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RedTouch

NEW INSIGHT IN NON-INVASIVE REJUVENATION: THE ROLE OF A 675 nm LASER SOURCE SYSTEM

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New Insight in Non-Invasive Rejuvenation: the Role of a 675 nm Laser Source System

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Introduction

In the last decade we have seen a greater request for non-ablative and non-invasive skin rejuvenation treatments. More and more patients ask for results associated to a minimum pain and lower risk of side effects.

The new RedTouch (DEKA, Calenzano – Italy) system properly provide an answer to these needs by selectively reaching different targets in the skin structure in order to address all the modifications inevitably induced by either chrono- and photo-aging.

The main actin carried out by RedTouch primarily involve both pigmentation and neocollagenogenesis issues.

The purpose of this study was to evaluate the effectiveness and the safety of RedTouch device with the use of preliminary parameters guaranteeing minimum pain and the absence of side effects such as hyperpigmentation, hypopigmentation and blistering.

Description of the System

The RedTouch (Figure 1) is equipped with a 675 nm laser source with emission in the red site of the visible spectra and it is assisted by a scanning system to generate micro-zones of sub-ablative and selective thermal damage to the skin.

RedTouch is also equipped with an integrated contact skin cooling system (Figure 2) to preserve the epidermis from thermal rise. The high affinity with melanin and collagen fibers (Figure 3), combined with minimal interaction with the vascular component, makes this system promising in the treatment of benign pigmented lesions, skin photo-rejuvenation and remodeling of atrophic scars, reducing the risk of side effects and simplifying post-treatment management.

Figure 1. RedTouch laser system.

Figure 2. RedTouch handpiece with the integrated skin cooling.

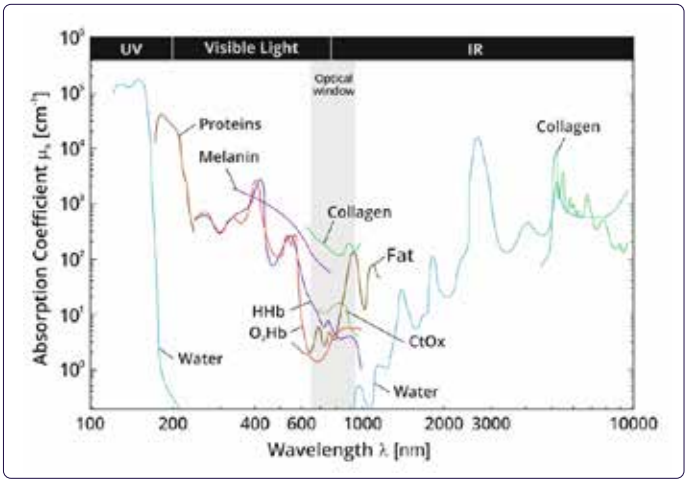

Figure 3. Collagen and main skin components absorbtion spectra[1,2].

Pre-Clinical Study with Histological Analysis

To evaluate the effects of non-ablative Red Touch laser, both fractional (for rejuvenation) and non-fractional (for pigmentary) emission mode, two different animal models were adopted. A non-pigmented ex-vivo sheep shaved groin skin area was selected to simulate a dermal rejuvenation treatment; moreover a pigmented ex-vivo sheep sample was selected to simulate a pigmentary treatment. The being quite hairless and thin epidermal layer structure make this sample similar to human facial skin. The area was treated with the RedTouch system (Fractional Mode: Power 10 W, Dwell Time 400 ms, Spacing 0.5 mm, Cooling 5 °C - Pigmental Mode: Power 10 W, Dwell Time 100 ms, Spacing 0 mm, Cooling 5 °C). 2 mm punch biopsies were taken immediately after the laser session. The specimens for histological analyses, were fixed in 10% neutral formalin, dehydrated through a gradeted series of alcohol (or ethanol), cleared in Histoclear, and embedded in paraffin. Some 4-5 μm thick sections were obtained, and then stained with haematoxylin & eosin for light microscopy evaluation. Photomicrographs were taken with a Nikon microscope, through a digital photocamera (Nikon Digital Sight DS-U1)) connected with a personal computer hosting the software Nis Elements D 3.2 (Nikon). Data shows micro thermal damaged zones of 1 mm diameter up to 300-400 μm depth (Figure 4) for fractional mode and homogeneous damage of the pigment component on the entire scan area in the pigmented tissue macroscopically attributable to a paradoxical blackening in the pigmented mode settings (Figure 5).

