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ORIGINAL ARTICLE

Electro-optical synergy (ELOS™) technology for nonablative skin rejuvenation: a preliminary prospective study

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Abstract

Background and objectives In this preliminary prospective study, we evaluated the efficacy and safety of nonablative wrinkle treatment using combined radiofrequency (RF) and optical energy (Polaris™). The dual energy technology of Polaris™, called ELOS™, which stands for electro-optical synergy, uses synchronous pulses of bipolar RF current and pulsed visible light (diode laser) delivered in the same pulse.

Materials and methods Twenty-four subjects with periorbital and perioral wrinkles received six treatments at 4-week intervals with the Polaris™ WR (Syneron, Inc., Israel, 900 nm, max. RF energy 100 J/cm^3, max. laser energy 50 J/cm^2). Each treatment consisted of two passes over the treatment area using pulsed optical and RF parameters that were determined by the patient's skin phenotype and distribution of target chromophores. The follow-up period was 3 months after the last treatment.

Results Independent scoring of blinded photographs showed a wrinkle score improvement of at least 1 (0 = no improvement, 1 = medium, 2 = good, 3 = excellent improvement) 3 months after the last of six treatment sessions. There was no difference between periorbital and perioral wrinkle reduction. Fifty-eight per cent (14/24) of the subjects reported a notable wrinkle reduction; 16% noted mild to moderate oedema and erythema lasting for no more than 1 day. Scarring or pigmentary changes were not detected. The average pain score was 0.6 (0 = no pain, 5 = intolerable pain).

Conclusion Multiple treatments with the Polaris™ WR produced objective and subjective reduction of periorbital and perioral wrinkles. The occurrence of side-effects and pain was very low. The clinical effect may be caused by matrix coagulation of the deep dermis by the RF and selective thermolysis of blood vessels with the 900 nm diode laser.

Introduction

In recent years, ablative procedures with CO_2 and Er:YAG lasers have proved to be effective and reproducible means of treating perioral and periorbital wrinkles.[1–3] With these procedures it is possible to achieve superficial ablation and selective heating of dermal collagen, which leads to reactive dermal neocollagen formation and tightening of the facial skin.[1,4–6] The major disadvantage of ablative treatment methods is the erosion of large surfaces, which necessitates a recuperation period of 1–2 weeks. There are also potential risks (infections, scarring, hyper- and hypopigmentation[1,7,8]), which is why new options in nonablative skin rejuvenation have been the subject of research for the past few years. Nonablative laser and intense pulsed-light (IPL) systems, which may tighten the skin without harming the epidermis, are currently being examined as alternatives. Analogous to the ablative methods, the mechanism of action is based on selective thermal damage followed by new collagen formation.[9]

However, even this approach is limited by several factors: unsatisfactory efficacy, erythema that lasts several days, other inconvenient side-effects, and dark skin types.[9]

Electro-optical synergy (ELOS™) technology is a newly developed method that uses the synergistic effects of two different kinds of energy to achieve selective heating of dermal target structures while protecting the surrounding tissue.

Materials and methods

Twenty-four females with periorbital and perioral rhytids were enrolled in a preliminary prospective study conducted from May 2003 to January 2004. Written informed consent following full explanation was obtained from all patients before therapy. The inclusion criteria were age 35–70 years, Fitzpatrick skin types I–IV, Fitzpatrick wrinkle scores I–III, periorbital or perioral wrinkles, no laser or other peeling or pharmaceutical pretreatment, no botulinum toxin injections and no topical retinoids or other topical antiwrinkle therapy in the past 6 months.

In the study population the ages ranged from 39 to 69 years (mean 52 years, median 51 years). There were 14 persons with skin type II and 10 with skin type III. The Fitzpatrick wrinkle score was I in 16 subjects, II in five subjects and III in three subjects. A total of 35 areas were treated. An area was defined as either a perioral or a periorbital region. Of the 35 areas treated, 15 were periorbital and 20 were perioral (see Table 1).

