
Indications, clinical and histological results of non ablative laser treatment with K-laser TFL Thermafractionalase.

Elena Giardini, MD (PADOVA, ITALY).

Federico Fiori, MD (MILANO, ITALY).

BACKGROUND AND OBJECTIVE

Fractional photothermolysis is a new laser technique which allows to create microscopic thermal damages (so called microbeam) on the treated area, preserving tissue surrounding each wounds. This technique is used to treat and get better the skin disease due to age, acne or traumatic lesions. A clinical and histological approach on dermal and epidermal tissue treated with fractional photothermolysis is analyzed.

MATERIALS AND METHODS

The study was performed on 39 healthy subjects, in particular 30 women and 9 men with an age range of 35-65 years, who have been treated with Klaser TFL Thermafractionalase, which exploits 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 is evaluated using the Fitzpatrick's classification.

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

Each group was composed of 13 subjects: 3 were treated with Low, 5 with Mid and 5 with High modality.

The treatment was performed in localized test sites of the body. These sites were used to check the effects of the laser treatment.

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 an anesthetic topic cream was applied to all patients 1 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 a constant fluence.

For each treatment the operator executes 1 horizontal and 1 vertical scansion on the skin for a uniform application during treatment.

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

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 treatment's effectiveness 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, immuno-soppression, metabolic disorders, previous history of cheloids or pregnant women, can not be treated.

INTRODUCTION

The ablative skin resurfacing is commonly performed with CO₂ or Er:YAG laser.

The first one is considered, at the moment, the most effective laser device able 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 edema, crusting and discomfort. In addition, patients may experience long lasting changes in skin pigmentation, scarring and infection.

The Er:YAG laser is a gentler alternative. It causes less damaging effects and allows for faster healing, but this laser is not as 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; it 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 fibroblasts 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 hits the localized sectors producing slight itching. Discomfort and pain sensation generally decrease within 1 hour after treatment and completely disappear in a 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 after and 3 months the treatment.

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

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

The results proved an overall reduction of wrinkles, skin spots and acne scars.

The clinical results were as follows:

- 25 patients: VERY GOOD RESULTS
- 14 patients: GOOD RESULTS

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

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

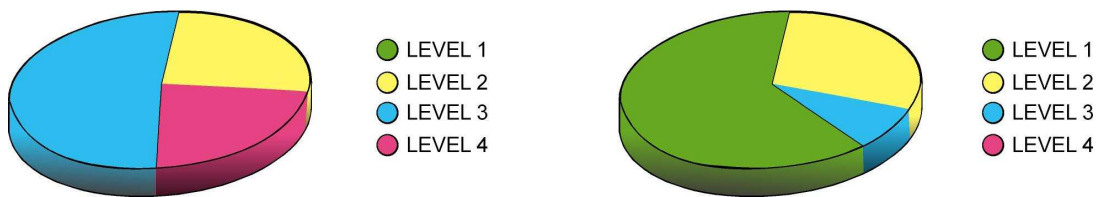


Table 1:First group. Before and after the treatment.

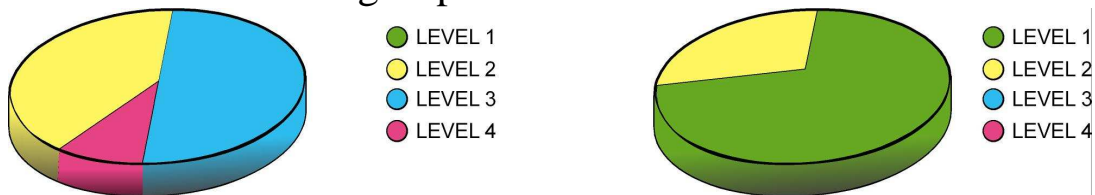


Table 2:Second group. Before and after the treatment.

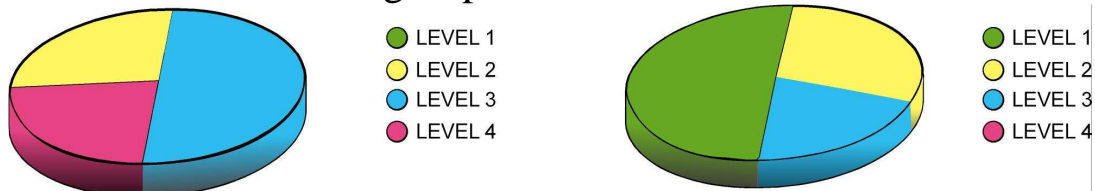


Table 3:Third group. Before and after treatment.

