# A Preliminary Study on the Safety and Efficacy of a Novel Fractional $CO_2$ Laser With Synchronous Radiofrequency Delivery

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## ABSTRACT

Building upon the fractional $CO_2$ technology incorporated into the first generation SmartXide DOT (DEKA / ElEn, SpA, Calenzano, Italy) introduced in the U.S. in 2008, a second generation SmartXide Quadro has recently been introduced. This is a versatile device that has the ability to combine fractional $CO_2$ laser output for skin resurfacing with the synchronous delivery of bipolar radiofrequency (RF) energy for deeper, more diffuse heating. A pilot study was undertaken to demonstrate the safety and efficacy of the SmartXide Quadro, employing both fractional $CO_2$ laser output combined with the synchronous delivery of radiofrequency energy for the treatment of facial rhytides and acne scars. Ten patients, all women, six with facial rhytides and four with acne scarring, were treated with the SmartXide Quadro, a variably pulsed $CO_2$ laser with Pulse Shape Design® technology, a microablative DOT scanner and synchronized bipolar RF emission. Each patient was treated with a single fractional $CO_2$ laser-RF treatment; laser and RF parameters varied according to the severity of the rhytides or acne scars and were based upon both manufacturer-recommended settings and surgeon experience. Follow-up was at three days, one week, 2 weeks, and one month, three months, and six months after treatment. Results were judged by comparison of preoperative and post-operative photos evaluated by independent physicians, preoperative and post-operative grading by treating physicians, subjective evaluation of results by the patients themselves, and tabulation and categorization of adverse events (AEs).

The SmartXide Quadro variably pulsed $CO_2$ laser with a microablative DOT scanner, with synchronous delivery of bipolar RF energy emission, proved to be both safe and effective in the treatment of facial rhytides and acne scars. The single treatment protocol was well tolerated and recovery was similar to fractional $CO_2$ laser skin resurfacing alone. The AEs were minimal and no significant complications occurred.

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## INTRODUCTION AND BACKGROUND

Carbon dioxide ($CO_2$) laser skin resurfacing has been the "gold standard" for cutaneous facial resurfacing of photo-damaged skin since its emergence in the marketplace in the mid-1990s.[1-4] Fully ablative $CO_2$ laser (λ = 10,600 nm) technology was excellent for the treatment of facial wrinkles,[1-3] acne scars,[5-6] sun damage and solar elastosis, but fell into some disfavor due to its inability to be used off the face; its requirement for effective anesthesia; the nature of and downtime associated with recovery following treatment; and the significant risk of dyschromia and scarring. Prolonged post-operative erythema and transient hyperpigmentation were common findings; late (greater than one year post-operatively) hypopigmentation was also not uncommon. These side effects and complications plagued even the most cautious practitioners and well-chosen patients.[7-14]

The concept of fractional photothermolysis (FP) was described by Manstein et al, in 2004.[15] Fractional photothermolysis heats only a fraction of the epidermal and/or dermal architecture leaving intervening areas unchanged. These intact bridges of unaltered skin between the microscopic treatment zones (MTZ) result in rapid healing because the healing occurs not only from the adnexa, but also from the adjacent intact skin bridges. The combination of fractional photothermolysis and $CO_2$ lasers gave rise to the fractional or micro-ablative $CO_2$ laser technology used so widely today.[16-17] Ablative fractional skin resurfacing with a $CO_2$ laser ablates portions of both the epidermis and the dermis.[18-19] It successfully treats wrinkles, acne scars and other types of scars, striae, benign pigmented lesions such as lentigines, solar elastosis and others features of aged or photo-damaged skin.[20-22] Due to the inherent technologic design of FP, it can be used on the face and elsewhere on the body; such areas as the neck, chest, and upper and lower extremities can be treated safely with ablative fractional resurfacing. Furthermore, concurrent full-face fractional ablative $CO_2$ laser skin resurfacing can be safely performed with a facelift in order to address rhytides and solar elastosis not ameliorated during a rhytidectomy.

