
Skin Renewal Using a Combination of Electrical and Optical Energies – Clinical Study

Antonio Del Giglio M.D., James Shaoul M.D.

Introduction

Skin renewal is a non-medical term for a variety of skin treatments, such as pigmented lesion removal, vascular lesion removal, wrinkle reduction, and improving skin texture. Intense pulsed light has proven to be an effective methodology for treating a wide variety of lesions. The basic theory behind the use of all devices is selective photothermolysis, utilizing a pulse of light in the proper wavelength and for the proper duration¹. Pulse dye laser was first used a few decades ago to treat superficial blood vessels, such as Port Wine Stain (PWS). Since then, many systems were developed using different technologies and wavelengths. It is a huge challenge to design a machine that can treat a variety of lesions because lesions differ greatly in terms of chromophores, size and depth. Lasers were usually used only on one specific type of lesion since the wavelength is fixed, and it is defined by the laser device in use. The development of Intense Pulsed Light allowed the user to change the filter and thus enabled different chromophores to be targeted, at a variety of depths².

Pigmented lesions, such as lentigines, café au lait, and nevi spili, contain a high concentration of melanin and are usually superficial. The ideal optical parameters for treating such lesions are 580-1000 nm, with a short pulse duration. Vascular lesions are harder to treat since the range of vessels varies from the superficial, measuring a few tens of microns in depth and diameter, as in PWS, up to 2mm in both diameter and depth for leg veins. Treatment of the former (e.g. PWS) requires shorter wavelengths and pulse duration, while the latter type of lesion requires longer wavelengths and longer pulse duration. Non-ablative wrinkle treatment is currently done with two devices: one utilizes a wavelength of 1.32 microns combined with surface cooling, while the second uses low energy, at 585 nm. In both cases, some improvement can be seen after several treatments.

Because of the wide diversity in lesion depth, size, and type, several devices are usually required in order to effectively treat lesions and improve skin texture.

The theoretical limit of all light-based devices is reached when treating targets at depths that require the light to pass through the epidermis in order to reach the lesion. In such cases, treatment parameters should be optimized to reduce absorption of visible and infrared light by melanin in the epidermis. For this reason, optimization of light-based treatment has now reached the saturation point. In order to achieve a new level of safety and efficiency, innovation in the underlying technology is required.

Study objectives

The multi-site clinical study was conducted with the aim of evaluating a new method of skin treatment. The main idea behind the method is to combine two types of energies: optical energy and electrical (conducted RF) energy. This combination allows the use of less optical energy, at a level that is safe even for dark skin. The reduction in optical energy is compensated for by utilizing a different, non-optical type of energy that, like optical energy, is also selectively absorbed by the target structure. The other key requirement for the additional energy was that it not affect the melanin of the epidermis. We found that electrical energy, in the radio frequency (RF) range, was a perfect fit with the above-mentioned criteria for combination with optical energy.

The study was conducted using Syneron's Aurora SR Skin Renewal system, which utilizes a combination of conducted electrical energy in the RF range and optical energy. Light pulse in the visible and the near infrared range was applied simultaneously with a pulse of conducted RF energy. Absorbed energy comprised electrical energy and optical energy in approximately equal parts. Conducted RF energy was applied via the electrodes embedded in the system applicator and brought into contact with the skin surface. The geometry of the electrodes was optimized to provide an energy penetration depth of 4mm. In the study, higher RF energy and lower optical energy were used for dark skin.

Methods and patients

Sixty-one treatment sites on 47 male and female patients with Fitzpatrick's skin types 2 to 4 were selected for the study. The treatment sites included various pigmented and vascular lesions, with varying degrees of skin texture. Table 1, below, shows the distribution of patients by age. The range of ages was 29-72 years old.

Table 1.

<i>Age group</i>	<i>Number of patients</i>
<i><41</i>	<i>9</i>
<i>41-60</i>	<i>40</i>
<i>>60</i>	<i>12</i>

A variety of lesion types were chosen for the study, as shown in Table 2, below.

Table 2.

<i>Treatment target</i>	<i>Number of patients</i>
<i>Vascular lesion</i>	<i>20</i>
<i>Pigmented lesion</i>	<i>26</i>
<i>Skin rejuvenation</i>	<i>15</i>

Informed consent of all participants was obtained and the body sites to be treated were identified and photographed. A baseline evaluation of lesion condition and skin texture was obtained by the investigators. The target areas were shaved prior to treatment. No topical anesthetic cream or other anesthetic was applied.

The Aurora SR system, which employs a combination of optical and conducted RF energy for skin renewal, was used for the study. RF energy was applied to the skin surface via two electrodes embedded in the applicator of the system. The shape and the distance between the electrodes are optimized for penetration of up to 4mm. It is important to note that RF energy absorbance does not depend on skin pigmentation, but is determined by the electrical parameters of the tissue. As the target tissue becomes hotter the impedance becomes lower, therefore more RF current flows, further increasing the target temperature. The frequency of the RF current in the pulse is optimized to penetrate through the skin surface and to be selectively absorbed by the target.

In the study, the optical energy range used varied from 15 to 45 J/cm², while the RF energy range was 10-20 J/cm³. Skin temperature was maintained at around 5° Centigrade by the effective epidermal cooling provided by the system.