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 treatment. In fact the previous tables demonstrate a mild to moderate improvement in all the three groups.

The following pictures (fig.1,2) demonstrate pre and post treatment results of the first group who were treated for periorbital and perioral wrinkles.



Before



After



Before



After



Before



After

Fig 1: First group



Fig 2: First group

The following pictures (fig. 3) demonstrate pre and post treatment of 2 patients of the second group who were treated for lentigo.



Fig 3: Second group

The following pictures (fig. 4) demonstrates pre and post treatment of the third group who were treated for acne scars.

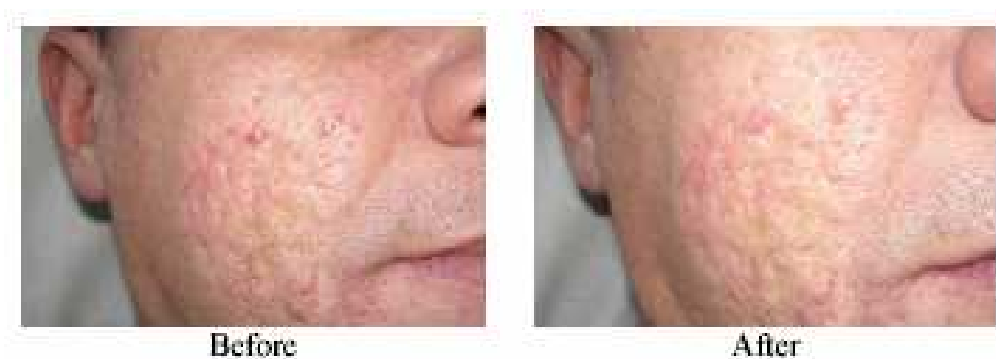


Fig 4: Third group

The arm of a patient of the first group is also used to 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 remains 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, which leads to disruption of the dermo-epidermal junction and the beginning of the formation of subepidermal clefting. No inflammatory infiltrate is yet seen in the region surrounding the thermal columns. The vessel around each thermal column is coagulated and no haemorrhage into the surrounding tissue is present.

The picture (fig. 6) shows the results of the biopsy of tissue sample 1 day after. At that time the epidermis is repaired. Microscopic epidermal necrotic debris represents the elimination of thermally damaged keratinocytes. Microscopic epidermal necrotic debris is loaded with melanin. This one resides in the epidermis in a subgranular location and contains a substantial amount of pigment. Subepidermal clefting is now more pronounced in the area of 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 occasional foci of new vascular surrounding and infiltrating the thermal zones.