In addition to being able to be used off the face, this fractionally ablative technology also can reduce healing and downtime as well as the potential for the side effects and complications associated with traditional, fully ablative $CO_2$ laser skin resurfacing. While the ablative quality of the treatment delivers

excellent results in wrinkled, photo-damaged, solar elastotic, or scarred skin, the fractional quality of the treatment reduces intra-operative discomfort, post-operative pain, and healing time, and allows for treatment to be performed both on the face and elsewhere on the body.

Despite the versatility of fractional ablative devices, there is still some downtime associated with their use for facial rejuvenation. Fractional non-ablative devices evolved in an effort to improve rhytides and induce skin tightening without the downtime associated with the ablative devices. All of these systems show microscopic changes in dermal collagen. Some systems even demonstrate histologic evidence of neocollagenesis, but all non-ablative devices fall short of anything more than very mild clinical improvement in the appearance of photo-damaged skin. Often, there is no visible clinical improvement at all. Since there is no epidermal injury, there is no significant tightening of wrinkled, lax, solar elastotic skin.[17,23]

Because only modest success could be demonstrated with non-ablative lasers, various transcutaneous radiofrequency (RF) devices were introduced as another attempt at non-ablative heating of tissue to treat rhytides, acne scars and skin laxity of the face and elsewhere on the body.[24-34] RF is another type of electromagnetic radiation whose primary effect in tissues is thermal. In the skin and superficial subcutaneous tissue, RF heats the tissue causing collagen degeneration; the wound healing mechanism that ensues leads to further collagen remodeling, neocollagenesis, and wound contraction. The net clinical effect is an improvement in rhytides, skin tightening, and diminished skin laxity. As RF is not light, it is independent of chromophore interaction and does not disturb epidermal melanin. Therefore, it is able to heat the dermis, remodel collagen, and tighten the skin without disrupting the integrity of the epidermis. All Fitzpatrick skin types can be treated.

Radiofrequency energy can be delivered as monopolar or bipolar current; the so-called "multipolar" current is a computerized algorithm based upon bipolar RF delivery. Regardless of which type of circuit is utilized in a device, heat is generated as the energy meets resistance, or impedance, in the tissues. Monopolar RF typically penetrates more deeply than bipolar RF, but it is coupled with more intense levels of pain and greater safety concerns. Bipolar RF, although it cannot penetrate as deeply as monopolar RF – about ½ the distance between the fixed electrodes – has a distribution of current, and therefore heating, that is more controlled and predictable.

The SmartXide Quadro device couples the synchronous delivery of fractional $CO_2$ laser energy with bipolar RF energy. This study was performed to assess the safety and efficacy of the synchronous delivery of $CO_2$ laser and bipolar RF energy in the treatment of facial rhytides and acne scars.

## MATERIALS AND METHODS

Ten patients, all women, six with facial rhytides and four with acne scarring, were treated with the SmartXide Quadro (DEKA / EIEn, SpA, Calenzano, Italy), a variably pulsed $CO_2$ laser (wavelength = 10,600nm) with Pulse Shape Design technology, a microablative DOT scanner and synchronized bipolar RF emission. Pulse Shape Design technology allows the operator to choose the type, or histologic shape, of $CO_2$ laser pulse to use in each clinical situation. There are three pulse shapes from which to choose: the S-pulse, D-pulse, and H-pulse. The S-pulse is similar in histologic pulse profile to that of the first generation SmartXide DOT; it is bowl-like in shape, has a larger zone of coagulation, and surrounding thermal damage than the D-pulse and is more superficial in penetration (papillary dermis). The D-pulse penetrates deeper into the reticular dermis and is more "V"-shaped with greater ablation and a more limited zone of coagulation and surrounding thermal damage than the S-pulse. The H-pulse has a shorter pulse duration and higher peak power than either the S-pulse or D-pulse; therefore, it is the most ablative in nature of the three pulse shapes (personal communication and review of histology, Stefania Tenna, MD, PhD, Department of Plastic Surgery, University of Rome).

