 mg respectively, although no patients required this treatment.

Treatment

On the day of treatment, the patients arrived with clean faces and no makeup. 45 minutes before starting the combined resurfacing they were asked to remove all metal items. After cleansing the face again with a non-alcoholic detergent, a layer of topical anaesthetic was applied in the form of a Vaseline ointment containing benzocaine 20%, lidocaine 6% and tetracaine 4% in occlusive buffers. An elastic head band was applied to keep the hair, previously sprayed with thermal water, out of the operating field during treatment. This also helps prevent involuntary movements that could expose the patient to the risk of burning due to the shifting of the electrodes during the RF emission, as we will see below.

After removing the anaesthetic with sterile gauze soaked in cold saline solution, the operating bed was lowered until the patient was in a supine position.



Figure 5. Post-treatment medication.

Stac	1, 2 and 3
Mode	D-Pulse and S-Pulse
Energy per pulse	**15, 30, 45 and 60 mJ**
RF Energy	90, 40, 10 J and RF Off

Table 5.

The operator sat next to the patient's head; in this position, besides ensuring maximum patient comfort it is also possible to control of the stability of the head, necessary for performing this new procedure in safety. With the appliance placed on the same side as the physician's hand holding the handpiece, "full face" scanning is started. The treatments take about 30 minutes.

During the emission of energy in the single scanning operations with the HiScan DOT/RF system, it is important to remember that the RF emission is combined with the CO_2 laser beam that causes vaporization. For these two electrodes to work correctly and fit perfectly against the skin surface, a slight pressure must be exerted with no interruptions in the transmission between the RF emission phases. The skin acts as a carrier.

Moreover, the electrodes must be kept constantly wet by placing gauze soaked in saline solution near the scanner, or by applying the special wet sponges supplied with the system to the electrodes. This simple action ensures contact of the skin surfaces with the forks throughout the entire process. The area around the eyes and nose and any cavities are treated without RF emission since excessive folds make it difficult to correctly position the scanner's electrodes on the skin. Special attention is paid to these apparently insignificant technical aspects since