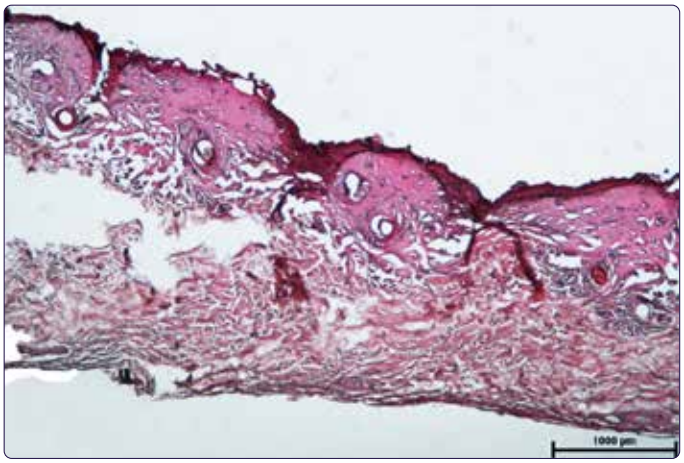

Figure 4. Non pigmented ex-vivo sheep sample. 15x15 mm rectangular scan shape with 500 μm of spacing for the fractional treatment of the collagen component. Micro thermal damaged zones with epidermal preservation.

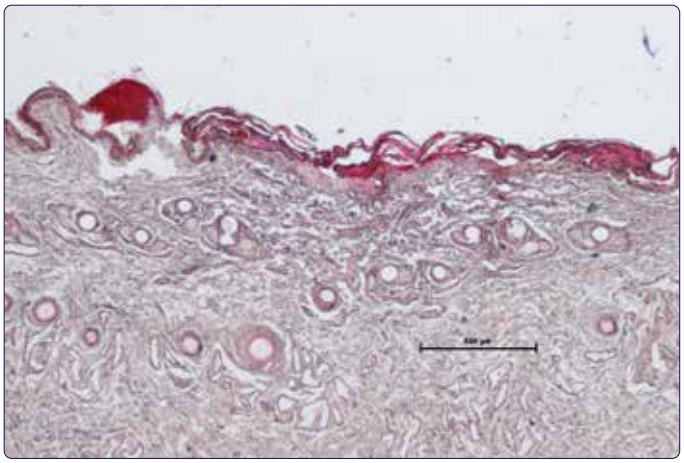

Figure 5. Pigmented ex-vivo sheep sample. Circular scan shape of 6 mm with 0 μm of spacing for the treatment of the pigmentary component (Paradoxical darkening).

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Materials and Methods

A total of 19 patients were enrolled for evaluating the RedTouch effects on wrinkle, texture, pigmented disorders and acne scars.

The exclusion criteria for this study (same as per the contraindications of RedTouch system), were considered:

- Hypersensitive to light in the "visible to near-infrared" wavelength range.
- Taking medication that is known to increase sensitivity to sunlight.
- Takinganticoagulantand/orimmunosuppressant.
- Having seizure disorders triggered by light.
- Pregnancy.
- Having a personal or family history of skin cancer.
- Exposition to the sun in the three weeks prior to treatment (for any skin type).
- Tattoo or skin disorders in the treatment area.

Assessment and Evaluation

- Picture have been taken with a digital camera either before and 3 months after the last treatment session.
- For wrinkle, texture and pigmented disorders the efficacy of treatment was evaluated using the 9 points Fitzpatrick Elastosis and Wrinkles Scale (FEWS) (Table 1) assessed by investigator as compared to baseline.
- For acne scars the efficacy of treatment was evaluated by 9 points Goodman and Baron's Quantitative Global Acne Scarring Grading System (GBQGASGS) (Table 2), assessed by investigator as compared to baseline.
- Safety and tolerance were also evaluated using the Visual Analogue Scale (VAS) of 5 points: 0 – None, 1 – Slight pain, 2 – Moderate pain, 3 – Severe pain, 4 – Intolerable pain.
- Adverse effects such as blistering, scarring, burns, hypopigmentation or hyperpigmentation have been monitored.

