Photorejuvenation using ELOS™ Technology

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In the last few years, a treatment called Photorejuvenation has become increasingly popular. Photorejuvenation is not an accurate term, and individuals refer to different types of lesions when using this terminology. In general, this technique is used to remove lentigines and other similar lesions, vascular lesions such as telangiectasias, reduction of wrinkles and general improvements in the skin texture. However, there are a number of technical problems that must be dealt with in order to a have successful and safe outcome. The lesions being treated can vary in color, size and depth. Utilizing the theory of selective thermolysis, pulsed light can be targeted (in combination with specific filters) to different chromophores and at various depths in the skin. Vascular lesions vary in size and depth; superficial vessels are better treated with shorter wavelengths and shorter pulse durations, where as deeper vessels are better treated by longer wavelengths with longer pulse durations. Pigmented lesions, such as lentigenes, are prime targets for Photorejuvenation and their removal contributes to the overall cosmetic outcome of a procedure. These lesions are typically superficial in the epidermis and typically will respond to pulsed light with a short pulse duration in a frequency range of 580 - 1,000 nm.

One of the limitations to the entire process is the barrier that the epidermis presents to the light penetrating to reach the deeper dermis; the epidermis absorbs heat and is at increased risk for burns and pigmentary reactions. If a system could be developed to bypass this problem, then better and safer treatments could be obtained. The principals of selective thermolysis would still apply, but pulse durations would be less then the thermal relaxation time of the target.

A new technology is now available from Syneron Inc. known as ELOS™ which stands for electro optical synergy. The Aurora™ system uses a unique method of energy delivery to the skin, which has been shown to be very successful for photorejuvenation. ELOS technology combines pulsed light optical energy and radio-frequency (RF) electrical energy in a way that is very efficient and safe. The optical component is pulsed light with a wavelength of 580-980nm and the electrical component is bipolar radio-frequency at a frequency of 1 MHz. Both optical and electrical components are delivered to the skin as a combined pulse with a duration range from 20-200 milliseconds.

Traditionally, pigmented and vascular lesions have been treated with either laser or pulsed light devices. Common problems associated with these devices include (a) optical energy too low, producing reduced efficacy or (b) optical energy too high, producing collateral damage around the target with undesirable side effects to the epidermis and dermis. By utilizing both optical and electrical energy, treatment can be made very effective without compromising safety. To further enhance efficacy and safety, a hand piece with integrated contact cooling is utilized to provide epidermal protection with a mild form of topical analgesia.

To understand the beauty of the Aurora ELOS system, it is first important to study the components and mechanisms that make it work. Once the cooling hand piece has cooled the epidermis, the bipolar electrodes attached to the crystal (filter) test the skin temperature via impedance (resistance) to establish a base line for future pulses. (See diagram 1)