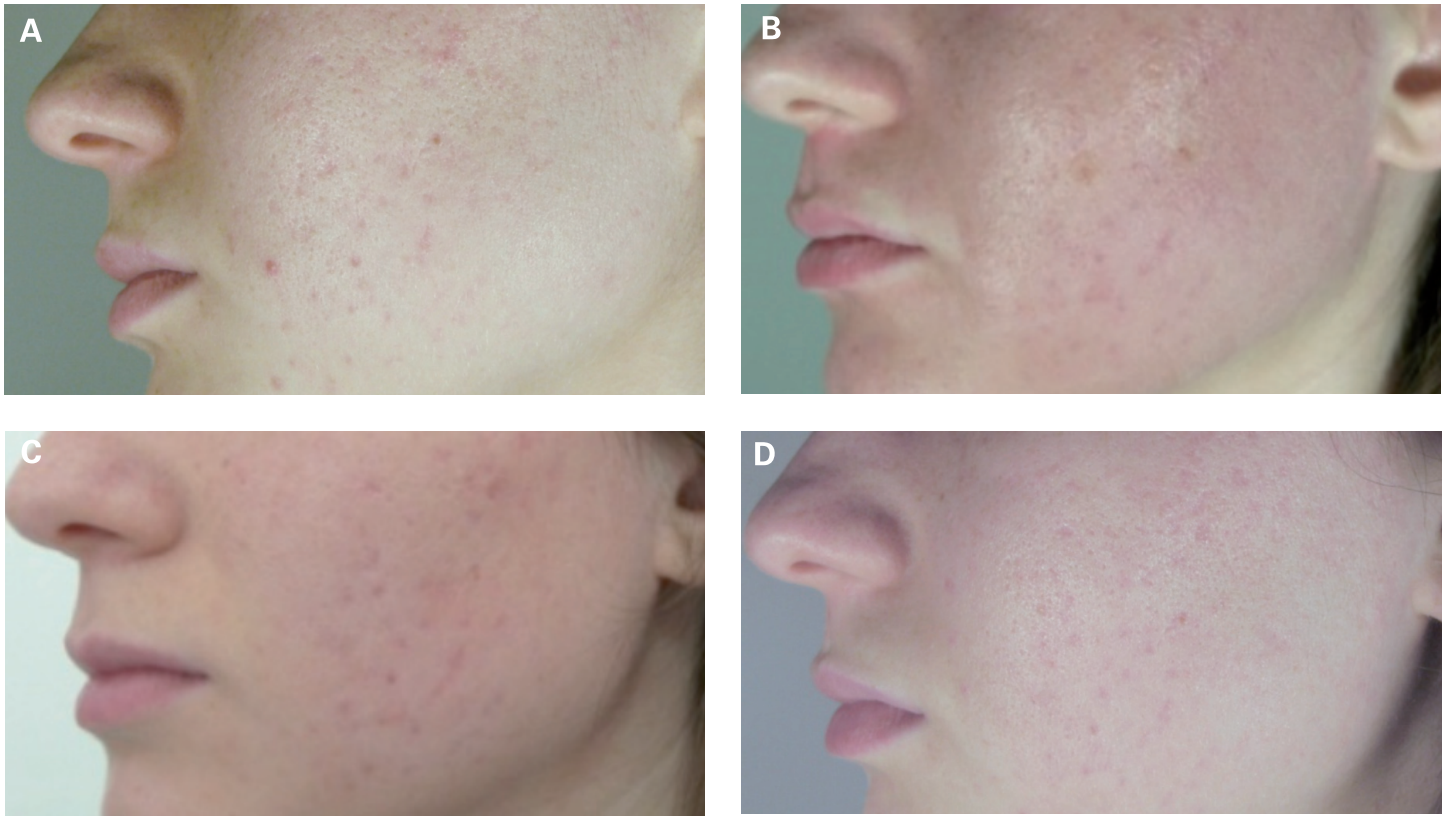
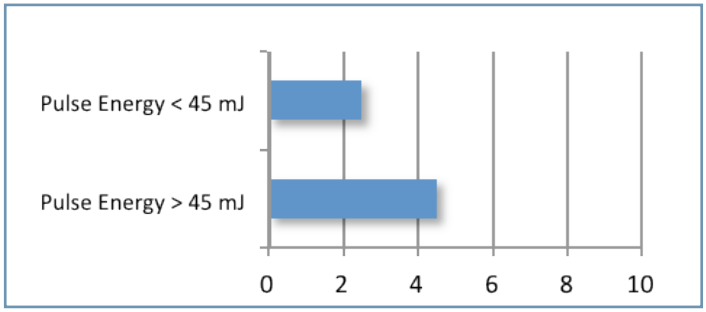


Figure 6. (A)-(B)-(C)-(D) Clinical case no. 1 - T0, T1, T2 and T4. Patient aged 21, phototype II, atrophic acne. Laser CO_2: Dwell Time 1000 µs, Spacing 500 µm, Pulse Energy 30 mJ, Stack 2, S-Pulse. RF: Power 10 W, 1 sec. Downtime 3 days.

