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Original Research

Non-ablative skin remodeling: an 8-month clinical and 3D in vivo profilometric study with an 810 nm diode laser

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BACKGROUND: Non-ablative remodeling has recently been proposed as a new anti-aging treatment with no downtime.
OBJECTIVE: This study aimed to evaluate objectively, with a three-dimensional (3D) in vivo profilometric study, the efficacy and safety of non-ablative skin remodeling with an 810 nm diode laser on periorbital wrinkles with an 8-month follow-up.
METHODS: Ten female patients (mean age: 55 years) were treated three times at 1-month intervals and then evaluated 5 months after the last treatment. Patients were evaluated using clinical data, standardized photographs and 3D in vivo profilometry in order to quantify the degree of improvement. This objective method evaluates the general degree of roughness (anisotropy) and the depth of the wrinkles.
RESULTS: An observer independent from the study showed slight improvement in the quality of the skin and visual aspect of the wrinkles at 3 months. Eight months later this was confirmed to a lesser degree by clinical and 3D profilometry. No immediate or late adverse effects were noted at any stage of the procedure.
CONCLUSION: This study demonstrated that irradiation with a 810 nm laser emitting in a pulsed mode and connected to a cooling system reduced anisotropy of the skin and improved the clinical aspects of the wrinkles. Results appear quickly at 3 months and are stable at 8 months. *J Cosmet Laser Ther* 2004; 6: 11–15

Introduction

There has been a great interest in the development of non-invasive and non-ablative methods to effectively improve the appearance of wrinkles without patient downtime.

In 1997, Anvari et al[1] described the first method of cryogen spray cooling performed in combination with a non-ablative Nd:YAG 1320 nm laser. Spatially selective photocoagulation achieved thermal injury in the papillary and upper reticular dermis. This procedure controlled thermal dermal damage, leading to subsequent collagen remodeling while preserving the epidermis. Ross et al[2] evaluated an Er:glass laser for non-ablative skin remodeling, but the parameters used caused severe thermal damage which led to side effects and no remodeling. In 2002, Fournier et al[3] published a clinical study with histology, ultrasound imaging, and silicone imprints involving 60 patients with a follow-up at 6 months.

The purpose of the current study was to evaluate the efficacy and safety on periorbital wrinkles of a new DS66 Nidek 810 nm diode laser (Gamagori, Japan) for non-ablative skin remodeling. Objective techniques such as three-dimensional (3D) in vivo profilometry were emphasized in this study.

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Materials and methods

Laser system

We used the new DS66 Nidek diode laser system at 810 nm. A 4 mm spot size beam was delivered through a fiber optic handpiece. We used fixed parameters: the duration of pulses was 182 ms and they are delivered with a fluence of 29 J/cm^2 at 20 W. The 4 mm spot handpiece was connected to a cooling system.

Cooling system

The skin was cooled with a contact sapphire TEC cooling device (Nidek, Gamagori, Japan) in direct contact with the skin. Cooling is obtained by purified water circulating in the tip at 5°C. This handpiece has a 20×20 mm window and is connected to a scanner device to select a pattern adapted to the area to treat. Two passes were made.

Patients and clinical protocol

Ten female patients (mean age 55 years; range 40–62 years) were entered into the study. Each patient had periocular rhytids (crow's feet). For each patient, age, sex, and phototype were recorded. Phototype was evaluated using Fitzpatrick's classification (I–VI). All periorbital areas involved in this protocol had received no previous aesthetic treatments (such as lifting, filling injections, peelings, lasers, botulinum toxin).

There was no visible clinical endpoint in this procedure. Unwanted effects were systematically noted before after each treatment (A, none; B, erythema; C, edema; D, blister; E, hyperpigmentation; F, hypopigmentation).

Clinical photography

Clinical photographs were obtained at baseline and at the 1, 3, and 5-month follow-up visits. Standard lighting and viewing (45° and profile) were used. All photographs were taken with the digital camera Fotofinder (Teachscreen, Griesbach, Germany). Clinical assessments were performed on randomized photographs by one observer independent from the study. Wrinkles were categorized into four groups determined by the mean pretreatment score using a scale of 0–4, where 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = marked.

3D in vivo profilometry

Patients were positioned in front of the VisioFace special measurement bench. This bench includes a head-maintaining system and a mobile carrier on which a 3D sensor is mounted. The 3D microtopography of skin was recorded with the DermaTOP optical 3D in vivo scanner (Breuckmann, Germany; Eotech SA, France). The 3D sensor is based on optical triangulation; a white, light fringe projection technique; and digital image processing. A projector using a microslider device creates the parallel stripe pattern sequence which is projected onto the skin surface and depicted on the CCD chip of a high-resolution camera. Images are digitized and transferred for computer-assisted quantitative evaluation measurement. Mathematical algorithms embedded in the analytical software reconstruct the data into a highly precise 3D profile of the skin surface.