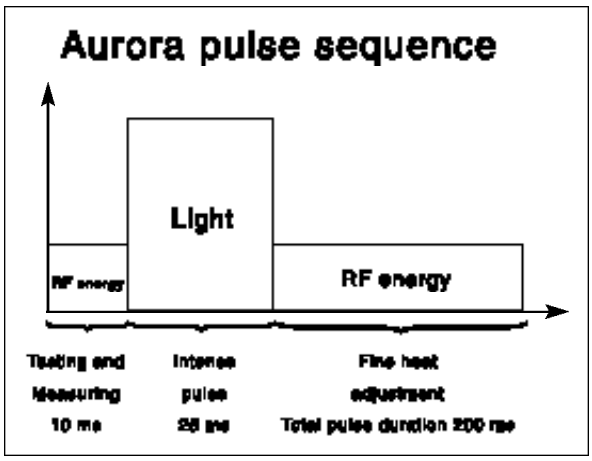


DIAGRAM 1

Superficial melanin and hemoglobin absorb well in the wavelength range of 580-980nm, target lesions such as lentigenes and telangiectasias absorb light energy that is converted to heat, raising the temperature of the target structure. Because the temperature is inversely proportional to the impedance, as temperature increases the impedance of the target structure decreases. The Aurora System continually monitors the temperature/ impedance factors by active dermal monitoring™, making it a smart, real time feedback device with a unique safety mechanism. In applying Ohm's Law to the application of energy to the skin, the following chain of events occurs. The epidermis is cooled, increasing resistance and lowering current flow, current flow preferentially seeks areas of low impedance in the dermis, which has a higher ambient temperature as a result of the initial pulse of optical light. RF energy flows from the active to the passive electrode and elevates the temperature of the target structures to a level of damage required for clearance. Another crucial fact is that RF energy is not absorbed by melanin and thus independent of skin color with no epidermal barrier to absorption as occurs with only optical energy.

In addition to the benefits of being able to reduce the incidence of optical induced side effects, the Aurora system provides an impedance safety limit (ISL%) to automatically shut off the RF energy pulse to prevent tissue overheating. The closed loop feedback from the impedance safety limit provides the operator with a numeric measurement (ISM) to monitor the efficacy of the pulse being delivered. A reading below 10 is indicative of insufficient fluence, while a reading close to the set treatment parameters is indicative of too high a fluence and should be reduced accordingly.

OBJECTIVE

This multi-center clinical study assessed the efficacy and safety of the Aurora skin renewal system utilizing ELOS technology. Pigmented and vascular lesions were studied. The pulsed light component range was 580-980 nm. The conducted RF was at a frequency of 1 MHz.

PATIENTS AND METHODS

The study group was composed of 15 patients divided into two groups, 9 patients in the vascular group and 5 patients in the pigmented lesion group. One patient was in both the vascular and pigmented lesion group. The vascular group was composed of eight female patients and one male patient with ages ranging from 29 years to 56 years. All patients' treatment sites were facial with Fitzpatrick skin type's I-III.

The pigmented lesion group was composed of 5 patients, Fitzpatrick skin type III, four female and one male ages 43 years to 56 years. Treatment area distribution was face (3), neck (2) and chest (1).

Protocol and technique

Informed consent was obtained from all participants. The treatment areas were identified and photographed. No topical or injectable anesthetic was used. All participants were screened and did not have any history of diabetes, keloid scarring, photosensitivity, use of Accutane within the last year, or current ASA intake.

The treatment protocol allowed for a total of 3 treatments to the test area, if necessary. Two to four weeks post first treatment; a second treatment was administered if there was less than 50% improvement. After a further two to four weeks, a third treatment was given if once again, there was less than 50% improvement.

In the vascular group 4 of 9 patients had 2 treatments. The other 5 patients had only 1

treatment. All of the participants in the pigmented group had 2 treatments.

Treatments were delivered by a contact cooled hand piece consisting of a 12x25mm filter with a light spectrum of 580-980nm that emits pulsed light. In addition, two electrodes surrounding the light filter deliver the conducted RF and are attached to the 25 mm sides of the filter. The rectangular shape and 8mm distance between the electrodes produces an RF penetration to a skin depth of 4 mm. The hand piece has integrated contact cooling from 5-20^{o} C to drive the RF energy where desired, protect the skin surface and reduce localized discomfort during energy delivery. A water based transparent gel was applied to the skin in a thin layer to obtain proper coupling of the electrodes to the skin. The handpiece was applied with minimum pressure, so the blood in the vessels was not squeezed away from the treatment zone.

For vascular lesions, RF energy was set at 10-12 J/cm^3, and the optical energy at 20-28 J/cm^2. For pigmented lesions, RF energy was almost always set at 12 J/cm^3 and the optical energy from 22-24 J/cm^2.

Results

Early observations

Transient erythema was seen in all patients following treatment. In some patients, the onset of erythema began five to ten minutes post treatment. The erythema resolved within several hours. Vascular lesions typically faded within one to two months, however several lesions faded within one or two days following treatment. The pigmented lesions typically became darker within one day after treatment. These lesions developed dark and occasionally black superficial scab, which peeled off within four to seven days. More resistant lesions took up to four weeks to totally clear.

