Epilation in dark skin (types V and VI) with integrated radio-frequency and optical energy

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INTRODUCTION Epilation with laser or intense pulsed light is now an established alternative to electrolysis for the removal of unwanted hair in clinical practice. Most systems provide a reliable, usually complete, but temporary loss of hair by inducing prolonged telogen. Published reports confirm that certain lasers emitting wavelengths in the red and near infra-red area of the electromagnetic spectrum produce varying degrees of permanent hair loss.[1,2] It appears that there is a dose response relationship for extended telogen versus permanent hair loss. Although lower fluences can achieve permanent reduction in some patients, it is generally attained using high fluences of 30 J/cm^2 or above.[3,4,5] At the fluences effective for long-term or permanent hair reduction the risk of epidermal injury and dyschromia increase, particularly with tanned, olive-colored (type III), dark (types IV and V), and black skin (type VI).[4]

The use of red light at 694-755 nm in pulse durations between 3-10 milliseconds with various methods of epidermal cooling is associated with a significant rate of side effects. For type I-V skin the overall rate of dyschromia can reach 20% and the rate of all adverse effects in type IV and V subjects is 18-38%.[6] Longer wavelengths of 800-1064 nm with 10-100 millisecond pulse widths and epidermal cooling reduce but do not eliminate the risk of adverse effects in skin types III-V. The treatment of black skin remains a problem for which there is limited information. Unpublished reports and industry literature suggest that Nd:YAG lasers with longer pulses are the most appropriate systems for skin types IV-VI. Yet published reports still describe blistering in 1.5% and dyschromia in 5% of treatment sites from a study group with skin types IV-VI treated with a 50 millisecond Nd:YAG laser.[7]

When pure optical energy is used for epilation the risk of epidermal injury is directly proportional to the fluence used. Photoepilation targets melanin in follicular and adnexal structures to achieve thermal injury but red or infra-red light is also absorbed by melanocytes and keratinocytes in the adjacent epidermis. The Aurora DS™ delivers a combination of radio frequency (RF) energy and a pulse of red to infra-red light to achieve the heating required for selective thermal injury. The energy deposited in the skin from RF energy is independent of skin colour and there is no epidermal barrier to absorption as occurs with optical energy. Only part of the heat required for selective injury to the target is produced by the fraction of optical energy contained in the electromagnetic pulse. This delivers effective heating and biologic effects at lower levels of optical energy. This should provide a lower risk of adverse effects in contrast to pure light-based treatment.

The use of RF energy to supplement the optical energy applied to the target tissue should allow for treatment of all skin types, since this form of energy is not absorbed by the pigment melanin. RF energy is applied externally by coupling two electrodes to the skin surface. The geometry of the electrodes and the duration of the RF pulse are precisely calibrated to achieve selective heating of the target lesion. During the application of the RF energy, the device measures changes in the skin impedance. There is an inverse relationship between changes in temperature and impedance. This allows the Aurora™ to perform active dermal monitoring, which makes it a smart device with a unique fail-safe mechanism.

The application of RF and light energy can only occur if the device detects optimal impedance. Active dermal monitoring™ controls the ratio of RF to light energy. During each pulse the hand piece measures the fall in impedance of the skin as the temperature rises. If the fall in impedance reaches a pre-set level (usually 30%), the device terminates the RF energy. Therefore, the total amount of energy applied to the target is actively regulated by change in temperature. This unique capability ensures that the total energy applied is precisely matched to the energy required for the desired change in temperature. Consequently, this device delivers lower levels of optical energy than other systems currently used. Active dermal monitoring™ should improve the therapeutic margin of safety and reduce the incidence of adverse effects.

OBJECTIVE

The purpose of the study was to determine the efficacy and safety of the Aurora DS™ device (Syneron Medical) for epilation in subjects with type V and type VI skin.

PATIENTS AND METHODS

Ten adult patients were selected for the study. All participants were screened for exclusion criteria of diabetes, photosensitivity, a history of keloid scarring, or therapy with Accutane within the past year, and current aspirin or iron therapy. There were 4 male and 6 female volunteers. The study group consisted of 7 East Indian patients with Fitzpatrick type V skin and 3 black patients with Fitzpatrick type VI. Body sites with uniform hair density were selected and an area measuring 2 X 4 inches was mapped for treatment. The distribution according to anatomic site was axilla (6), back (2), lateral face (1), and abdomen (1).

Informed consent was obtained and each study site was mapped. The area was first shaved leaving residual 'stubble' of approximately 1 mm. and a photograph taken to be used for the calculation of a baseline hair count. A close shave of the selected area was carried out prior to treatment. No topical or local anesthetic was employed.

An Aurora DS™ system delivering RF and optical energy in an integrated pulse profile was used to perform the study. The geometric design of the RF electrodes conducts energy through the skin to a depth of 4 mm. Three equal pulses of light for a total duration of 25 milliseconds are emitted at calculated intervals during an RF pulse of 200 milliseconds. The optical energy delivered is a spectrum of light in a waveband from 680-980 nanometers. The device provides contact epidermal cooling through the hand piece applicator and maintains skin temperature at around 5 degrees Centigrade. A transparent water-based gel was used as a contact medium and light pressure on the applicator during treatment ensured proper coupling of the electrodes to the skin.