The device is capable of delivering power from 0.5 to 50W $CO_2$ laser energy and from 1 to 50W RF energy. Pulse width, or dwell time, and the spacing between the MTZs, or DOTs, also known as the DOT spacing, are also parameters that are chosen by the operator. These choices are based on the anatomic area being treated, the clinical entity being treated, the experience of the operator, the desired clinical effect of the treatment and the clinical downtime desired by the patient. Dwell time can range from 100 to 2000 microseconds and DOT spacing from 2000 to 0 microns – the latter being fully ablative.

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The patients ranged in age from 36 to 76 years with a mean of 56.3 years and a median age of 58.5 years. Fitzpatrick skin types were I to III. Each patient reviewed and signed the informed consent documents for this IRB-approved protocol (Essex IRB, Lebanon, NJ). Standard inclusion and exclusion criteria were used; others specific to this type of study included no history

**TABLE 1.**

| Average Scores for Diary Symptoms During First Two Weeks Post-Op<br>1 = None 2 = Mild 3 = Moderate 4 = Severe (N=10) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Time post-op | Itching | Burning | Stinging | Pain | Swelling | Redness | Crusting |
| Day 1 | 1.3 | 2.7 | 2.0 | 2.3 | 2.9 | 3.6 | 1.9 |
| Day 2 | 1.3 | 1.9 | 1.8 | 1.6 | 2.7 | 3.4 | 1.8 |
| Day 3 | 1.8 | 1.5 | 1.5 | 1.3 | 2.4 | 3.3 | 1.7 |
| Day 4 | 1.5 | 1.4 | 1.4 | 1.3 | 2.3 | 3.0 | 1.6 |
| Day 5 | 1.7 | 1.2 | 1.1 | 1.2 | 1.9 | 2.7 | 1.7 |
| Day 6 | 1.7 | 1.3 | 1.2 | 1.1 | 1.8 | 2.7 | 1.6 |
| Day 7 | 1.7 | 1.2 | 1.2 | 1.1 | 1.7 | 2.5 | 1.4 |
| Day 10 | 1.7 | 1.1 | 1.1 | 1.1 | 1.4 | 1.8 | 1.3 |
| Day 14 | 1.4 | 1.1 | 1.1 | 1.1 | 1.1 | 1.4 | 1.0 |



of oral retinoids for at least one year prior to treatment and no use of topical steroids or topical retinoids for 3 months prior to treatment. Urine pregnancy tests were performed on all women still having their menstrual periods. No other serum or urine tests, x-rays, or EKGs were required to participate in the study.

Each patient was instructed to shower and wash the face with 3% hexachlorophene topical scrub for 48 hours prior to treatment. One hour prior to the procedure, each patient had topical anesthetic ointment applied to the entire treatment area (lidocaine/prilocaine/ phenylephrine, Custom Scripts Pharmacy, Tampa, FL). At the time of treatment, the topical anesthetic ointment was removed and the face was prepped with 3% hexachlorophene topical scrub and draped in a sterile fashion with wet towels. All appropriate laser safety precautions were taken. Each full face resurfacing procedure takes approximately one hour to perform. During the procedure, if the patient is at all uncomfortable, the topical anesthetic is supplemented with local infiltration anesthesia using buffered 1% lidocaine, 1:100,000 units of epinephrine.

Each patient was treated with a single fractional $CO_2$ laser-RF treatment of the entire face; laser and RF parameters, including pulse shape choice, varied according to the severity of the rhytides or acne scars and were based upon both manufacturer-recommended settings and surgeon experience. Patients with more superficial rhytides were treated with the S-pulse and RF; those with deeper rhytides and those with acne scarring were treated with the D-pulse and RF. The H-pulse was not used in this study. Treatment with the RF technology requires sheaths on the metal electrodes (supplied by the manufacturer) and they need to moistened with water about every 10-15 pulses. Good contact of both electrodes with the skin is required in order to effectively deliver an even distribution of RF energy with each pulse and to prevent unwanted thermal damage to the skin.

