
INDICATIONS, CLINICAL AND HISTOLOGICAL RESULTS OF NON ABLATIVE LASER TREATMENT WITH K-LASER TFL THERMAFRACTIONALASE

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Background and objectives

Fractional photothermolysis is a new laser technique which allows to create microscopic thermal damages, called microbeams, on the treated area, preserving the surrounding tissue from any lesion. This technique is used to treat and improve the skin disease due to age, acne or traumatic lesions. A clinical and histological approach on dermal and epidermal tissue was analyzed.

Materials and Methods

The study was performed on 39 healthy subjects, in particular 30 women and 9 men, with an age range between 35 and 65 years, who were treated with K-laser TFL Therafractionalase, exploiting the combination of a 1540nm and a 980nm wavelength. For each patient age, sex and phototype (skin type I-IV) were recorded; in particular phototype was evaluated according to the Fitzpatrick classification.

The subjects were divided into 3 groups on the basis of age, sex and treatment: the first group joined together patients with periorbital and perioral wrinkles, the second patients with solar and age spots and the last one patients with different levels of acne scars on the face.

Every group was composed of 13 subjects: 3 were treated with Low, 5 with Mid and 5 with High modality. The treatment consisted of scanning with the scanner handpiece each patient in the selected area. No cooling system was used.

The treatment consisted of 3 sessions at 4 week intervals. Note that an anaesthetic topic cream was applied to all patients one hour prior to each treatment.

The scanner handpiece allows to irradiate the skin surface with a variable number of spots (3,5,7,9) maintaining the fluence constant.

For each treatment the operator executed one horizontal and one vertical scansion on the skin for a uniform application during treatment.

The average fluence applied to the test site was 21 mJ/cm² ("Low" modality), 30 mJ/cm² ("Mid" modality) and 45 mJ/cm² ("High" modality).

The effects on the tissue were checked at established times: immediately after, 1 day after, 7 days after the laser application. The final assessment was made after 3 months.

Photographic proof of the effectiveness of the treatment was documented with Skin Tester F800, based on the scanning of treated areas for the evaluation of skin spots, wrinkles and acne conditions.

To test the treated area an histological analysis was performed after 3 months. A Zeiss microscope was used to analyse the tissue samples.

Subjects with skin diseases (dermatitis, herpes or skin cancer), active infections, immunosuppression, metabolic disorders, previous history of keloids, or pregnant women, can not be treated.

Introduction

The ablative skin resurfacing is commonly performed with CO₂ or Er:YAG laser. The first is considered, at the moment, the most effective laser device to repair the photo damaged tissue. However, while removing the entire epidermis of the treated area, CO₂ produces significant and prolonged post-treatment side effects, such as oedema, crusting and discomfort. In addition, patients may experience long lasting changes in skin pigmentation (hypo and hyperpigmentation), scarring and infection.

The Er:YAG laser is a gentler alternative; it causes less damaging effects and allows for faster healing, but this it is less effective in collagen remodelling. It does not affect the treated dermis as significantly as the CO₂ laser.

The new concept in skin resurfacing is called fractional photothermolysis. This is a non ablative technique which creates microscopic homogeneous thermal spots at a particular depth on the skin (less than 1 mm). The fractioning of the laser affected area is of fundamental importance during the healing process and new skin regeneration procedure, principally because the microspots are surrounded by healthy tissue which triggers off an intense process of tissue regeneration and of fibroblasti and consequent collagen and elastin production.

The purpose of this study is to determine the effectiveness of this innovative laser technique on both the healing response of the human tissue and the formation of new collagen in the dermis.

Results

All patients tolerated the treatment well and pain levels were directly related to the energy of the microbeam. The device hit the localized sectors producing slight itching. Discomfort and pain sensation generally decreased within 1 hour after treatment and completely disappeared in one single day.

Digital pictures of each patient were taken before and after the treatment. Additional pictures were taken in specified time frames: immediately after, 1 day after, 1 week and 3 months after the treatment.