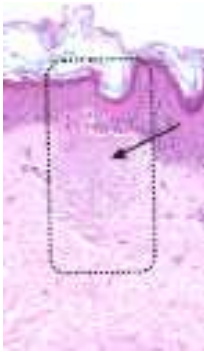


Fig 5: Immediately after treatment

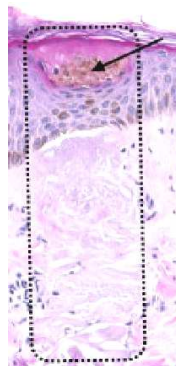


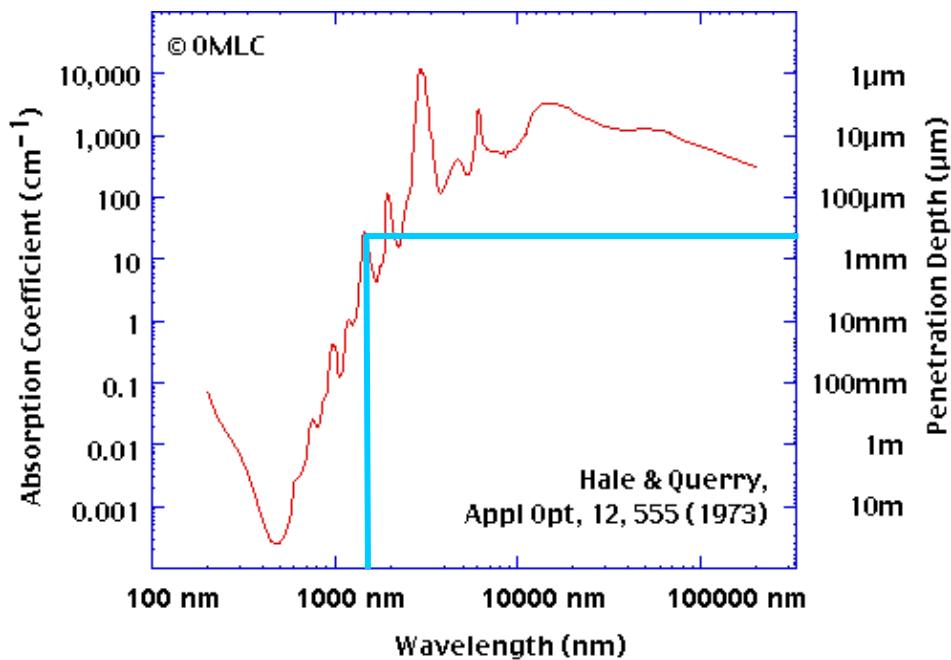
Fig 6: One day after



Fig 7: Seven days after

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

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

Dermal and epidermal zone necrosis are present within a well defined area of less than 100 μm of diameter's beam and a maximum depth of 800 μm.

The day after there is no more epidermal defect.



Fig 8: Low level

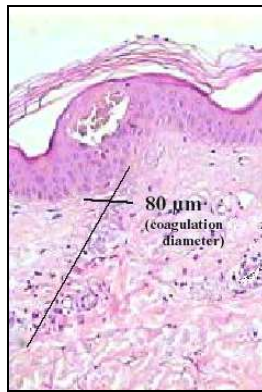


Fig 9: Mid level

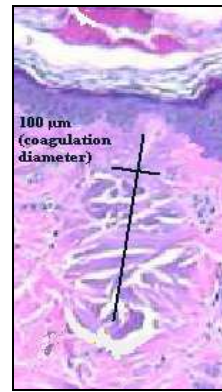


Fig 10: High level

CONCLUSION

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

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

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 that is surrounded by healthy skin tissue. This fractional and well focused laser application allows for the intense and rapid process of tissue regeneration and fibroblasts production triggered off by the surrounding healthy skin.

This study has demonstrated that irradiation with this wavelength enables the production of new collagen with a fast recovery of the dermis. In fact, the columns of thermal damage after 1 day are completely repaired.

These ones are completely replaced within collagen and no evidence of dermic fibrosis is observed after 3 months.

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.

REFERENCES:

1) Prospective direct comparison study of fractional resurfacing using different fluences and densities for skin rejuvenation in Asians.

Kono T, Chan HH, Groff WF, Manstein D, Sakurai H, Takeuchi M, Yamaki T, Soejima K, Nozaki M.

Department of Plastic and Reconstructive Surgery, Tokyo Women's Medical University, Tokyo

2) Shin response to fractional photothermolysis.

Hans-Joachim Lambach, MD, Zeina Tannous MD, R.Rox Anderson MD and Dieter Manstein MD

3) Enhanced efficacy of photodynamic therapy after fractional resurfacing: fractional photodynamic rejuvenation.

Ruiz-Rodriguez R, López L, Candelas D, Zelickson B.

Department of Dermatology, Clínica Ruber, Madrid, Spain

4) A systematic histologic analysis of nonablative laser therapy in a porcine model using the pulsed dye laser

Ravinder Dahiya MD, Samuel M. Lam MD, Edwin F. William III MD

5) Nonablative remodelling: clinical, histologic, ultrasound imaging and profilometric evaluation of 1540 nm ER:Glass Laser

Nathalie Fournier MD, Serge Dahan MD, Gilbert Barneon MD, Stephane Diridollou PHD, Jean Michel Lagarde

6) Fractional photothermolysis for the treatment of surgical scars: a case report.

Behroozan DS, Goldberg LH, Dai T, Geronemus RG, Friedman PM. DermSurgery Associates, Houston, TX 77030, USA.

7) Fractional Photothermolysis: a new concept for cutaneous remodelling using microscopic pattern of thermal injury

Dieter Manstein MD, G.Scott Herron MD, PhD, R.Kelh Sink PhD, Heather Tanner MS and R.Rox Anderson MD.

8) Clinical trial of a laser device called fractional photothermolysis system for acne scars.

Hasegawa T, Matsukura T, Mizuno Y, Suga Y, Ogawa H, Ikeda S. Department of Dermatology, Juntendo University School of Medicine, Bunkyo, Tokyo, Japan.

9) Fractional photothermolysis: treatment of facial and nonfacial cutaneous photodamage with a 1,550-nm erbium-doped fiber laser.

Wanner M, Tanzi EL, Alster TS.

Washington Institute of Dermatologic Laser Surgery, Washington, DC 20005, USA.

10) The use of fractional laser photothermolysis for the treatment of atrophic scars.

Alster TS, Tanzi EL, Lazarus M. Washington Institute of Dermatologic Laser Surgery, Washington, DC, USA.