The level of RF energy was set at 18 joules/cm^3 for type V skin and at 20 joules/cm^3 for type VI skin. Test pulses were carried out on an area adjacent to the study site to determine the level of optical energy suitable for each patient. For patients with type V skin optical energy of 16 joules/cm^2 and for type VI skin 14 joules/cm^2 was used as a starting point. Each pulse was increased by increments of 1 joule/cm^2 . The energy level at which each patient first experienced discomfort was selected to carry out the study treatment. The range of fluences used for the study was 16-20 joules/cm^2 for type V subjects and 14-17 joules/cm^2 for type VI subjects. Pulses were placed in an adjacent non-overlapping pattern over the entire study site using the Aurora DS™ device.

Serial photography and clinical examination were used to evaluate the subjects at 1-3 days, 2 weeks, 1 month, and at 4-7 months to determine hair loss and whether any complications had occurred. The last photograph at 4-7 months was used to calculate a hair count and determine the incidence of any long-term complications, notably dyschromia and scarring. Values for hair counts before and after treatment were obtained by photometric analysis of magnified images projected on to a white background. Counting was carried out over the entire treatment area by two blinded observers working independently and an average determined for each value. The percentage hair loss was calculated for each study volunteer.

RESULTS

Fifty percent (5/10) of the subjects obtained a hair loss of more than 35% and the mean hair loss for the entire group was 30.20% (SD=7.59), with a range of 13 to 75.4%. There were two patients with type V skin who showed no change in hair counts. The three patients with black skin achieved a mean hair loss of 29% without any instances of epidermal injury, dyschromia or scarring at 2 weeks, 1 month and 3 months after the treatment.

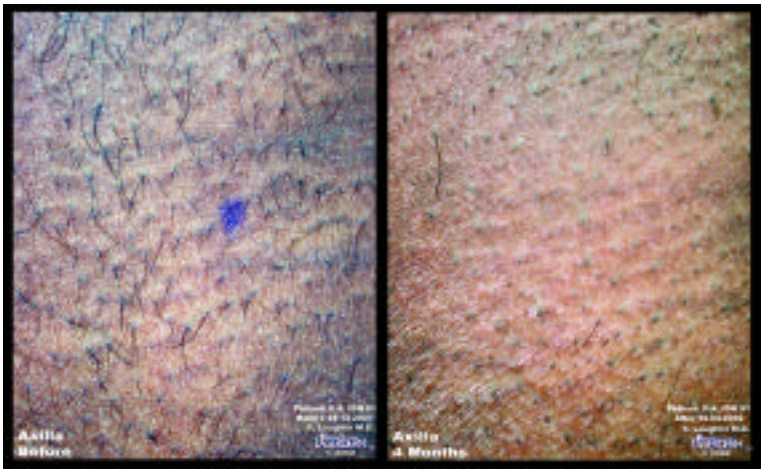

Figure 1 *Patient with type VI skin showing 55% hair loss at 4 months after one treatment of his axilla at RF 20 J/cm^3 and optical fluence 15 J/cm^2.*

Figure 1 shows a patient with type VI skin who obtained a 55% hair loss in the axilla at 4 months after a single treatment. In the entire group there were no cases with blistering at the 1-3 day follow-up visits and the overall rate of complications was zero.

DISCUSSION

There is a compelling need for safe and effective epilation in pigmented skin, particularly type VI patients, who in addition to unwanted hair may develop pseudo-folliculitis and keloidal scarring. The results obtained in this study confirm that a single treatment with combined RF and optical energy produces significant hair loss in dark and black skin without any of the expected side effects associated with all types of light-based treatment.

The follow-up time of 3 months does not allow for the quantitative assessment of temporary versus permanent hair loss using the formal criteria of stable hair loss over specified periods of time for each anatomic area. However, it is now recognized that photoepilation shocks anagen hairs into premature telogen and triggers a telogen-to-anagen switch that results in synchronous regrowth after the induced telogen has ended.[8] Clinical observations and published reports confirm that once regrowth occurs, any resulting hair loss generally becomes stable, and translates into long-term reduction (extended telogen), and eventually permanent hair loss.[1,2] Therefore, the substantial hair loss produced by