After the 3 sessions established protocol, all patients were asked to fill out a questionnaire to check their satisfaction:

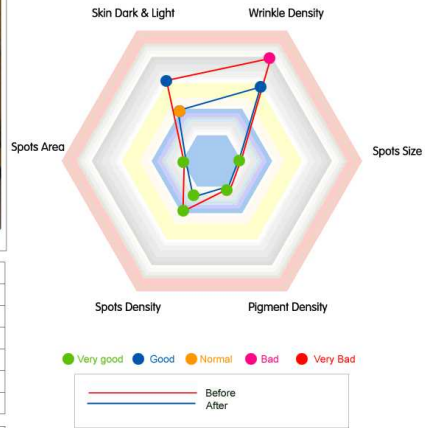
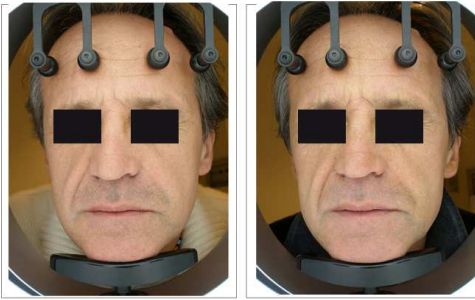
- VERY GOOD
- GOOD
- SATISFACTORY
- POOR
- NO RESULTS

The results proved an overall reduction of wrinkle, skin spot and acne scar. The clinical results were as follows:

- 25 patients VERY GOOD RESULTS
- 14 patients GOOD RESULTS

Facial Scan Report

No. : _____ Name : _____ Sex : _____ Age : _____ Tel. : _____



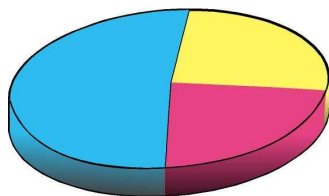
	Very Low	Low	Normal	High	Very High	Tips
Skin Dark & Light	[Progressive bar from green to red]					
Winkles Density	[Progressive bar from green to red]					
Spot Size	[Progressive bar from green to red]					
Pigment Density	[Progressive bar from green to red]					
Spot Density	[Progressive bar from green to red]					
Spot Area	[Progressive bar from green to red]					

Memo :

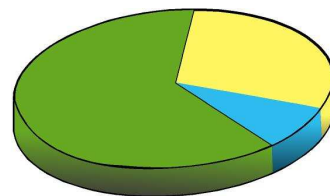
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The following tables (table 1,2,3) highlight the overall improvements after completing a cycle of treatments with laser equipment K-laser TFL thermafractionalase.

Criteria: Level 1 (slightly evident skin conditions) to Level 4 (significantly evident skin conditions)

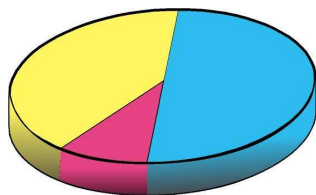


- LEVEL 1
- LEVEL 2
- LEVEL 3
- LEVEL 4

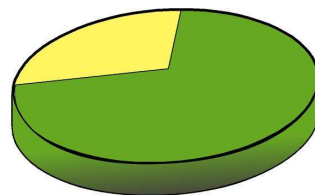


- LEVEL 1
- LEVEL 2
- LEVEL 3
- LEVEL 4

Table 1: First group: skin refreshing treatment. Before and after treatment.

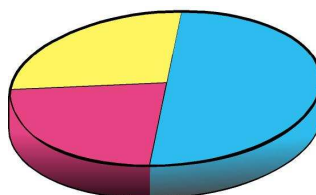


- LEVEL 1
- LEVEL 2
- LEVEL 3
- LEVEL 4

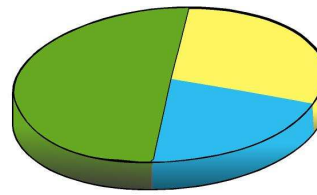


- LEVEL 1
- LEVEL 2
- LEVEL 3
- LEVEL 4

Table 2: Second group: pigmented lesions treatment. Before and after treatment.



- LEVEL 1
- LEVEL 2
- LEVEL 3
- LEVEL 4



- LEVEL 1
- LEVEL 2
- LEVEL 3
- LEVEL 4

Table 3: Third group: acne scars treatment. Before and after treatment.

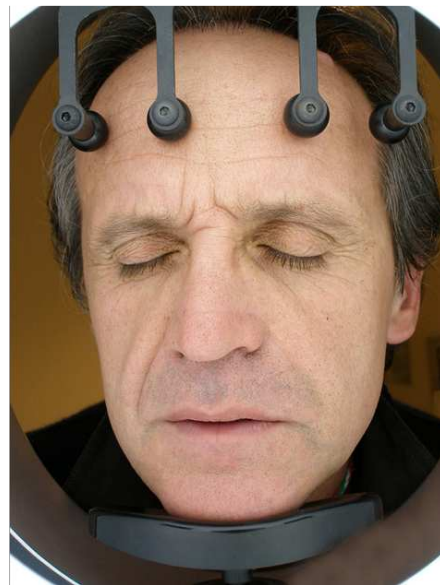
The four different levels represent the various skin conditions of the patients after the treatment.