The evaluation software of the system calculates the roughness parameters of the acquired surface topography. A 20×20 mm^2 portion of the topography was extracted in the region of interest around the wrinkles of the peri-orbital area. A total of 30 profiles arranged in a parallel array were extracted from the selected surface. The region was measured in the exact area at each time with high reproducibility with a 5 μm resolution analysis.

Three different roughness equations were used to analyze the data: Ra, Rz and Lr. For Rz, the profile is divided in five sections, the peak-to-valley amplitude within each section is recorded and the average of these values is calculated to reflect the depth of the fine wrinkles; Ra is the average of the height differences between profile points and the mean of three different equations mentioned above and reflects the 'mean roughness'; LR is the calculated distance between points where the mean line intersects the profile.

In summary, the three different roughness equations are used to quantify anisotropy of the skin with high reliability. Lr is the average value of periodicity of the profile. Ra is the arithmetic average of the absolute values of all points of the profile: it is the height of the rectangle with the same length and surface as the profile encloses in the specified sector. Rz is the mean peak-to-valley height and is the arithmetic average of the maximum peak-to-valley height of the roughness values.

Protocol treatment and follow-up

Patients did not use sun protection before or after the treatment, even in summer, since melanin absorption at 810 nm is very low. No anesthesia was used. Along every wrinkle, 4 mm shots were juxtaposed with the scanner pattern. Since there was no clinical endpoint visible with this technique, slight overlapping was accepted.

Patients were treated three times at monthly intervals and had a control visit 5 months after the third and last treatment.

For each session, digital pictures were taken at baseline (T0), before the second session (T1), and at 5 months after the last session (T2). Side effects were recorded. Three-dimensional profilometry was carried out before treatment, at 1 month, and then 5 months after the last session.

Statistical analysis

Observer-evaluated pretreatment and post-treatment photographs by paired randomized comparison were at baseline, before treatment (T0), at one month after the first session (T1) and 5 months after the second and last session (T2). Differences between the pretreatment and post-treatment mean scores were then determined and a paired *t*-test was performed.

Objective data using quantitative 3D in vivo profilometry were analyzed by one author at Biophyderm (Montpellier,

France) at baseline and 5 months after the last session. Student's statistical tests were used to highlight the results.

Results

Photographs

Global mild improvement appeared around the third treatment and with progression 5 months after. Some of the wrinkles became smoother, especially roughness between rhytids on the crow's feet. None of the patients had full clearance of their wrinkles. Fisher's exact test found no significant statistical differences (Figure 1).

Profilometry 3D imaging

A reduction of 13% ($p<0.01$) of the LR value was observed between T1 after one session andT2 5 months after the last session. A reduction of 14.9% ($p<0.01$) of the Rz value was observed between T1 after one session and T2 5 months after the last session (Figure 2).

Side effects

For all treatments, no side effects were reported: scored as 'A' for all patients. With this laser at these parameters, there were no immediate visible effects: no swelling, no erythema and no bleaching. Consequently, there were also no late visible side effects such as dyspigmentation.

Discussion

Numerous treatments including glycolic acid,[4] retinoids,[4] salicylic acid,[4] and a variety of chemical peeling[5] and laser skin resurfacing[6] have been developed to improve photoaging and wrinkling. The major disadvantage is the requisite recovery period following the procedure.

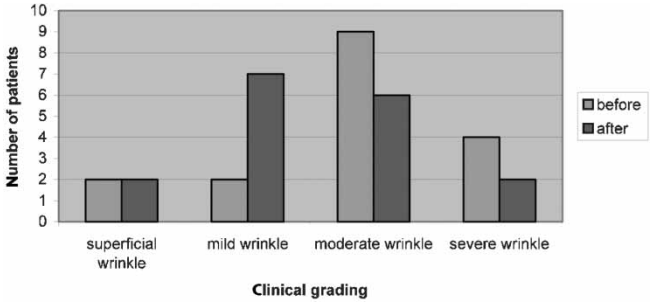

Figure 1
Clinical improvement of different wrinkles.

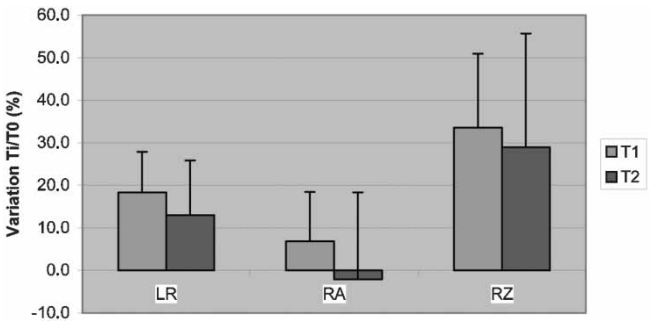

Figure 2
Improvement of roughness parameters between T1 and T2.

