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WHITE PAPER

RedTouch

NON-ABLATIVE REJUVENATION WITH A 675 nm LASER SOURCE FOR IMPROVING COLLAGEN



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Non-Ablative Rejuvenation with a 675 nm Laser Source for Improving Collagen

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Introduction

Wrinkles and dyschromia are the main clinical skin changes associated with ageing. Well-organised and oriented collagen fibres contribute to its firmness and softness. As the skin ages, degradation of the collagen and abnormal accumulation of elastin can cause a loss of thickness and elasticity, resulting in wrinkles. Localised and generalised chromatic changes can also simultaneously appear with the accumulation of melanin.

The purpose of this study is to assess cutaneous rejuvenation with a new 675 nm fractionated laser (RedTouch, DEKA, Italy). The system includes a 675 nm laser source with red light-emitting spectrum and is aided by a scanning system to generate sub-ablative and selective micro-zones of thermal damage to

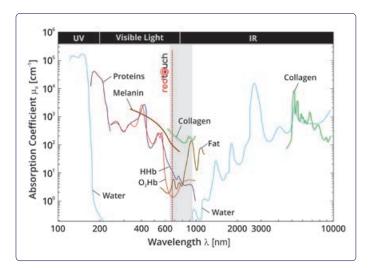


Figure 1. Absorption spectrum of the various chromophores present in human tissue. An optical window is observed that includes the wavelength of 675 nm, with high absorption by the concomitant collagen with a limited effect on the vascular component.

the skin. The system also includes a contact-cooling system to preserve the epidermis from excessive temperature increase. The high affinity with melanin and collagen ^[1-2] (Figure 1), combined with a minimum interaction with the vascular component and with water, make this system very promising both for the treatment of benign pigmented lesions and in photorejuvenation, reducing the risk of side effects and simplifying post-treatment management.

Materials and Methods

The study included 13 patients (2 men and 11 women from 45 to 67 years, with a mean age of 58 years) with phototype II (54%) and III (46%) who presented signs of skin ageing (wrinkles, sagginess, hyperchromia).

Study exclusion criteria: patients with hypersensitivity to light; use of drugs known to increase sensitivity to sunlight; patients with convulsive disorders triggered by light; pregnant patients; patients with a personal or family history of skin cancer; patients exposed to sun within three weeks prior to treat; presence of tattoos or skin disorders in the areas to be treated.

Patients underwent 3 sessions (TX1, TX2 and TX3) with the RedTouch System once monthly (Power: 10 W, Dwell time: 75-400 ms, spacing: 0-1.5 mm, cooling: 5 °C, 1 or 2 passes). Topical anaesthesia was applied throughout the treatment cycle in only 10% of cases. All treatments were performed with the use of a clear transparent gel.

Before starting treatment, areas targeted by the procedure were cleaned with a delicate soap rinsed



off with plenty of water. Assessment of the treatment parameters was done using spot tests based on the skin type and the tolerability level. The endpoint was considered mild redness and, in the case of hyperchromia, paradoxical blackening of the lesions after a few minutes.

After the procedure the treated area was cleaned with cold water, dried with wadding and a noncortisol local anti-inflammatory cream was applied. There was no need to further cool the treated area as the high-performance scanner cooling system already performs this function during treatment. Use of sun protection was recommended for the entire period of the study.

Clinical response to treatment was assessed by the investigator using the 9-point Fitzpatrick Elastosis and Wrinkles Scale (FEWS)^[3] (Table 1) comparing it to baseline (T0). Follow-ups were performed after 30 days of every treatment (TX1FU, TX2FU and TX3FU) and in any case before or during the subsequent treatment.

Treatment tolerance was assessed using the 5-point Visual Analogue Pain Scale (VAS): (0 – None, 1 – Slight pain, 2 – Moderate pain, 3 – Severe pain, 4 – Intolerable pain). Redness was classified using a 5-point redness scale (0 – None, 1 – Trace, 2 – Moderate, 3 – Marked, 4 – Severe).

Adverse effects associated with the laser treatment such as redness, oedema, pain, blisters, hypo/ hyperpigmentation, scarring, dry skin and allergic reactions were monitored.

Lastly, the patient's perceived subjective assessment of the improvement was also recorded, having them fill in a questionnaire unaided by the study staff. Every patient filled in the questionnaire for both the pigmentation part and the part regarding wrinkles and texture, based on a 5-point scale (0 – No improvement, 1 – Slight improvement, 2 – Moderate improvement, 3 – Good improvement, 4 – Excellent improvement).

Results

An overall improvement was recorded in both benign hyperpigmentation and wrinkles through the 9-point FEWS with a positive decrease in the assessment score (Score \pm SD) from T0 with 6.1 \pm 1.7 until the follow-up of the last treatment (TX3FU) with 3.8 \pm 1.9. A significant statistical difference was

Class	Score	Wrinkling	Degree of Elastosis
I	1-3	Fine wrinkles	Mild (fine textural changes with subtly accentuated skin lines)
	4-6	Fine to moderate depth wrinkles, moderate number of lines	Moderate (distinct papular elastosis, individual papules with yellow translucency, dyschromia)
111	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. The 9-point Fitzpatrick Elastosis and Wrinkles Scale (FEWS).