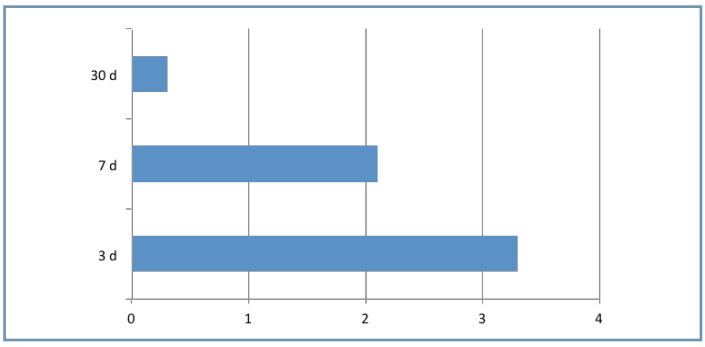
incomplete adherence of the entire surface of one of the electrodes on the skin when using high powered RF and without the aid of sponges could cause an increase in the fluence, with excessive overheating of the skin and the risk of burns (Fig. 4). Immediately after every scanning there will be a greyish coloration of the epidermis that turns pearlescent; this is the sign of fractioned epidermolysis caused by the vaporization which also helps delimit the surfaces progressively treated. After a few minutes, the treated area becomes erythematous which allows for ensuring correct overlapping of the scanning. It is recommended not to remove this tissue layer either before or after treatment even though it is vaporized tissue since it acts as a biocompatible medication for the lesion. All patients reported slight burning associated with a swelling sensation approximately 10 minutes after starting treatment and once 30% of the face had been treated. These symptoms were moderate and associated with intense heat which was felt until the end of treatment. During treatment of the first six patients, a SmartCryo-type cryogen air-cooling device was used which according to patients, did not alter the compliance of the treatment. This device could help patients treated without a topical anaesthetic.



Graph 1. Pain index (0 – 9).

After treatment, all patients had extensive erythema and oedema and they reported intense heat and a swelling sensation all over the face (Fig.5).

These symptoms showed great improvement when sprayed continuously with "Aveene"-type thermal



Graph 2. Erythema index (0 – 4).