The statistic data were automatically compiled by the Skin Tester on a comparison basis of the patients results after the treatment. In fact the previous tables demonstrate a mild to moderate improvement in all the three groups.

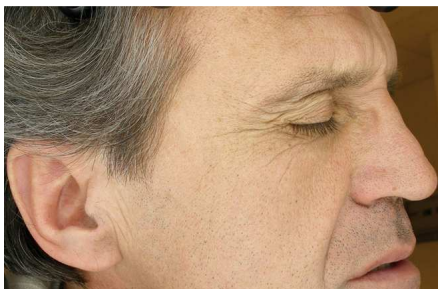
The following pictures (fig.1) show pre and post treatment results on patients of the first group, who were treated for periorbital and perioral wrinkles.



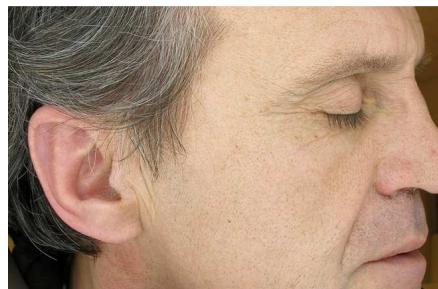
before



after



before



after

Fig. 1: First group

The following pictures (fig. 2) show pre and post treatment of 2 patients of the second group, who were treated for pigmented lesions.



before



after



before



after



before



after

Fig 2: Second group

The following pictures (fig. 3) show pre and post treatment on patients of the third group who were treated for acne scars.



before



after



before



after

Fig 3: Third group

The arm of a patient of the first group was also used to determine the histological effect of the treatment on different fluence. The skin was fixed in 10% of formalin and embedded in paraffin.

Biopsies were performed immediately after the treatment (see next picture). Microthermal zones with columns of altered collagen can be distinguished. The entire stratum corneum remained intact. The figure (fig. 5) shows that immediately after the treatment epidermal and dermal cell necrosis are present and are well defined on an area of 100 μ m, which corresponds to the microbeam's diameter.

The epidermal damage is predominantly positioned in the lower half of epidermis and leads to the disruption of the dermo-epidermal junction and the beginning of the formation of subepidermal clefting. No inflammatory infiltrate is seen in the area surrounding the thermal columns. The vessel around each thermal column is coagulated and no haemorrhage is present into the surrounding tissue.

The picture (fig. 6) shows the results of the biopsy of tissue sample 1 day after. At that time the epidermis was repaired. Microscopic epidermal necrotic debris represent the elimination of thermally damaged keratinocytes. The microscopic epidermal necrotic debris are loaded with melanin. These reside in the epidermis in a subgranular location and contain a substantial amount of pigment. The subepidermal clefting is now more pronounced in the area of the thermal zones and overlies a well-defined zone of homogenized collagen.

After 7 days (fig. 7) the epidermis is free of dyskeratosis and spongiosis. There is no evidence of residual clefting in the dermal-epidermal junction. The dermal microthermal zones still show cones of thermally altered collagen. There is a regressing inflammatory infiltrate with new vascularization surrounding and infiltrating the thermal zones.