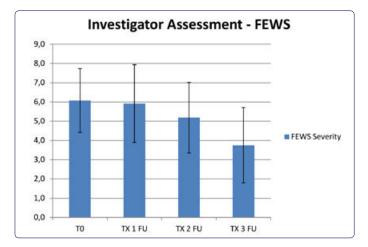


found (p <0.01). A progressive change was therefore found in the skin ageing severity condition at T0 of Class II-III until follow-up after the third treatment, TX3FU, of Class I-II (Figure 2).

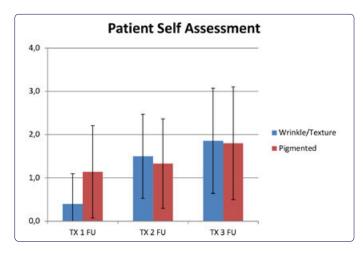
All patients declared that they were satisfied with both treatments (wrinkles/texture and pigmentations) by completing a questionnaire with an assessment score (Score \pm SD) at follow-up after the last treatment (TX3FU) of 1.9 \pm 1.2 for wrinkles/ texture and 1.8 \pm 1.3 for pigmentations (Figure 3).

The opinion of the subjects with regard to pain (VAS Pain) and discomfort during the treatment remained constant for all sessions (T1, T2 and T3) and a value of 1.5 ± 0.7 was recorded, between the levels of "Slight pain" and "Moderate pain".

Short-lasting, mild redness occurred in all patients immediately after treatment, resolving itself within a few hours of treatment. Hyperpigmentations, from a progressive darkening of the lesions, resolved within 10-15 days. This was considered the treatment endpoint, as explained to the patient, not to be confused with real side effects. No persistent redness was found. On a scale of 0 to 4, the short-lasting post-treatment redness remained constant across all sessions (T1, T2 and T3) and was 1.5 ± 0.5 , i.e. between "Trace" and "Moderate" levels.









Possible formation of tiny little micro-scabs were observed as infrequent event. No treatment was required and full recovery was obtained in a time varying from a few days up to a maximum of 2 weeks. No other side effect was found.

Discussion

Both non-ablative and ablative $(CO_2 \text{ or infrared} Er:YAG)$ devices with a 1320-1540 nm spectrum emission currently available affect water to transform laser energy into heat. The photothermic effect then generates an increase in the temperature that indirectly also involves collagen fibres and stimulates them. Although effective, these types of treatment require significant downtime to be managed and concorded with the patient.

Instead the RedTouch System works directly on the collagen component contained in the skin (Figure 1): the selectivity of its emission allows for acting within an optical window that maximises the affinity with collagen fibres and minimises interactions with the vascular component. This mechanism of action translates into a procedure that uses minimal energy levels that facilitate execution of the treatment and do not require special preparations of the skin. The only side effect observed with this photorejuvenation treatment is mild redness that disappears a few



hours after treatment. The pain felt is reduced also thanks to contact cooling that induces further and temporary dermal ischemia.

The post-operative course took place making posttreatment socially invisible.

Conclusions

Treatment with 675 nm laser, both for wrinkles/ texture (Figure 4,5 and 6) and superficial benign hyperpigmentation (Figure 7 and 8), was effective and safe in the subjects treated. The new technology, with a high affinity to collagen and melanin, has been shown that it does not to add significant side effects, that treatment can be performed with minimal discomfort and that post-treatment can be managed with minimal downtime without interruptions to the patient's normal daily life. Like with all nonablative photorejuvination treatments to improve texture, at least two- or three-monthly sessions are recommended. Initial permanent effects are visible about two months after the first session. This is how long it takes for maturation of the new collagen fibres stimulated by the RedTouch System.



Figure 4. Photorejuvination treatment of the neck. Images before (A) and after (B) 3 RedTouch System treatment sessions.

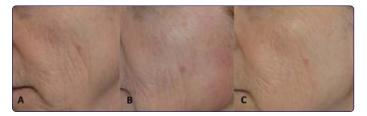


Figure 5. Photorejuvenation treatment of the face. Images before (A), of the redness-endpoint after the treatment (B) and of the result obtained 1 month after (C) 2 RedTouch System treatment sessions.



Figure 6. Chrono-ageing treatment of blotches and wrinkles of the décolleté (the middle part was treated, above the crease between the breasts). Images before (A) and 1 month after (B) a single RedTouch System treatment session.

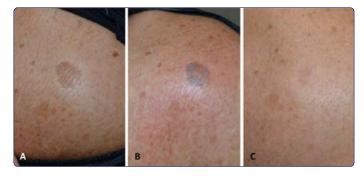


Figure 7. Treatment of a blotch on the shoulder. Images before (A), of the darkening-endpoint of the lesion after the treatment (B) and the result obtained 3 months after (C) a single RedTouch System treatment session.



Figure 8. Chrono-ageing treatment of hand blotches. Images before (A), and after (B) 2 RedTouch System treatment sessions.



As a final note, we report that all patients observed a further subjective improvement in the results obtained over the weeks, even after the last followup recorded in this study.

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