Each patient was provided with a 10-day course of oral valacyclovir and ciprofloxacin. Topical treatment following the procedure included cleansing of the treated area with water

**TABLE 2.**

| $CO_2$ Pulse Energy and Fluence and RF Dose / Subject | | | |
|---|---|---|---|
| Subject | $CO_2$ Pulse Energy (mJ) | $CO_2$ Fluence ($J/cm^2$) | RF Dose (J/cm3) |
| 1 | 37.8 | 5.23 | 60.0 |
| 2 | 29.1 | 4.03 | 40.0 |
| 3 | 37.8 | 5.23 | 60.0 |
| 4 | 37.8 | 5.23 | 26.7 |
| 5 | 49.2 | 6.81 | 40.0 |
| 6 | 51.6 | 7.14 | 40.0 |
| 7 | 62.0 | 8.58 | 30.0 |
| 8 | 62.0 | 11.02 | 60.0 |
| 9 | 67.0 | 11.91 | 60.0 |
| 10 | 73.2 | 24.20 | 60.0 |
| Average | 50.75 | 8.94 | 47.67 |

and application of ½% hydrocortisone ointment in a plain white petrolatum base; this was performed every three to four hours until re-epithelialization is complete.

Follow-up was at three days, one week, two weeks, and one, three, and six months after treatment. Some patients were not able to be seen at six months after treatment and were seen upon their return to the NY area. Data was collected to evaluate healing, outcomes, side effects, and complications. Results were judged by comparison and grading of preoperative and post-operative photos evaluated by independent physicians, preoperative and post-operative grading by treating physicians, subjective evaluation, and grading of results by the patients themselves and tabulation and categorization of adverse events (AEs). Patients were asked to complete diaries every day for the first two weeks following the procedure; data was collected on itching, burning, stinging, pain, swelling, redness, and crusting, and each patient was asked to grade these symptoms from 1 = none to 4 = severe (Table 1). In addition, all patients were asked

**TABLE 3.**

| Comprehensive Grading Scale for Subject Self-Assessment of Rhytides / Wrinkles and Acne Scarring | | | |
|---|---|---|---|
| | | Categories for Assessment | |
| Grading Scale | Descriptive Parameter | Rhytides / Wrinkles | Acne Scars |
| 0 | None | None | None |
| 1 | Mild | Wrinkles mostly with animation, few, superficial | Few, superficial, more obvious with animation |
| 2 | Moderate | Wrinkles at rest, multiple, localized, superficial | Multiple superficial "icepick" or broad-based acne scars, obvious w/o animation |
| 3 | Advanced | Wrinkles at rest, multiple, but mostly on forehead, peri-orbital, perioral, some superficial, some deep | Multiple "icepick" and broad-based acne scars, ~50% superficial, ~50% deep |
| 4 | Severe | Wrinkles at rest, numerous, deep, pan-facial, extensively distributed, deep cervical creases | Extensively distributed, deep, "icepick" and broad-based acne scars, confluence of scars, face and neck |



**FIGURE 1.** 69-year-old woman (Subject 1 in Table 2) before **a,b)** and 8 months after full face treatment **c,d)** with synchronous fractional $CO_2$ laser and RF energy for rhytides.




to complete a subjective comprehensive grading scale for self-assessment of their wrinkles or acne scars both pre-operatively and at the final post-operative visit (Table 3).

## RESULTS

All patients were judged to have clinical improvement in the appearance of their facial rhytides or acne scarring as a result of this single treatment protocol with synchronous delivery of fractional $CO_2$ laser and RF energy (Figures 1 - 3). As tabulated in subject diaries, most patients had some degree of itching, burning, stinging, pain, swelling, redness, and crusting following treatment; the number of days until the resolution of each depended upon the intensity of treatment (Table 1).