Class	Score	Wrinkling	Degree of Elastosis
I	1-3	Fine wrinkles	Mild (fine textural changes with subtly accentuated skin lines)
II	4-6	Fine to moderate depth wrinkles, moderate number of lines	Moderate (distinct papular elastosis, individual papules with yellow translucency, dyschromia)
III	7-9	Fine to deep wrinkles, numerous lines, with or without redundant skin	Severe (multipapular and confluent elastosis, thickened yellow and pallid cutis rhomboidalis)

Table 1. Fitzpatrick Elastosis and Wrinkles Scale (FEWS)[3].

Grade/Type	Grade 1 (1-10 lesions)	Grade 2 (11-20 lesions)	Grade 3 (>20 lesions)
A) *Milder scarring (1 point each)* Macular Erythematous or pigmented Mildly atrophic dish-like	1 points	2 points	3 points
B) *Moderate scarring (2 point each)* Moderately atrophic dish-like Punched out with shallow bases, small scars (<5mm) Shallow but broad atrophic areas	2 points	4 points	6 points
C) *Severe scarring (3 point each)* Punched out with deep but normal bases, small scars (<5mm) Punched out with deep abnormal bases, small scars (<5mm) Linear or troughed dermal scarring Deep, broad atrophic areas	3 points	6 points	9 points
D) *Hyperplastic* Papular scars Keloidal / Hypertrophic scars	2 points Area <5 cm^2 6 points	4 points Area 5-20 cm^2 12 points	6 points Area >20 cm^2 18 points

Table 2. Goodman and Baron's Quantitative Global Acne Scarring Grading System (GBQGASGS)[4-5].

Participants

A total of 19 patients, all women, mean age of 49.9 (range 22–85 years), Fitzpatrick skin types I-III (I-5%, II-42%, III-53%) were enrolled for treatment of Wrinkle, Texture, Pigmented disorders and Acne Scars (Table 3). Patient, were treated with RedTouch every month for a maximum of 4 sessions (mean of 2.5 ±1.0 treatments).

ID	M/F	Area	Treatment	Age	Photo type	Score Before	Score 3 Months FU	Pain	Number of Treatments	Side Effect
1	F	Face	Wrinkle	61	2	7*	5*	1	4	None
2	F	Neck	Wrinkle	58	2	4*	3*	1	4	None
3	F	Face	Texture / Pigmented	56	2	4*	3*	2	4	None
4	F	Face	Texture	35	2	3*	2*	1	1	None
5	F	Face	Texture / Pigmented	60	3	6*	4*	1	1	None
6	F	Face	Texture / Pigmented	60	3	7*	5*	1	2	None
7	F	Neck	Texture / Pigmented	78	3	7*	6*	1	2	None
8	F	Face	Texture / Pigmented	65	3	5*	4*	1	2	None
9	F	Face	Texture / Pigmented	22	2	6*	4*	1	2	None
10	F	Face	Texture / Pigmented	85	3	7*	6*	1	2	None
11	F	Face	Wrinkle / Pigmented	54	3	6*	3*	1	4	None
12	F	Face	Acne Scars	29	2	2**	1**	2	3	None
13	F	Face	Acne Scars	31	2	2**	1**	1	3	None
14	F	Face	Wrinkle / Pigmented	73	3	7*	6*	1	2	Some micro burns
15	F	Face	Texture / Pigmented	30	2	2*	1*	2	2	None
16	F	Face	Acne Scars	29	3	3**	2**	1	3	None
17	F	Axilla	Texture / Pigmented	42	1	3*	2*	2	1	None
18	F	Face	Acne Scars	44	3	3**	1**	1	3	Some micro burns
19	F	Face	Texture / Pigmented	37	3	3*	2*	1	2	None

*Fitzpatrick Elastosis and Wrinkles scale (FEWS) **Goodman and Baron's Quantitative Global Acne Scarring Grading System (GBQGASGS)

Table 3. Summary of treatments for the 19 patients enrolled in this study.

Treatment Procedure

Before proceeding, the area to be treated (face and neck) was cleaned using a mild soap rinsed with plenty of water. The energy used to treat each individual patient was evaluated on a "test" area based on the skin type of the subject and to the degree of tolerability of the same. The answer of the test was noticeable within 5/10 minutes. The end point was considered a mild erythema and some associated edema.

The treatment involves the passage of the handpiece in contact with the skin surface to be treated, without applying excessive pressure, with spots that follow one another without overlap, but without leaving untreated areas.

It is recommended do not treat the same area with more than two passages. In Fact more passages may cause adverse effects such as burns and/or hyperpigmentation. It is necessary to pay attention above all on the areas closest to the bone surface (front, cheekbone etc.).