The treatment protocol consisted of six treatment sessions at intervals of 4 weeks (see Table 2). Each treatment consisted of two passes over the treatment area using pulsed optical and radiofrequency (RF) parameters that were determined by the patient's skin phenotype and distribution of target chromophores. The patients were treated with the Polaris™ system (Syneron, Inc., Israel). Its diode laser emits a wavelength of 900 nm with a maximum fluence of up to 50 J/cm^2 with the WR-handpiece and a pulse duration of up to 200 ms in combination with a 1 MHz bipolar RF energy (max. fluence up to 100 J/cm^3) with a pulse duration of up to 200 ms. We used a laser fluence of 26–30 J/cm^2 (mean 29.7 J/cm^2) and an RF fluence of 70–90 J/cm^3 (mean 83.7 J/cm^3).

Both forms of energy are transferred to the skin using the same handpiece (size 8 × 12 mm). The skin surface is cooled to 5 °C by means of an integrated contact cooling system. The contact between skin and handpiece is optimized with a contact gel (Syneron Inc., Israel). The pulse sequence starts after a short calibration phase with the simultaneous application of the laser pulse and RF energy. The transfer of bipolar RF current takes place through two electrodes that are applied directly to the skin and the RF pulse lasts longer than the light pulse. At first, the optical energy heats the target structures (haemoglobin in the dermal vessels) according to the principle of selective photothermolysis.[10] The heat is conducted to the surrounding tissue, which contains the collagen fibrils. This decreases the impedance of the tissue, and the RF current further heats the prewarmed structures.[11] Overheating is prevented by continuous monitoring of the impedance. Throughout the duration of the pulse, the temperature of the tissue is measured every millisecond and, in the case of overheating, the flow of RF current is automatically interrupted.

Table 1 Study population

Category	Absolute	Percentage
Gender		
Female	24	100
Male	0	0
Age (years)		
< 40	3	12.5
41–50	9	37.5
51–60	6	25.0
> 60	6	25.0
Fitzpatrick skin type		
I	0	0.0
II	14	58.3
III	10	41.7
IV	0	0.0
Fitzpatrick wrinkle score		
I	16	66.7
II	5	20.8
III	3	12.5
Treatment areas (several possible per patient)		
Periorbital	15	
Perioral	20	
Pretreatment		
No	24	100
Yes	0	0

Table 2 Treatment protocol

Category	Instance
Inclusion criteria	Age 35–70 years Periorbital or perioral wrinkles Fitzpatrick skin type I–IV Fitzpatrick wrinkle score I–III No laser or peeling pretreatment in the past 6 months
Number of sessions	6
Treatment interval	4 weeks
Number of passes	2
Laser fluence	26–30 J/cm^2
RF fluence	70–90 J/cm^3
Follow-up	3 months

By cooling the epidermis, which means an increase in the impedance, the RF current is prevented from flowing too superficially.

In the periorbital region, we kept a distance of about 1 cm from the eyelid as the RF energy and the laser light penetrate fairly deeply and we wanted to prevent bulbous affection. For eye protection, we used white plastic eye-shields.

We collected data on pain using a numerical analogue scale (NAS) ranging from 0 ('no pain') to 5 ('maximal pain'). Additionally, we recorded the duration of transient erythema, oedema and dysesthaesia after each treatment. The clearance or improvement of the wrinkles after six sessions was scored on a NAS of 0 ('none'), 1 ('medium'), 2 ('good') and 3 ('excellent') and was evaluated by means of quantitative and single blind assessment of the photographic documentation (0–100% with a granularity of 33%, which maps to the NAS of 0–3). The clearance was evaluated 3 months after the last treatment both by the patients themselves (subjective clearance) and by three independent physicians who were not otherwise involved in the study (objective clearance). Photographic documentation was carried out before the first session and 3 months after the last [EOS100 (Canon USA, Inc, Lake Success, NY, USA) with Agfa-chrome CTx 100 films (Agfa Corp, Ridgefield Park, NJ, USA)]. The photographs were standardized by using the same type of film, camera, laboratory, ring-flash and ambient light. It was not possible to use the same distance, angle or magnification because the regions to be treated were of different sizes and orientations.

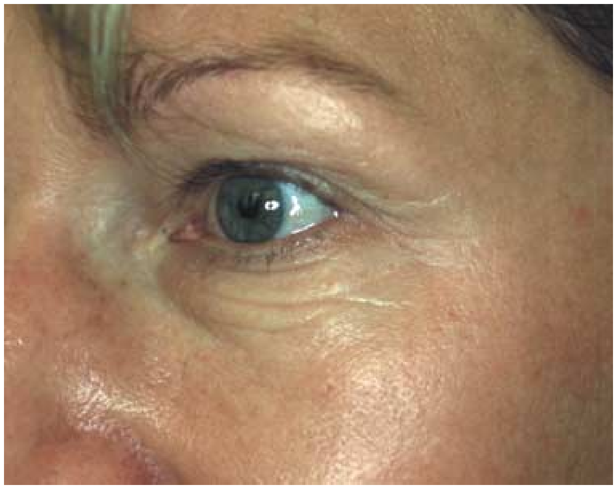

fig. 1 Periorbital wrinkles before treatment.