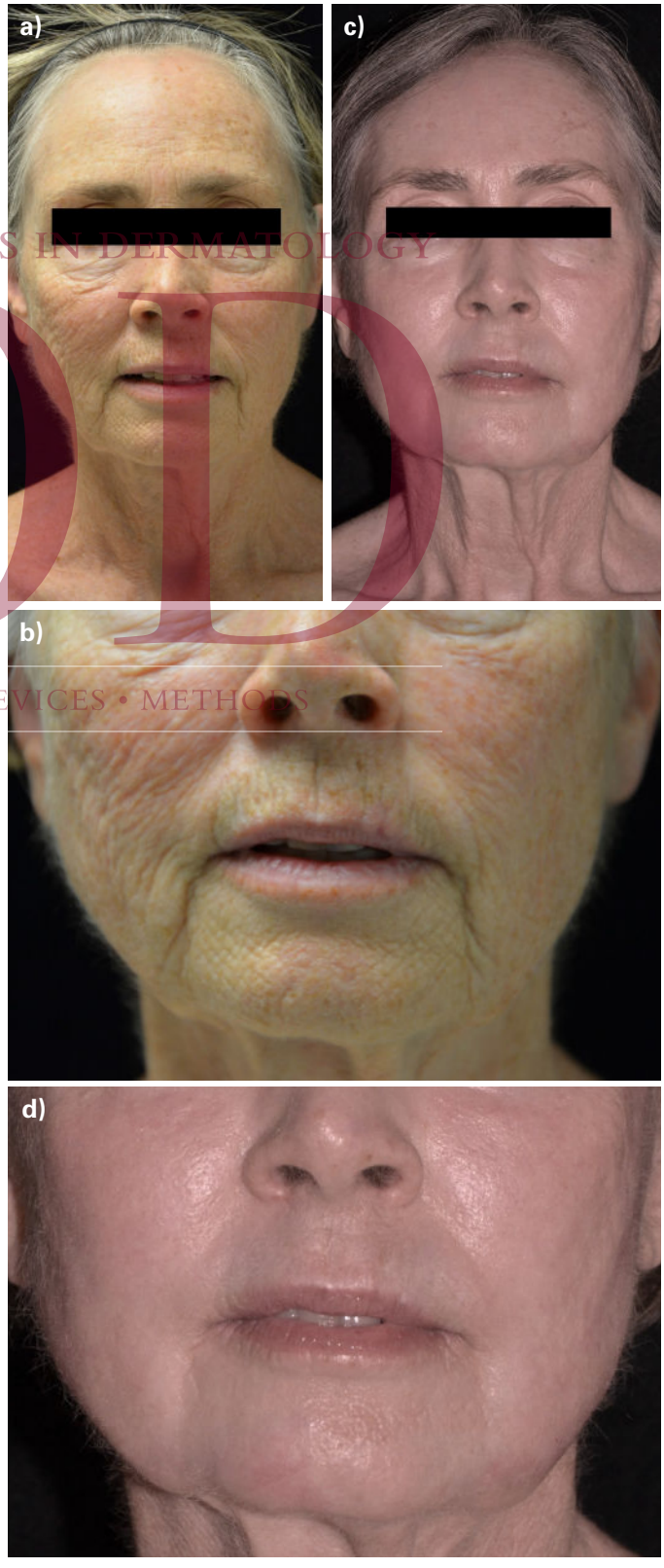
Similar to the recovery from standard, fully ablative $CO_2$ resurfacing and fractional $CO_2$ laser resurfacing alone, some patients experienced occasional milia during the post-operative period and two of the Fitzpatrick Skin Type III patients exhibited transient post-inflammatory hyperpigmentation (PIH). No patients had any residual PIH at three months following treatment.

No cutaneous viral or bacterial infections occurred during the post-operative period and no adverse visible scarring has been noted. In addition, no late hypopigmentation has been seen in the extended follow-up period of the patients included in this study. One patient, in whom the degree of rhytidosis was quite severe, had higher pulse energies than any of the other patients; due to high combined laser and RF energy in this one patient, she sustained erythema that lasted almost two months. Her re-epithelialization was complete, however, by two weeks and her long-term outcome was excellent (Figure 3).