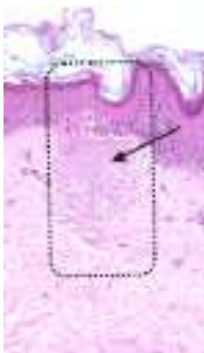


Fig 5: Immediately after treatment

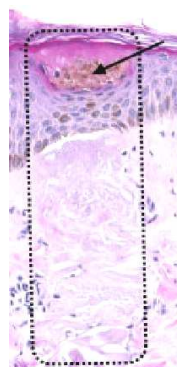


Fig 6: 1 day after

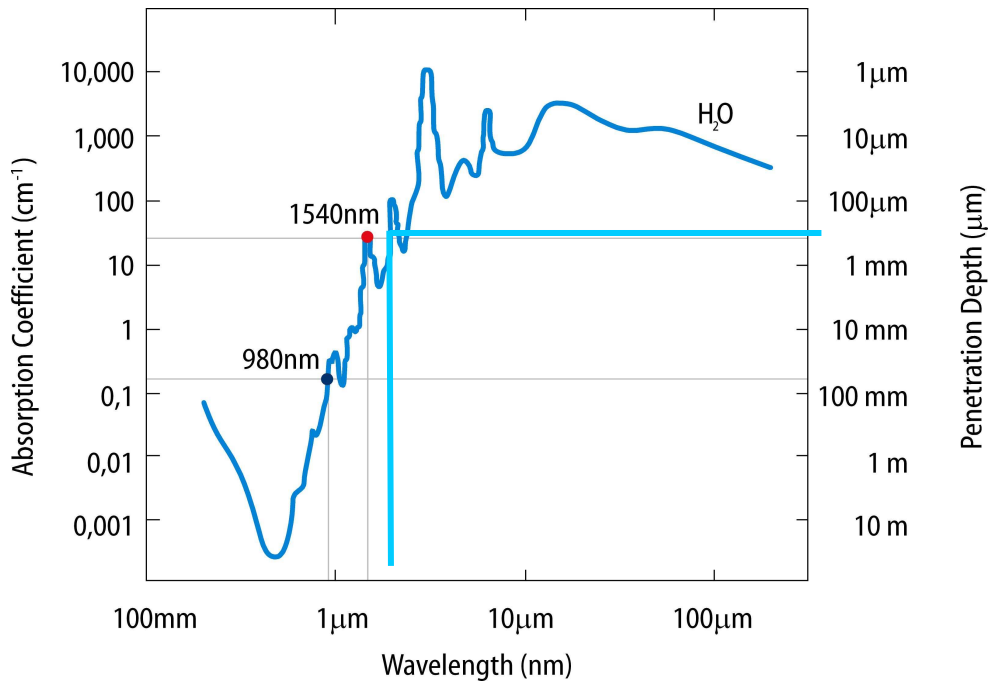


Fig 7: 7 days after

In the biopsy after 3 months there is no evidence of dermal fibrosis or residual cones of altered collagen. No more evidence of inflammatory infiltrate.

The microthermal zones have less than 1 mm diameter and a penetration depth which changes according to the energy of the pulse.

The following graph shows the absorption coefficient (cm⁻¹) and penetration depth (μm) of the wavelength at 1540 nm.



The following figures (fig. 8,9,10) show what happens immediately after a treatment with 3 different levels of fluence: 21 mJ/cm² (“Low” modality), 30 mJ/cm² (“Mid” modality) and 45 mJ/cm² (“High” modality).

Dermal and epidermal zone necrosis are present in a well defined area of less than the 100μm diameter of the beam and at a maximum depth of 800 μm.

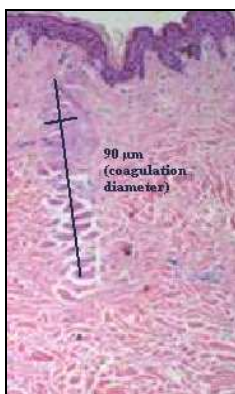


Fig 8: “Low” modality

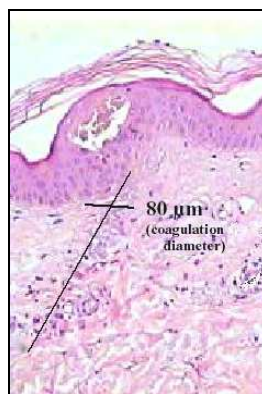


Fig 9: “Mid” modality

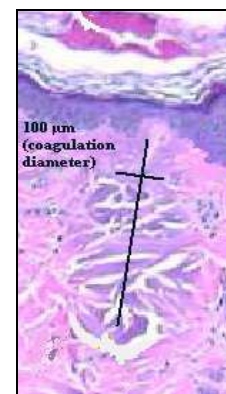


Fig 10: “High” modality

Conclusion

On the basis of the present study, this new laser technique can be considered a safe and effective treatment for wrinkles, skin spots and acne scars, without the discomfort of the traditional methods.

The typical side effects of the ablative devices such as marked erythema or crusting in all the treated area with this new laser technology are absent.

The images and histological data of the thermal columns resulting from this type of laser application reveal the treatment of a well defined and localized area surrounded by healthy skin tissue.

This study demonstrated that irradiation with these wavelengths enables the production of new collagen with a fast recovery of the dermis. The columns of thermal damage after 1 day are completely repaired. After 3 months collagen is completely rearranged and no evidence of dermal fibrosis is observed.

The ease with which this new technology can be applied, the lack of side effects and its absolute effectiveness make it a complete and unprecedented method.

The latest results encourage further testing and accurate diagnostic study of this novel method of treatment.