The application of topical anesthetics is usually not necessary. If used, it was completely removed before proceeding with the treatment.

According with the specific patient needs, a different setting protocol was selected on the system (Table 4).

Only one patient (ID:18) was treated with topical anesthesia. All treatments have been performed with the use of a transparent ultrasound gel.

After the session, if necessary, cool the treated area down by using a wrung cold water compress and then locally apply an anti-inflammatory non-cortisone cream which the patient can re-applied at home. Throughout the period of treatment it is strongly recommended for the patients to use sun protection screen not lower than 50.

Results

Photographic evaluation proved relevant improvement (on both pigment and texture) of photo-damaged and scared skin (Figure 6-10)., Significant improvement in facial wrinkle and texture was noted according to the FWES (Table 5 and Figure 11) and the GBQGASGS (Table 5 and Figure 12) three month after the last treatment session . The scores decreased significantly from baseline to 3 months follow-up after the last treatment too. The treatment was well tolerated (average pain score: 1.2±0.4) (Figure 13). No side effect has been recorded apart from some small and rare burn due to bad positioning of the handpiece on the skin that resolved in ten days.

Treatment	Power	Dwell Time	Spacing	Cooling
Wrinkle	10 W	200-250 ms	1-1.5 mm	5 °C
Pigmented lesion	10 W	100-150 ms	0 mm	5 °C
Fine Textural change	10 W	125-175 ms	1-1.5 mm	5 °C
Acne scars	10 W	300-400 ms	1-1.5 mm	5 °C

Table 4. Treatment protocol.

Figure 6. Before and 3 months after the last treatment. 3-montly sessions.

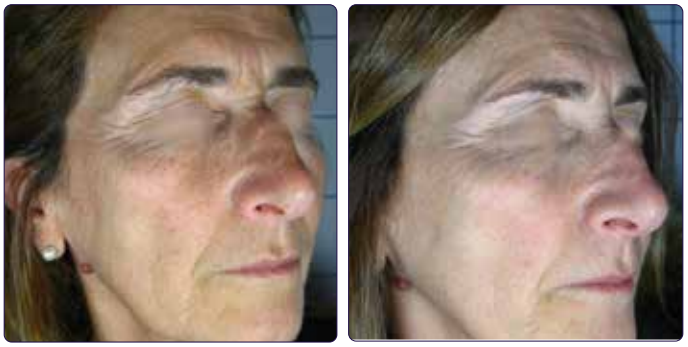

Figure 7. Before and 3 months after the last treatment. 3-montly sessions.

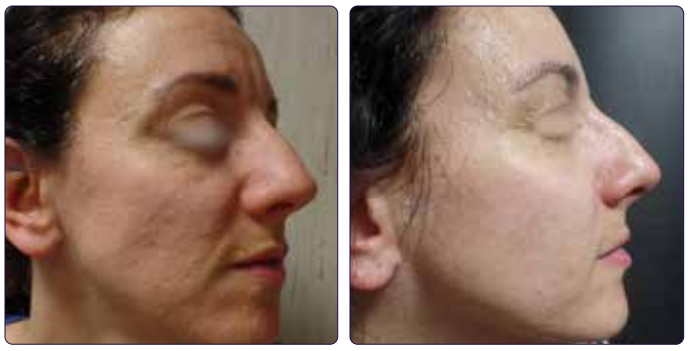

Figure 8. Before and 3 months after the last treatment. 3-montly sessions.

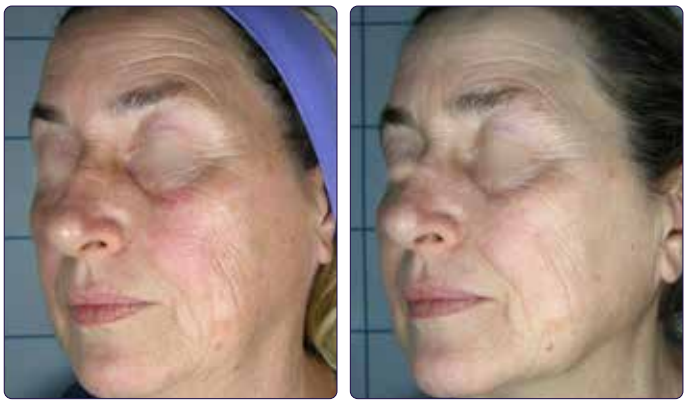

Figure 9. Before and 3 months after the last treatment. 4-montly sessions.