The mechanism of photoaging and wrinkling is not clearly elucidated, but Fisher et al[7] found that UV irradiation induces metalloproteinases in the skin that include collagenase and gelatinase, which subsequently degrade dermal collagen.

Evidence of skin remodeling has been shown by Biesman et al (unpublished data) with the DS60 diode 810 nm on a piglet model with epidermal preservation. This study presented the follow-up at 5 months of a new device, a diode 810 nm, in collagen remodeling. Pain was minimal or absent and patients had no downtime period.

In this study, we observed that clinical improvement with randomized photographs was evident with moderate and severe wrinkles and subtle for superficial and mild wrinkles. However, clinical photographs are dependent on the quality of the pictures, the exposure, and the eye of the observer (Figure 3). Three dimensional skin in vivo profilometry shows an improvement in the roughness and depth of wrinkles (Figure 4). Objective data obtained from 3D skin in vivo imaging are not observer-dependent and allowed comparison with some others studies.

After three treatment sessions with a diode 810 nm laser, we quantified improvement of surface topography using 3D in vivo skin profilometry. At 8 months the greatest percentage improvement was observed. The results were the following: a reduction of 13% of the average value of periodicity of the profile Lr ($p<0.01$) and a reduction of 14.9% of the depth of fine wrinkles Rz ($p<0.01$) between T1 and T2. Clinical efficacy on roughness parameters of the surface topography is statistically significant between T1 and T2.

Friedman et al[8] observed the same improvement during the first months, suggesting that collagen remodeling begins after 1 month and plateaus around 6 months. Other quantitative methods of 3D morphometric analysis to assess age-related skin wrinkles were proposed with reproducibility (9). Three-dimensional in vivo profilometry provides a real time, objective analysis of patient-specific characteristics potentially enabling clinicians to predict the limitations and efficacy of various aesthetic procedures.

These results were obtained with an absolute lack of side effects for all the patients who were not practicing sun protection. This means that the risk of hypo- or hyperpigmentation is almost none with this wavelength and the parameters used in our study.

A complication in Menaker's study[10] with a 1320 nm non-ablative laser was found in three of 10 patients. They observed pitted scarring after blistering. Blistering could generate complications and scars and needs to be avoided in all cases. In a study by Ross et al[3] with Er:glass, remodeling was obtained, as were a lot of unwanted effects such as scars and blisters on the postauricular area, which is not a sun-damaged area. This seems due to the interpulse time and bony zone. Fournier et al,[11] in their second study, found that results were stable at 14 months. Our own study needs further follow-up to evaluate the stability of the results.