During the course of the study, there was an overall trend to increase the pulse energies of the $CO_2$ laser; this is consistent

**FIGURE 2.** 43-year-old woman (Subject 9 in Table 2) before **a)** and 7 months after full face treatment **b)** with synchronous fractional CO2 laser and RF energy for acne scarring.


**FIGURE 3.** 67-year-old woman (Subject 10 in Table 2) before **a,b)** and 12 months after full face treatment **c,d)** with synchronous fractional CO2 laser and RF energy for severe rhytides.






with increasing familiarity with the device, its use and the results being seen (Table 2). The last patient treated had the highest pulse energies and $CO_2$ laser fluence used, but the RF dose was similar to many others treated in the study; this is the patient referenced in Figure 3.

When using the RF energy, good contact of both of the electrodes with the skin is mandatory in order for the RF energy to be delivered, distributed evenly, and to avoid unwanted thermal damage to the skin. As with many devices, there is a learning curve in use; very convex areas, the perioral area and the periorbital areas pose some challenges and there were a few episodes of unwanted thermal damage from lack of adequate contact of the RF electrodes with the skin. These all healed uneventfully.

On the Comprehensive Grading Scale for Subject Self-Assessment of Rhytides / Wrinkles and Acne Scarring (Table 3), each subject (100%) demonstrated at least a one grade improvement at the six-month visit compared to their pre-operative grade. Three of the ten subjects (30%) demonstrated a two-grade improvement.

## DISCUSSION

This preliminary study demonstrates the safety and efficacy of a variably pulsed $CO_2$ laser with Pulse Shape Design® technology, a microablative DOT scanner, and synchronized bipolar RF emission for the treatment of facial rhytides and acne scars. All patients treated demonstrated improvement in the appearance of rhytides and acne scarring, sustained no significant adverse events, and recovered uneventfully. One patient – subject 10 –

sustained prolonged erythema, but her ultimate recovery and her cosmetic result were excellent.

Although this device adds RF to the first generation SmartXide DOT, the time and course of healing did not appear significantly different from that associated with the predicate device. That is, by adding the RF for additional diffuse heating of the deeper tissues, there was no delay or impairment of the healing response. Theoretically, the addition of RF contributes additional heating to the tissues, stimulates more overall neocollagenesis and provides better overall skin tightening.[24-34]

One of the drawbacks of this device, as the manufacturer has it programmed at the present, is that the RF cannot be used as a stand-alone device. Diminishing the energy output of the CO2 laser and increasing the space between the DOTs emitted from the scanner can almost mimic "Pure RF", however. This effectively allows almost unaccompanied delivery of the RF energy for more diffuse non-ablative skin-tight tightening. While the $CO_2$ laser can be used as a stand-alone device, it would be nice to be able to use the RF in that way as well.

Another drawback of this device, compared to the first generation SmartXide DOT, is that it is more cumbersome to use – due primarily to the incorporation of RF delivery capability. The RF electrodes serve as spacers on the scanning handpiece and they are thicker than those on the first generation SmartXide DOT. This can make it more difficult to visualize the skin during treatment. In addition, when RF is being used, the electrode sheaths must be moistened every 10-15 pulses.

The benefit of this device, compared to the first generation SmartXide DOT as well as many other fractional ablative $CO_2$ devices, is its versatility. With the choice of three different pulse profiles – S-pulse, D-pulse, and H-pulse – the flexibility in power, dwell time, DOT spacing, and pulse stacking, and the ability to increase overall deeper and more diffuse dermal heating by adding RF makes this device an excellent choice for the treatment of a wide assortment skin problems.

## DISCLOSURES

The authors were provided with the SmartXide Quadro device with which to perform this study by the manufacturer, DEKA, Calenzano, Italy.

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