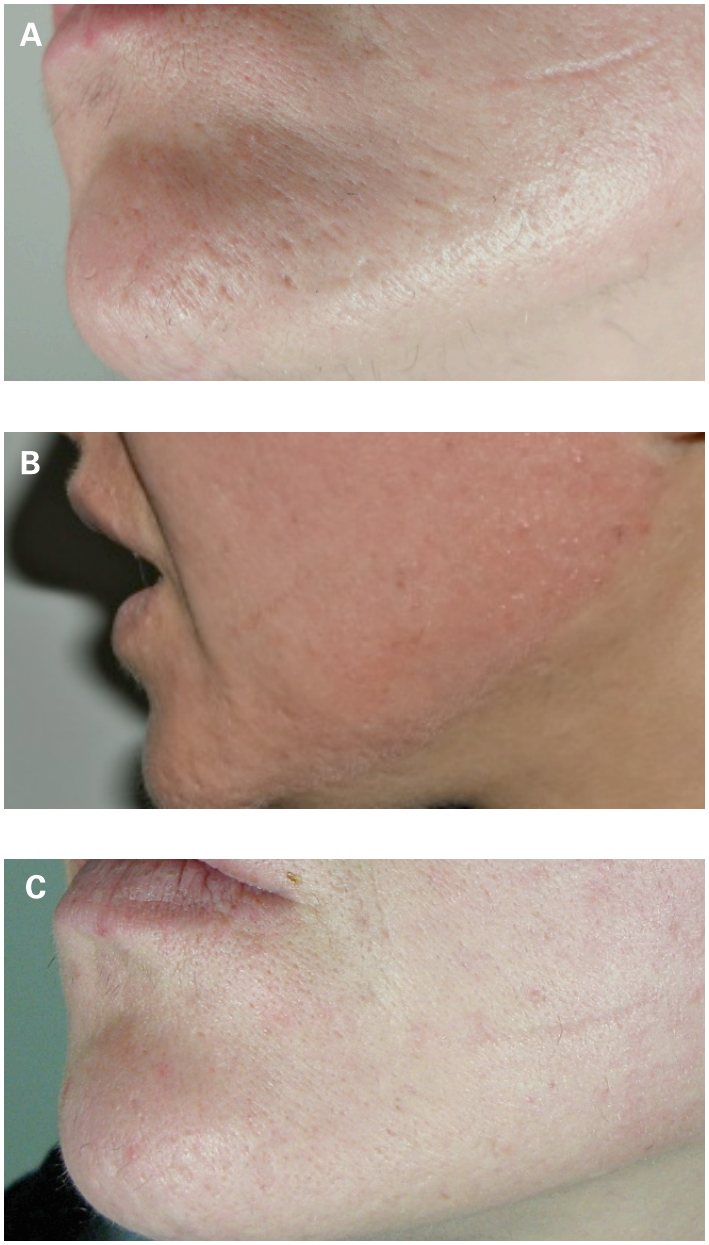


Figure 7. (A) - (B) - (C) Clinical case no. 2 - T0, T1 and T4. Patient aged 34, phototype III, "ice pick"-type scars Laser CO2: Dwell Time 1000 µs, Spacing 500 µm, Pulse Energy 60 mJ, Stack 2, D-Pulse. RF: Power 30 W, 3 sec. Downtime 5 days.

water combined with a low flow of cold air from the SmartCryo for about 15-20 minutes. Following, a cream containing 50% Gentamicin and 50% moisturiser (such as Biafin) previously diluted with thermal water in a sterile container, was applied with a brush to the entire surface (Fig. 6). This gave great relief from the side effects until they disappeared about 45 minutes after treatment. The application of a cream is prescribed as home therapy to be repeated four times a day for three days after treatment. It is also recommended to hydrate the skin with thermal water 8-10 times a day after treatment.

Choice of Parameters and Settings

As suggested in preliminary protocols, standardized setting changes should be made to compare the results at different energy levels. More specifically, variations to the following SmartXide² functions were exploited: A total of 24 combinations were created with these parameters, making it possible to vary the total energy delivered in various modes in favour of the laser rather than the RF. As can be observed, besides the power offered, SmartXide² also enables variations to the energy level delivered based on the Stack and Pulse-Mode functions. This innovation ensures extremely precise adapting of the energy value per DOT pulse to the patient's clinical conditions and disease to be treated.

Patients suffering from deep atrophic post-acne scars were treated in D-Pulse mode, since this mode enables deeper energy distribution in the skin, seat of the scarring process, compared to the S-Pulse mode.

Four patients (16.6%) had a prevalence of "ice pick" lesions (deep) and were treated by delivering a laser pulse energy equal to 60 mJ (with RF energy of 90, 40, 10 J and RF Off). It was observed that with the same level of laser energy, the RF power and duration (< 30 W - 30 sec) were indirectly proportional to the post-op erythema. Patients with more superficial scars and finer lines on the face were treated in S-Pulse mode with the various settings randomly assigned.

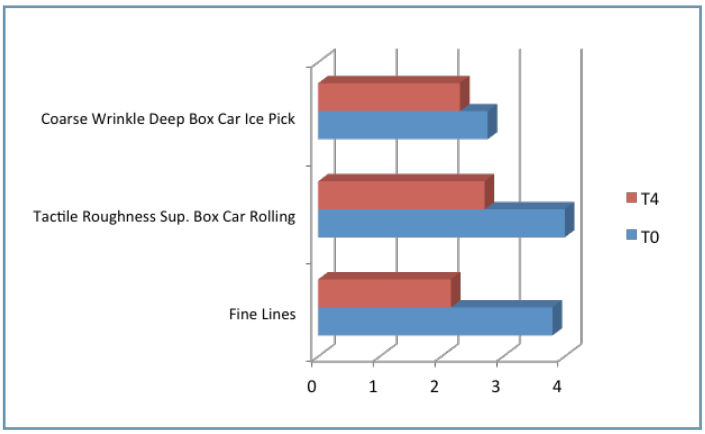
Results

A total of 24 patients completed the study and were evaluated by two doctors, a dermatologist and a surgeon. To quantify pain a 10-point scale was used where 0 was absence of pain and 9 was unbearable pain.