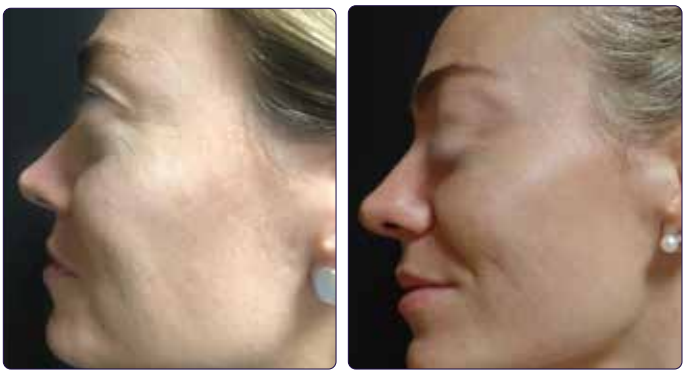

Figure 10. Before and 3 months after the last treatment. 2-montly sessions.

Scores	Patients	Before	3 months Follow up	Significance
Fitzpatrick Wrinkle and Elastosis Scale	15	5.1±1.8	3.7±1.6	p<0.001
Goodman and Baron's Quantitative Global Acne Scarring Grading System	4	2.5±0.6	1.3±0.5	p<0.01

Table 5. Statistical analysis with average scores of FWES and GBQGASGS evaluated before any treatment and 3 months after the last session with RedTouch system.

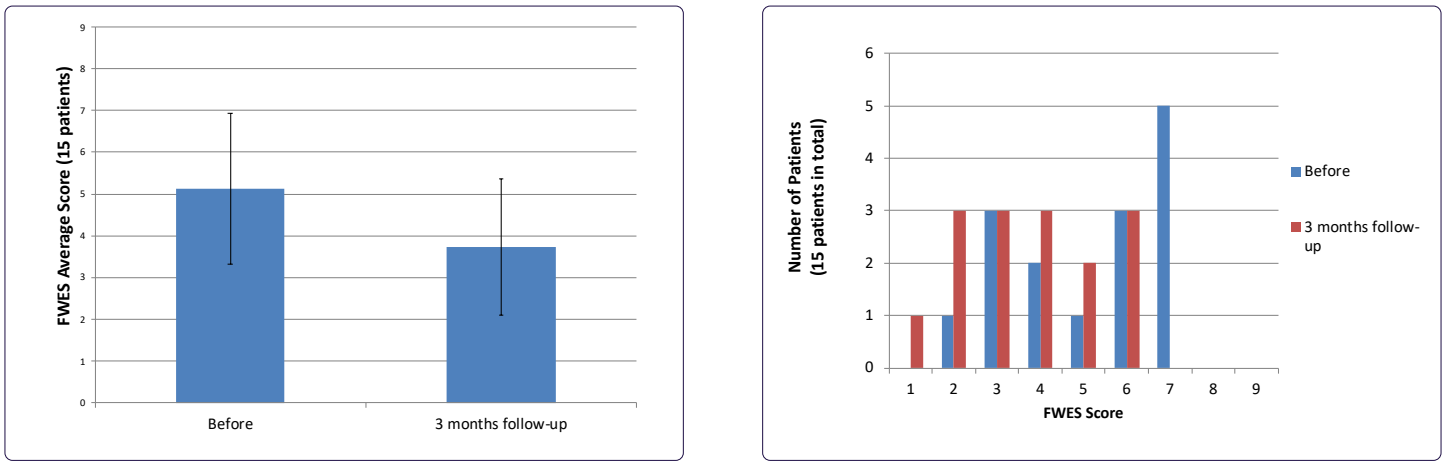

Figure 11. Histograms representing the FWES score progress before any treatment and 3 months after the last session with RedTouch system.