Treatment procedure and results

Treatment technique

In the study, transparent gel was used for skin hydration. Light pressure was applied via the applicator to the treatment sites in order to ensure good coupling of electrodes to the skin surface, while avoiding draining the blood vessels. It is very important not to apply too much pressure in order to prevent the light guide coming into contact with the skin.

On patients and/or body sites with darker skin, lower optical energy was used, while higher optical energy was used on patients and/or body sites with lighter skin. On larger facial or leg vessels of up to 1 mm, a long pulse mode was used.

Immediate response

In contrast to other purely optical devices, the Aurora SR system uses a low level of optical energy, which leads to slower heating of the target. Hence, the immediate response is somewhat different to the response usually achieved with optical energy alone.

Effective cooling protects the epidermis from heat damage. Transient erythema above the lesion was the only effect observed after the pulse. While erythema was observed in some patients, in most cases, it was delayed, appearing 5-10 minutes post treatment, and disappearing within a few hours. Pigmented lesions tend to respond slightly differently from other types of lesions, usually becoming darker a few minutes after treatment. They scab after 2-5 days and peel off 4-6 days after scabbing. As the cooling has the effect of delaying all side effects, the patients were asked to observe the treated site and to report any side effects noticed in the hours or days immediately following the treatment.

Follow-up observation

During the first week post treatment, skin texture improves gradually. Pigmented lesions usually take 2-3 weeks to clear, while large vascular lesions can take 8-10 weeks to disappear.

The study patients were observed one month after the treatment. Clinical examination of skin texture and lesion clearance was employed to access the efficacy of the treatment. Lesion clearance (see Tables 3 and 4, below) was assessed by the investigators.



Figure 1. Rosacea and rough skin texture on 40-year-old male. Skin type: III. Light fluence: 20 J/cm². RF energy: 15 J/cm³. Left: before. Right: Two months post two treatment sessions.

Table 3. Patient distribution by clearance group

Clearance group	Number of patients
0-25%	8
26-50%	32
51%-75%	15
75-90%	6

Table 4. Clearance by treatment target

Treatment target	Clearance
Vascular lesion	40.25%
Pigmented lesion	60.0%
Skin rejuvenation	37.3%

Discussion

The clinical study results show that the best clearance was obtained on pigmented lesions, with 60% average clearance. For vascular lesions and skin texture, the results were not as dramatic, with average improvement of about 40% noted. On vascular lesions, maximal RF energy (15-20 J/cm³) was used, while lower settings were used for pigmented lesions.

The level of optical energy varied, in the range of 15-45 J/cm².

For pigmented lesions, a single treatment should usually produce very good results. In cases where there are more than one type of pigmented lesion, with different colors, the darker lesions should be treated first, at low energy. In the next treatment session, energy should be higher to target the lighter lesions.

In the case of skin texture improvement, 3-4 treatment sessions are required. The skin texture gradually improves with every treatment.

Vascular lesions are somewhat more difficult to treat since they vary from superficial capillary lesions to deep, thick vein lesions. Superficial capillary lesions should be treated with a short pulse and a typical setting of 20-30 J/cm² of light and 10-15 J/cm³ of RF energy. Larger, deep veins should be treated with a long pulse mode, and a setting of 25-45 J/cm² for optical fluence, and 18-20 J/cm³ for RF energy.

Vascular treatments usually require about three treatment sessions to achieve good lesion clearance.



Figure 2. Sunburn on 46-year-old female. Skin type: III. Light fluence: 25 J/cm². RF energy: 15 J/cm³. Left: before. Right: Two months post two treatment sessions

Conclusion

Skin renewal procedures, such as treatment of pigmented and vascular lesions and improving skin texture, that are based purely on light energy systems (whether laser-based or using intense flash lamps) have reached their full potential for efficacy and safety. In order to treat the whole spectrum of lesions, one must use three or four different machines. Efforts to improve safety by using longer wavelengths, which are not highly absorbed by blood, have not proven successful on superficial lesions. On the other hand shorter wavelengths and pulse duration failed to treat deeper and larger lesions.

The current study of a combination of conducted RF and optical energies for skin renewal, as delivered by the Aurora SR system, showed very good results in terms of lesion treatment. Using a pulse energy that is significantly lower than the maximum that can be safely delivered to the target without damaging the surrounding tissue, with an additional pulse of RF, we demonstrated distraction of a variety of lesion targets. When pulses of RF energy in the higher range of 15-20 J/cm³, combined with optical energy in the range of 15-45 J/cm² and epidermal cooling, were applied to various body sites on the study subjects, no adverse effects were observed. The only post-treatment side effect observed was transient erythema, which disappeared within a few hours. The treatments were well tolerated by the subjects, none of whom required topical or other anesthesia.

The efficacy, absence of adverse side effects, and degree of patient comfort shown in the clinical study prove that the combination of conducted RF energy and optical energy, as delivered by the Aurora SR skin renewal system, is an excellent methodology for

skin renewal treatment of a broad cross section of lesion types and of the patient population.

References

1. Anderson RR, Parrish JA: Selective photothermolysis: precise microsurgery by selective absorption of pulsed radiation, *Science* 220: 524, 1983.
2. Goldman MP, Fitzpatrick RE, *Cutaneous laser surgery* chapter 2 p. 19-105.