Figure 8. After 5 days of treatment .

Patients treated with laser energy higher than 45 mJ reported pain equal to 4-5 that lasted about 30 minutes after the end of treatment, while patients treated with energies below 45 mJ reported a pain level of 2-3. Only one patient reported 3-4 level pain that lasted more than 30 minutes, however systemic administration of analgesics was not necessary. Oedema was the most evident clinical sign in 21 patients (87.5%) on the 1st day after treatment, and in 10 patients (41.6%) on the 3rd day after treatment. All patients reported gradual peeling of the ablated epidermis that started with small punctiform scabs on the 3rd or 4th day (MENDs -minor epidermal necrotic debris) and disappeared in 18 patients (75%) on the 5th day after treatment. Only one patient (4.1%) had MENDs beyond the 7th day after treatment on the forehead close to the hairline (Fig.7). The post-op erythema was quantified according to a 5-point scale (0=no erythema, 1=slight erythema, 2=average erythema, 3=moderate erythema, 4=severe erythema). In T2 the mean erythema was 3.3 points dropped to 2.1 in T3, and to 0.3 in T4 (Graph 2).



Graph 3. Average improvement on the Dover scale (0 – 4).

The patients were assessed by two doctors, a dermatologist and a surgeon, neither of whom knew the other's evaluation. In patients with wrinkles, as per the Dover et al. scale (modified here), there was evident improvement in skin imperfections (Graph 3). For Fine lines, the score was 3.80 in T0 versus 2.15 in T4. For tactile roughness it was 4.0 in T0 versus 2.07 in T4 while for Coarse wrinkles it was 2.55 in T0 versus 2.30 in T4 ($p < 0.05$).

For all patients treated, the number of permanent complications in T4 was 0%. Out of all 24 treatments the only transitory complication was burning due to incorrect use of the HiScan DOT/RF handpiece possibly after removal of the electrodes from the skin during the RF emission, and in any case without the application of protective sponges.

This data show that by using the recommended parameters and with a total amount of laser energy not exceeding 60 mJ per DOT, evident improvement is achieved in skin texture in T4 due to a significant reduction of fine lines and tactile roughness after one session. The statistical data referring to coarse wrinkles and atrophic post-acne scars entails the need to repeat treatment at a follow-up not less than 60 days after the first treatment.

The data analysis also allows for introducing a new objective parameter that is very useful in clinical applications of this procedure: "The Minimum Energy Levels" required to produce significant clinical and statistical results clearly relatex to the diagnosis (Table 6).

	Minimal Pulse energy	T0 (Before)	T4 (30 gg)	Down Time
Fine Lines	30 mJ	3.80	2.15	3 days
Tactile Roughness/ Acne Scars*	45 mJ	4.00	2.70	3/5 days
Coarse Wrinkles/ Acne Scars**	60 mJ	2.75	2.30	4/6 days

Table 6. Mean improvement on the Dover scale (0-4).
* superficial or rolling box car ** deep or ice-pick box car

For clinical results in patients suffering from atrophic post-acne scars, the physicians' assessments were recorded on a percentile scale divided into four classes from "no improvement" to "excellent result": 0-25% no or minimal improvement; 26-50% slight improvement; 51-75% good improvement; 76-100% excellent improvement, on a test area that was either the cheeks or chin.

In T4, 4 patients (33,3%) reported excellent improvement, 7 patients (58,3%) reported good improvement, and 1 patient (8,3%) slight improvement. No patients reported no improvement (0%) (Graph 4).