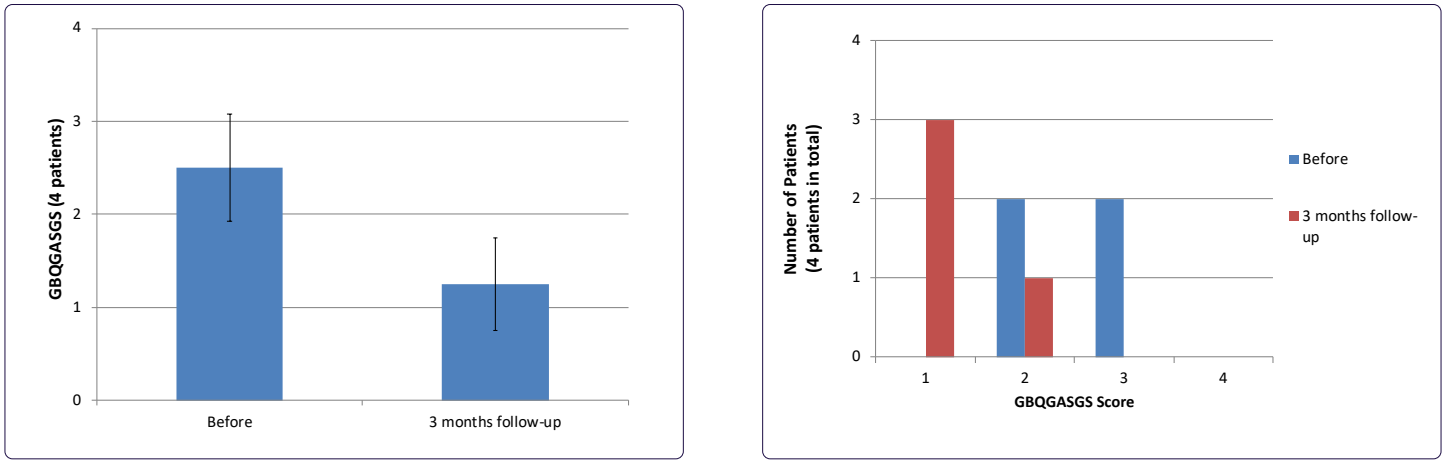

Figure 12. Histograms representing the GBQGASGS score progress before any treatment and 3 months after the last session with RedTouch system.

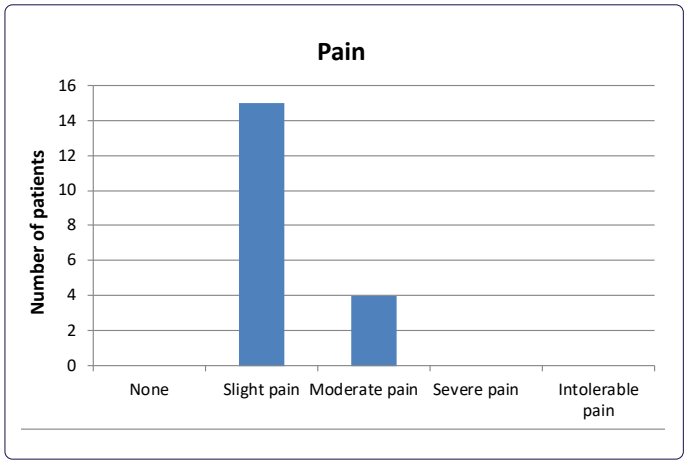

Figure 13. Patient pain evaluation during RedTouch session on 19 patient. Just only 1 patient requested local anesthesia.

Discussion

Compared to the systems currently on the market targeting water, due to the Near Infra-Red (NIR) range emission 1320-1540 nm, the RedTouch system acts directly on the collagen component contained at dermal level (Figure 3). The treatment is easy to perform and not require any particular skin preparation. The only observed side effect of this photorejuvenation treatment is a slight redness that disappears a few hours after the treatment. The perceived pain is reduced thanks to the contribution of skin cooling which induces a sort of transient ischemia.

The post-operative course takes place without any formation of microscopic epidermal necrotic debris (MENDs) typical of NIR systems and without dermo-epidermal detachment. This side effect is probably related to the greater focus on small spots (100-300 µm) of NIR systems. RedTouch instead creates micro-zones of thermal damage of about 1 mm which, thanks to the cooling and the selectivity of the dermal layer, do not damage the epidermal layer. The absence of crusts and/or micro-crusts does not change the patient's texture during the operative course and it makes the treatment socially invisible.

For the pigmentary component, the course of healing is quite similar to the one from pulsed light treatment.

As with all non-ablative photorejuvenation treatments, at least three monthly sessions are recommended. The first effects are visible about two months after the first session , which corresponds to the maturation phase of the stimulated collagen fibers.

Conclusions

An ideal patient for this kind of treatment is a patient with thickened skin, moderate/marked wrinkles, pigmented skin or with acne scars.

This type of laser treatment is definitely not ablative and requires simple post-treatment management with a minimal and transitory limitation of normal activities of patients.

References

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