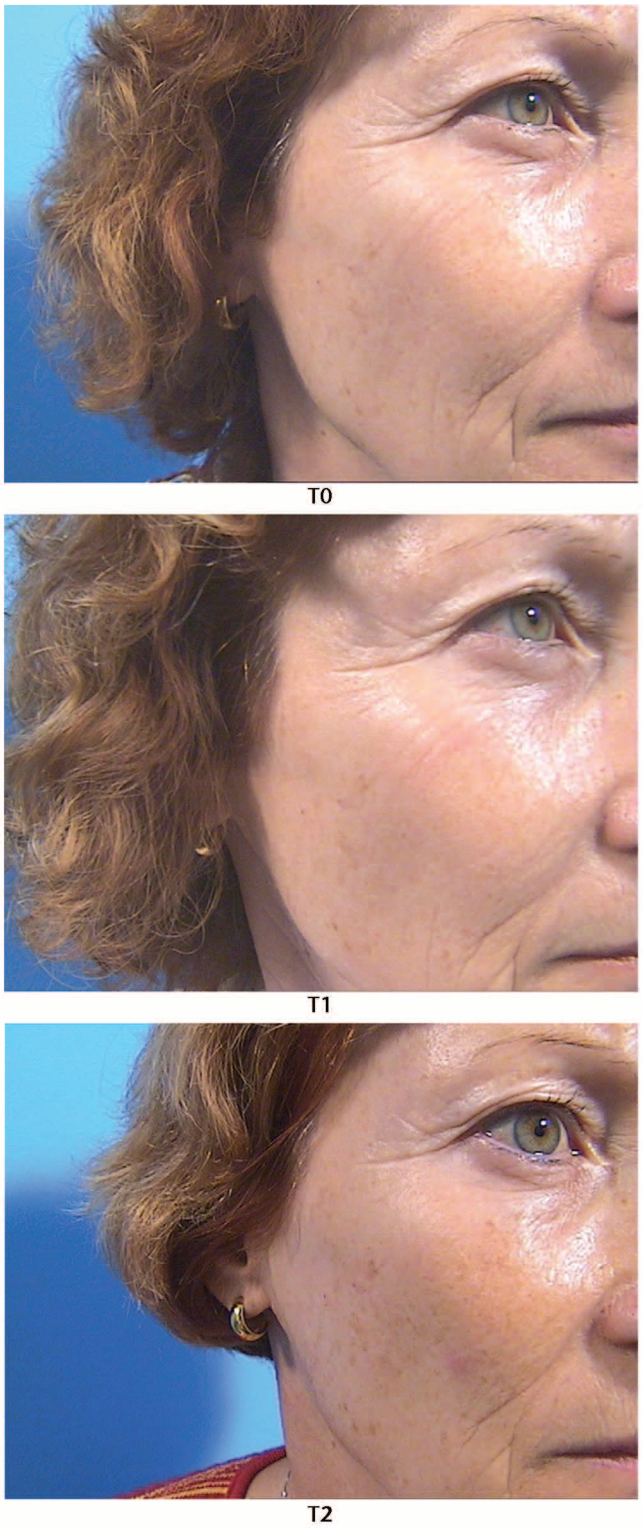

Figure 3
Clinical photographs: T0 (before treatment), T1 (1 month after the first treatment), T2 (5 months after the last treatment).

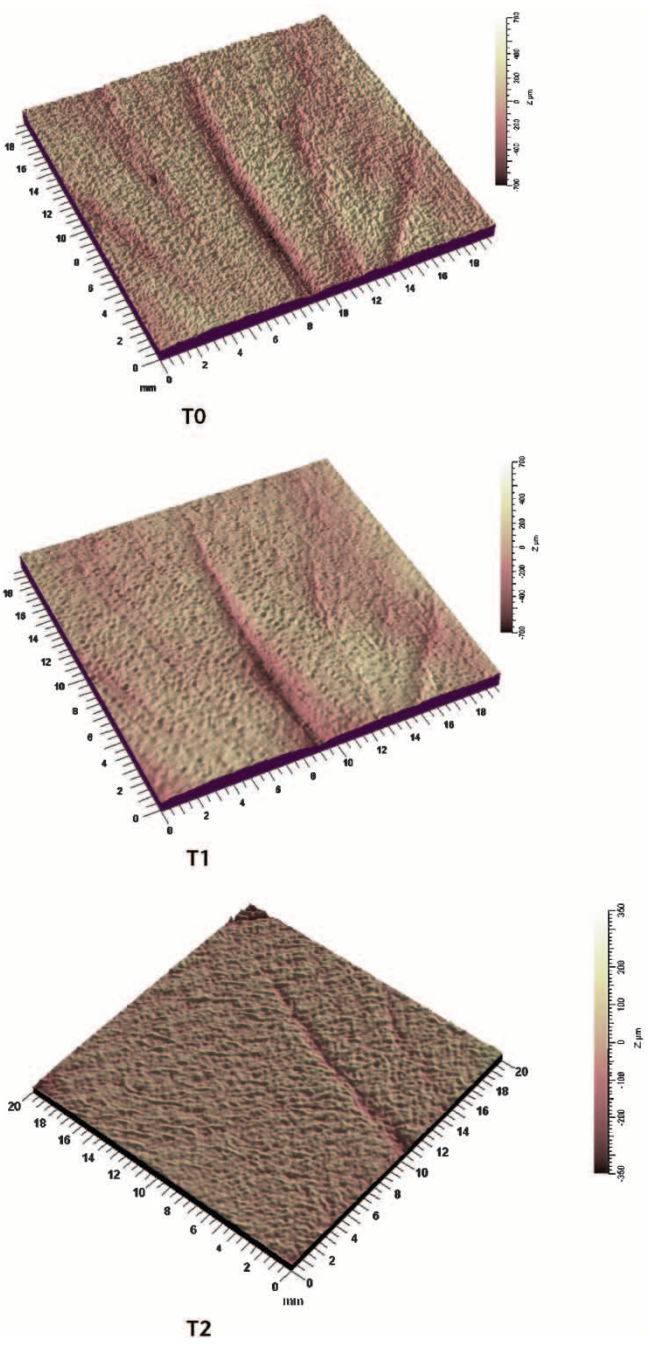

Figure 4
Example of 3D imaging: T0 (before treatment), T1 (1 month after the first treatment), T2 (5 months after the last treatment).

Conclusion

In this study, objective measurement with 3D in vivo profilometric study processes led to indisputable data. The clinical improvement is subtle and must be explained to the patient before continuing the procedure. Three treatments are enough to achieve slight improvement.

The 810 nm diode laser emitted in a pulsed mode connected to a cooling system is safe. There were no complications. Collagen remodeling and improvement continues after each session and requires months to reach its objective. Long-term follow-up is needed to assess the maintenance of this effectiveness.

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