Discussion

This study assessed the new device exploiting CO_2 Laser and Bipolar Radiofrequency, designed for skin rejuvenation and the treatment of scar outcomes with combined fractioned resurfacing. Current medical concepts and scientific literature, besides extolling the virtues of Fractioned Laser Resurfacing, also

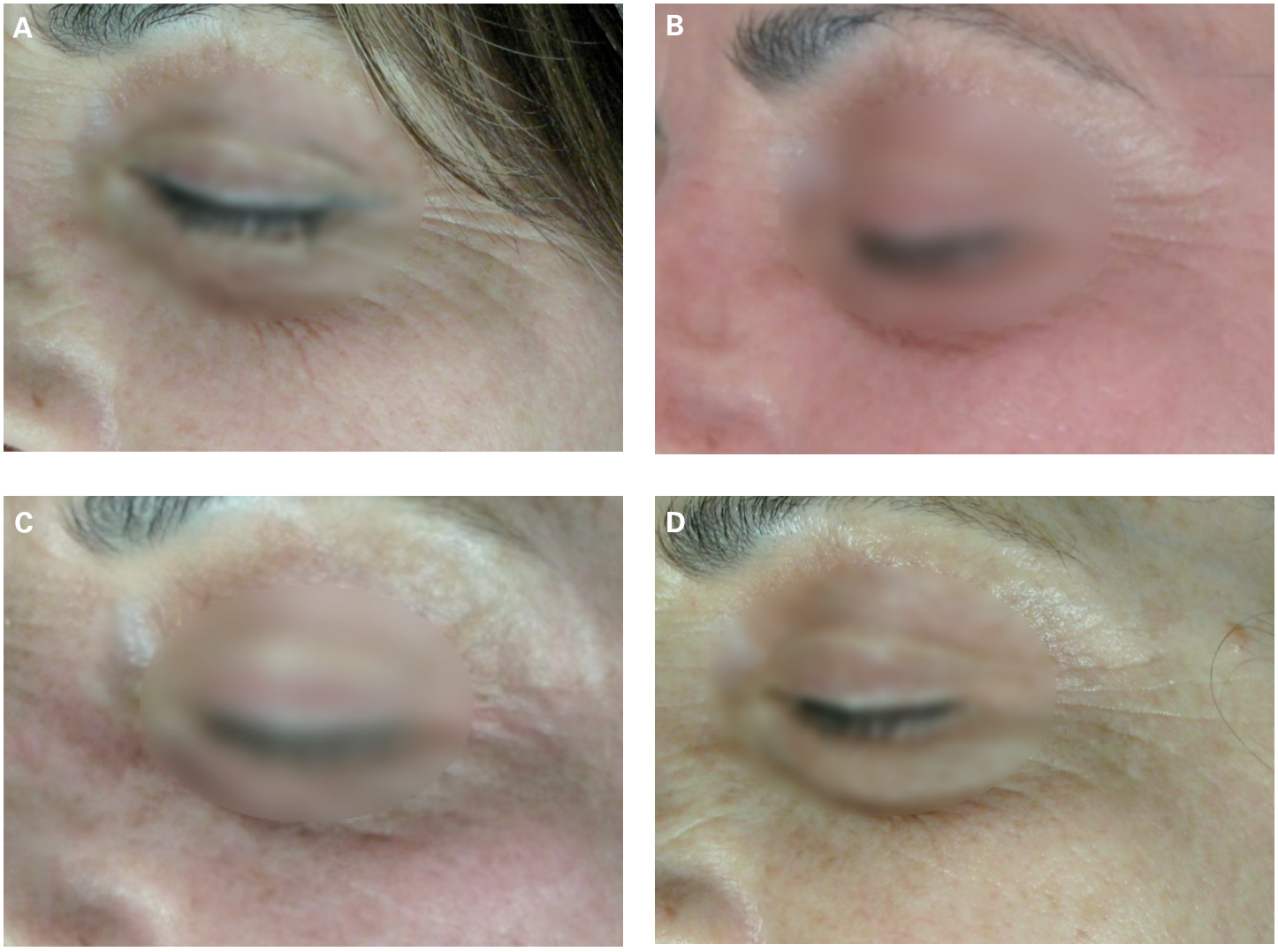


Figure 9. (A)-(B)-(C)-(D) Clinical case no. 3 - T0, T1, T2 and T4. Downtime 3 days Patient with wrinkles in area around the eyes, phototype II, Only CO_2 Laser: Dwell Time 1000 µs, Spacing 500 µm, Pulse Energy 45 mJ, Stack 3, S-Pulse.