Patient Distribution by Clearance Group

CLEARANCE GROUP	PIGMENTED LESIONS	VASCULAR LESIONS
0-25%	1	5
26-50%	4	5
51-74%	0	1
75-100 %	1	0

Follow-up Observations

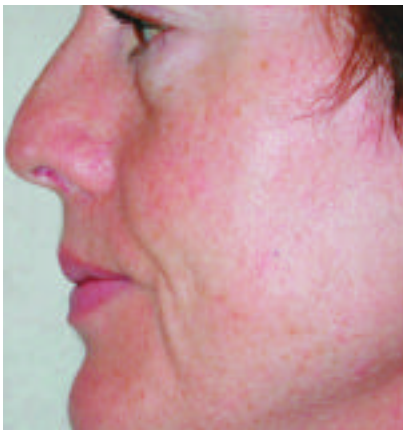
The pigmented lesions cleared quickly within two to three weeks. There were no cases of scars or post-inflammatory hyper-pigmentation or hypo-pigmentation. In comparison, the vascular lesions did not respond as well or as quickly. Maximum clearing took eight to ten weeks in most cases.

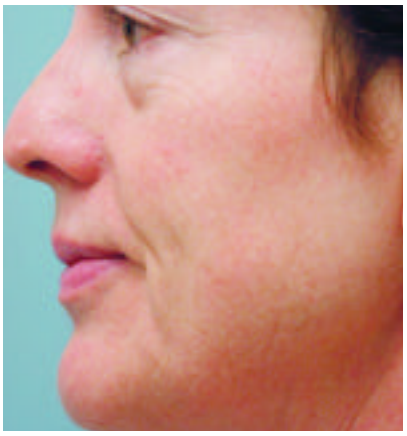
Discussion

In this study, pigmented lesions responded better than vascular lesions. Both types of lesions responded better with multiple sessions. The vascular lesions however, were more dependent on multiple treatments for a successful outcome. Some of the pigmented lesions did well with only one treatment. Clearance results could have been higher had the treatment settings been more aggressive. All of the participants were treated in an RF range of 10-12 J/cm^3. Increasing the fluence would have likely yielded higher clearances. The range of optical energies used was 20-28 J/cm^2. Increasing the optical fluence would have also yielded higher clearance rates.

Since this initial study, we have adopted a more aggressive approach using higher optical and RF settings. Typical energies being used presently are 28-30 J/cm^2 for pulsed light, and 18-20 J/cm^3 for the RF range. In special situations where resistance is encountered, the system can be adjusted to emit pulsed light at 35-40 J/cm^2, and 20 J/cm^3 RF, in the long pulse mode. Using these stronger settings, vascular and pigmented lesions can be cleared faster and more effectively without compromising safety. Examples are shown on Figures 1 and 2.

Pretreatment





After
4 treatments

Figure 1 Vascular and pigmented lesions, left cheek. (4 months from initial treatment). Final treatment settings 30J/cm^2 optical, 20J/cm^3 RF. Clearance range 50-75%

Pretreatment

After
6 treatments

Figure 2 Pigmented lesions, left cheek. (6 months from initial treatment). Final treatment settings 30J/cm^2 optical, 20J/cm^3 RF. Clearance range 75-100.%

Conclusion

This study showed that the Aurora ELOS system is very effective in treating telangiectasias and lentigenes while improving skin texture and reducing pore size. It is likely that even better results could have been obtained with higher fluences. However, by lowering the optical fluence and substituting additional RF energy, one can avoid most of the epidermal complications associated with high optical energies. In addition, the synergy between the optical and electrical energies, produce a more efficient delivery system for the energy needed to damage the target structures. The adjustability of the ISL% and ISM readings obtained with each pulse, allows the physician to maximize energy delivery in a safe environment. Patient comfort, the absence of most side effects and effective clearing of lesions, makes the Aurora ELOS system an excellent choice for anyone wishing to offer Photorejuvenation treatments to their patients.