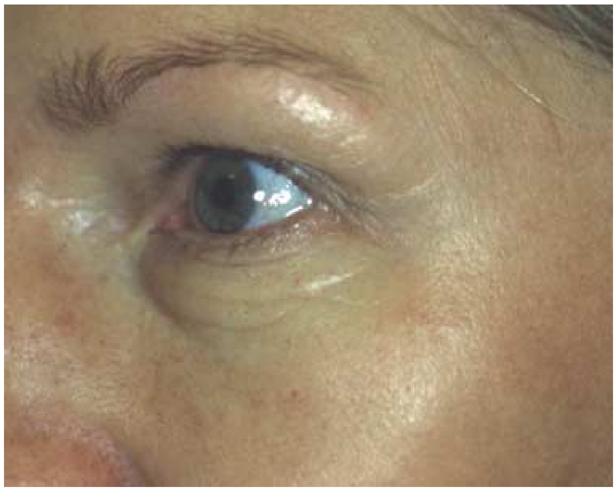

fig. 2 Periorbital wrinkles 3 months after six treatment sessions with Polaris™.

Results

With respect to the subjective clearance 3 months after the last treatment, 10 patients (41.7%) observed no improvement (0), in 10 patients (41.7%) there was a medium clearance (1), four patients (16.7%) scored the clearance as good (2) and none of them found the clearance excellent (3). This means that 58% (14/24) of the subjects reported medium or notable wrinkle reduction (figs 1–4). By contrast, the objective clearance was scored as follows: no improvement 6.2 (25.8%), medium improvement 12.8 (53.3%), good improvement 4.6 (19.2%), excellent improvement 0.2 (0.8%). This means that the independent observers reported medium or notable wrinkle reduction in 73% of the subjects. There was no difference between periorbital and perioral wrinkle reduction (see Table 3).

We observed transient erythema for a maximum of 1 day in two patients (8.3%), transient oedema in one patient (4.2%) and dysaesthesia (burning sensation) for a maximum of 4 h in one patient (4.2%). This gives a total of 16.7% of patients with short-term, transient side-effects.

With regard to pain, there were 11 patients with no pain (0) (45.8%), 12 patients with minimal pain (1) (50%) and one patient with slight pain (2) (4.2%). The average pain score was 0.6.

We did not observe any severe side-effects such as crusting, blistering, pigmentary changes or scarring.

Discussion

The use of RF energy is not new in medicine (e.g. unipolar electrocoagulation for haemostasis during surgical operations); in the field of aesthetic medicine, however, it has been used and evaluated for only about 2 years, among other methods for noninvasive skin rejuvenation.[12] So far, articles using ELOS™ technology, a combination of

fig. 3 Perioral wrinkles before treatment (arrow marks a reference point).

fig. 4 Perioral wrinkles 3 months after six treatment sessions with Polaris™.

bipolar RF and optical energy, have been published infrequently.[13,14] We investigated this innovative technology (with Polaris™) for the first time for nonablative skin rejuvenation with a prospective study design.

It is known that because of scattering, the maximal effect of light fluence is on the skin surface at the area of contact between the handpiece and the skin. Maximal RF current is in the dermis between the two contact electrodes because the geometry of the RF electrodes and the integrated cooling system are designed to apply the RF current to a depth of about 2 mm.[12] The Polaris™ handpiece creates an overlap of these two forms of energy inside the dermis, while on the skin surface the energies are separated spatially. Therefore, review of initial *in vitro* studies showed that the clinical effect on tissue was greatest at a depth of 1–2 mm, causing matrix coagulation of the deep dermis with RF and selective thermolysis of blood vessels with the diode laser.[15]