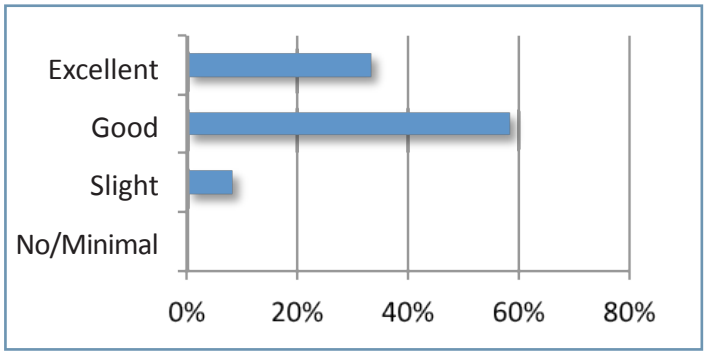
recommend the use of RF for non-ablative distension of the skin through volumetric heating of the deep derma. The SmartXide² system with the HiScan DOT/RF handpiece is able to provoke ablation, coagulation, necrosis and volumetric heating of the skin in just one emission.

We have demonstrated that by lowering the laser power and increasing the RF emission in terms of energy and exposure time, with the same mJ delivered, minimal skin damage is obtained with an average healing time of five days. The device is adjustable not only for balancing the two sources, but also for controlling the depth of tissue removed by ablation and the volume of coagulated tissue surrounding each single fraction.

It is possible to adjust the "grid" fractioning mode via which the HiScan DOT/RF hits the skin tissue, leaving more or less ample areas of only very mildly heated healthy tissue, the cells of which accelerate the healing processes.

In clinical terms, the effects obtained contribute to rejuvenating the skin, ensuring minimum side effects such as slight to moderate swelling, redness and heat sensation, which all cause very slight discomfort.

This technique is an additional evolution compared to other ablative and non-ablative technologies (Laser, RF, Pulsed Light) in which all the skin tissue is involved.



Graph 4. Index of improvement in T4 For atrophic post-acne scars.



Figure 10. (A)-(B)-(C)-(D) Clinical case no. 4 - T0, T1, T2 and T4 Patient with wrinkles on the neck, Phototype III Laser CO_2: Dwell Time 1000 µs, Spacing 500 µm, Pulse Energy 30 mJ, Stack 2, S-Pulse. RF: Power 30 W, 3 sec. Downtime 3 days.

The clinical assessments of the doctors who conducted the study and the feedback from the 24 patients undergoing treatment are clear indications of the safety of SmartXide² for skin resurfacing of both wrinkles and scars.

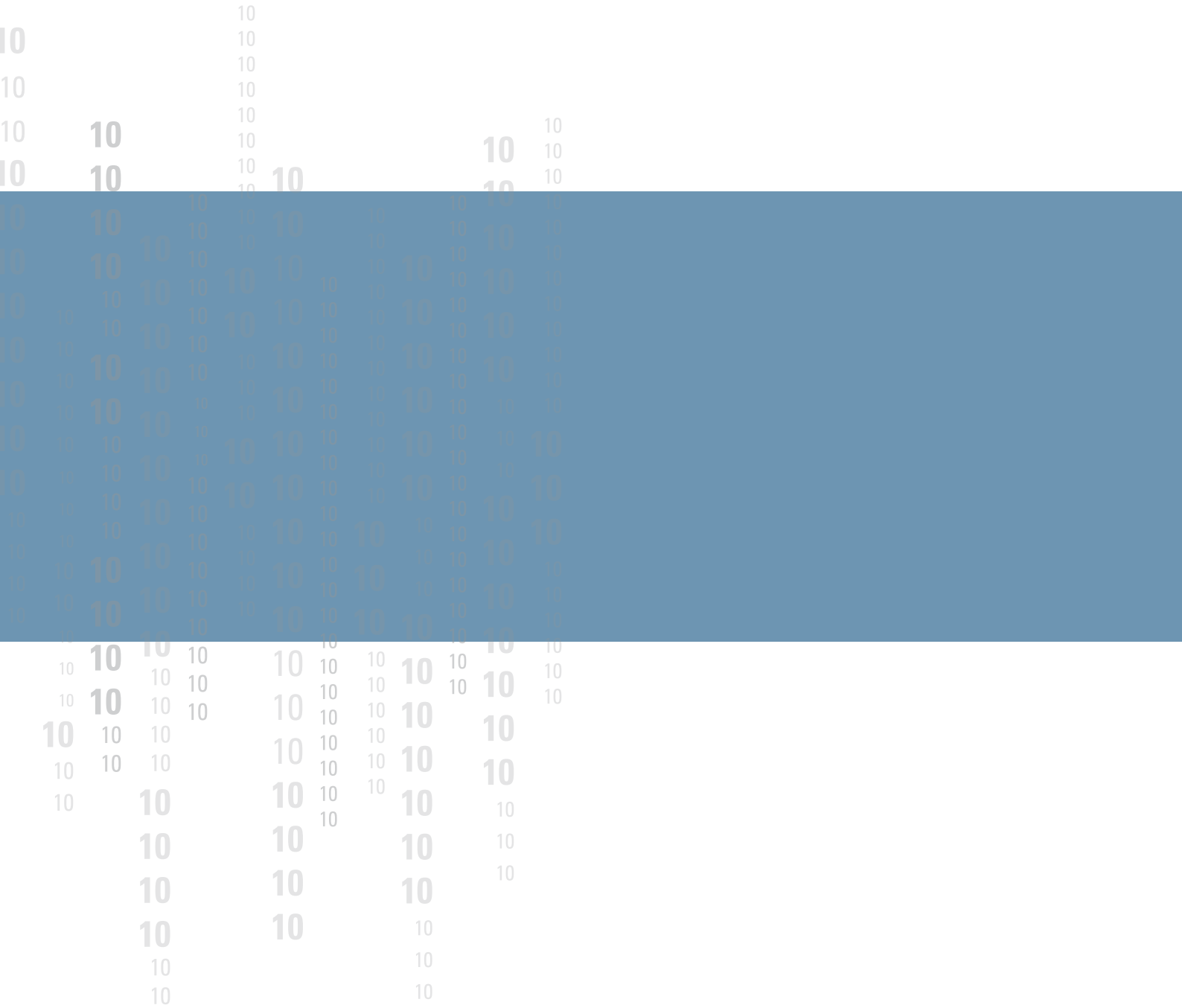
First impressions clearly indicate that by exploiting the HiScan DOT/RF system and its various settings, SmartXide² combines the satisfactory results of the ablative fractioned laser with the shorter healing times of non-ablative methods.

Conclusions

In my opinion, the introduction of SmartXide² as a face rejuvenating procedure, is a "revolutionary" turning point which, by exploiting the dual ablative – non-ablative method makes it possible to achieve combined Fractional Laser Resurfacing which can certainly be defined as IV generation Resurfacing.

I find this system extremely valid in clinical practise since it offers a wide range of treatments ranging from traditional laser resurfacing (II generation), to non-ablative photo-rejuvenation via the exclusive use of RF (III generation), and this new combined procedure.

First impressions clearly indicate that by exploiting the HiScan DOT/RF system and its various settings, **SmartXide²** combines the satisfactory results of the ablative fractional laser with the shorter healing times of non-ablative methods.



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