Table 3 Results

Category	**Absolute**	**Percentage**
Side-effects		
Transient erythema, max. 1 day	2	8.3
Transient oedema, max. 1 day	1	4.2
Dysaesthesia, max. 4 h	1	4.2
Pain		
0 = no	11	45.8
1	12	50.0
2	1	4.2
3	0	0
4	0	0
5 = maximal	0	0
Subjective clearance		
0 = no	10	41.7
1	10	41.7
2	4	16.7
3 = excellent	0	0
Objective clearance		
0 = no	6.2	25.8
1	12.8	53.3
2	4.6	19.2
3 = excellent	0.2	0.8

The heat produced by the RF current can be estimated using the formula: $H = E^2 \times R$, where E stands for the current density and R for the impedance of the tissue.[11,12] The impedance is negative-linearly proportional to tissue temperature, with a thermal coefficient A of approximately –2%/°C, and to the frequency of the RF current.[16,17] Therefore, the distribution of the RF current can be influenced by either preheating (optical energy) or precooling of certain structures or areas.[17] Preheating will decrease the impedance, therefore increasing the flux density of the RF current and consequently raising selective heat production (E^2 increases quadratically, whereas R decreases linearly). The combination of two energy sources enables the target structures (i.e. collagen fibrils) to be heated selectively without being dependent on the melanin content of the epidermis.

In 2002, Bitter and Mulholland[13] reported the results of their first 100 patients who had undergone five-time ‘fullface’-subsurfacing with the Aurora™ system, which is a combination of IPL and RF technology. They did not, however, provide any information on the study design. The percentage of wrinkle reduction in perioral and periorbital regions as well as on the forehead was reported by the patients to be 40–90%. Side-effects such as superficial blistering and crusting occurred rarely; transient erythema occurred in approximately 80% of the cases. With simultaneous superficial cooling, the pain caused by the pulses was considered to be minimal by the patients.

According to the patients, the combined therapy showed its effect faster, was more convenient and produced better results than the therapy with IPL alone.

In an extensive review, Grema *et al.*[9] reported that the primary goal expected of nonablative procedures is to accomplish long-lasting, effective reduction of wrinkles without major side-effects or long periods of recuperation. A critical assessment of the studies on this topic has, however, shown that this is unfortunately not the case. The side-effects range from minor transient erythema and cosmetically undesirable purpura to pinpoint bleeding and even to dyspigmentation and scarring.[18,19] Healing periods of 2 days to 2 weeks have been reported.

The range of side-effects in our study was very small. Crusting, blistering and pigmentary changes or scarring were not observed. Most of the transient erythema can be seen as reactive hyperaemia of the skin caused by the contact cooling of the skin surface. At this point, we should mention that, during treatment, the electrodes must at all times lie directly on the skin to prevent unnecessary skin irritation. This requires careful procedure and concentration throughout the treatment session. The pain was scored very low by the patients; no analgesics were necessary.

Nevertheless, we could show an improvement in the subjective as well as in the objective clearance after a follow-up period of 3 months. The discrepancy between the two clearance assessments may be caused by too high initial expectations on the part of the patients. As the adverse effects were very low, it should be possible to safely increase the treatment energies, which may lead to even better clearance. We suggest that development of the adjustments to the device (pulse sequence, energy density, passes per session, modification of intervals between treatments) will bring about improved efficacy, and we await further studies.

We observed that some patients responded better than others. The exact reason for this is unknown. In the patients who did not respond, the collagen induction may be less intense than in the other patients. This seems to be age dependent, because in older patients the proportion of nonresponders is greater than in younger patients.

Because of the synergistic effect of RF and laser light, lower levels of both energies can be used. This may reduce the risk of side-effects associated with either RF or optical treatment alone. Furthermore, it opens up the way for wrinkle treatment of darker skin types that, up to now, have hardly been treatable because of a high rate of side-effects.

Conclusion

ELOS™ technology is a promising new method in aesthetic IPL and laser therapy. Multiple noninvasive treatments with the Polaris™ reduced periorbital and perioral wrinkles in about 60% of the patients, while about 40% of the patients did not respond to the procedure. Side-effects and pain were very low. The clinical effect may be caused by matrix coagulation of the deep dermis by the RF and selective thermolysis of blood vessels with the 900 nm diode laser.

Controlled prospective studies with longer follow-up periods aimed at optimization and intensification of the treatment parameters need to be conducted to evaluate the significance of these devices for the treatment of wrinkles as well as vascular and pigmented lesions in the future.

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