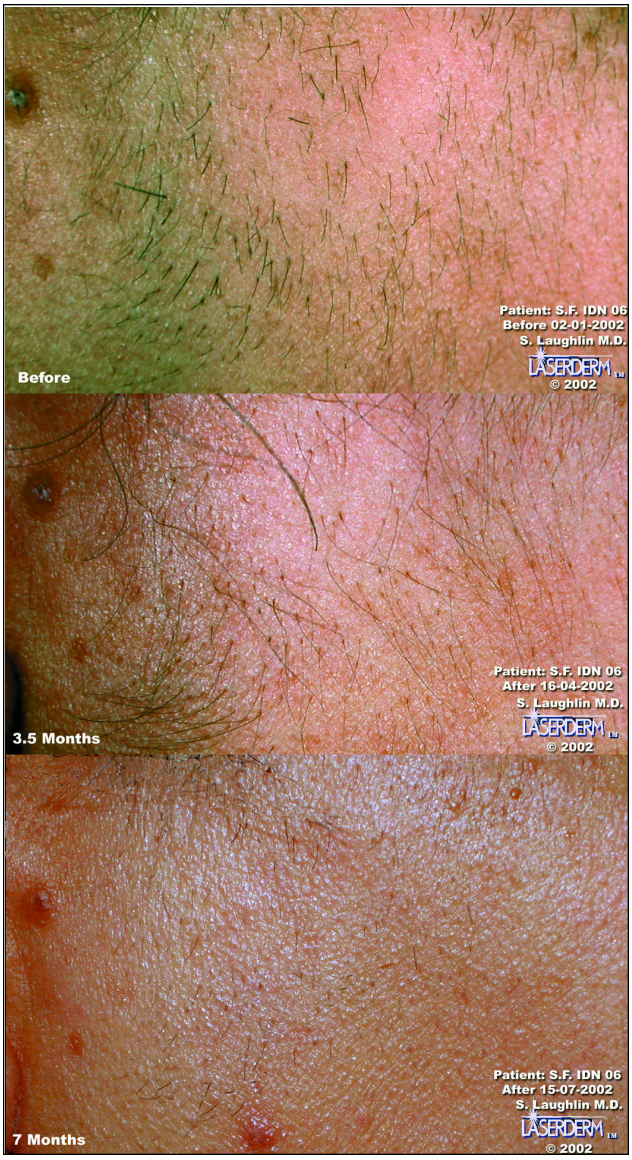

Figure 2 *Patient with Type V skin obtains a 39% hair loss at 3.5 months after one treatment of the pre-auricular region of her face at RF 18 J/cm³ and optical fluence 20 J/cm² . Afurther reduction in hair count is evident at the 7 month assessment.*

the Aurora DS™ in these subjects is likely to be long-term or permanent. The patient in **Figure 2** demonstrates stable hair loss at 3.5 months and at 7 months after a single treatment to the lateral face in the pre-auricular region. The normal growth cycle for facial hair is usually 2-3 months and stable hair loss at 7 months can be considered permanent. There is actually a further loss of hair between the 3 and 7 month follow-up, which is a phenomenon we have reported previously.[2]

Two participants showed no change in hair density but this does not necessarily mean there was no biologic effect. Photoepilation of terminal hairs may produce miniaturization of the follicle which results in hair fibers that are finer and lighter in color to the naked eye.[1] These changes may precede any reduction in hair density. This study was not designed to assess these changes which require sophisticated and complex methods of analysis.

This preliminary study provides persuasive evidence that integrated RF and optical energy can achieve effective epilation in pigmented skin without the usual risks associated with current methods of treatment. None of the study participants developed any blistering within the first 72 hours after treatment. The absence of early epidermal injury differentiates this method of treatment from those methods using pure optical energy. For ruby and alexandrite lasers using pulses up to 10 milliseconds, the rate of blistering was reported as 12% in 536 patients with skin types I-V.[6] There were only 33 patients with type V skin and no specific rate is given for this phototype but the rate must have been much higher than the rate of 12% for the whole group. For a 50 millisecond Nd:YAG laser the rate of blistering was 1.5% for 20 subjects with types IV-VI skin with no specific information given for the rate of vesiculation in types V and VI.[7] This lack of specific data on patients with the darkest skin is quite common in the published literature. The tendency to group them with type IV or still lighter skin obscures the actual incidence of complications in truly dark skin.

A closer look at several studies that suggest long-pulsed 800 nm diode and Nd:YAG lasers are safe and effective for dark or pigmented skin is very instructive. The use of the word 'dark' is relative. One study compares diode laser and long-pulsed Nd:YAG in dark-skinned patients, undertakes an extensive discussion of epilation in dark skin but did not include any subjects with type V or VI skin.[9] Other reports on the safety and efficacy of long-pulsed diode and Nd:YAG lasers contain no patients with the darkest phototypes.[10,11] However, even subjects with type II-IV skin developed dyschromia lasting up to 6-9 months.[11]

The incidence of dyschromia or pigmentary disturbance is an important issue in photoepilation. It is the serious complication which is most likely to occur, especially in the darkest phototypes. Scarring (atrophic or hypertrophic) is rarely reported in the literature, and its actual incidence in clinical practice is much lower than that of dyschromia. The limited information available suggests that long-pulsed diode and Nd:YAG lasers do not eliminate the problem in type V and VI skin. There were 5 patients with skin type V and 2 patients with skin type VI in a study using a long-pulsed 800-nm diode laser for epilation.[5] The overall rate of pigmentary change was 29% but the rate in type V and VI subjects was 60% and 100% respectively. The mean time for clearance was 3.2 months in the whole group which means that the time for clearing in the darkest patients must have been appreciably longer. In another study on 20 patients using a 50 millisecond Nd:YAG laser, there were 13 type V and 2 type VI subjects with a reported rate of 5% for dyschromia in the whole group.[7] The phototype-specific rate was not given, but the incidence was probably higher in the 15 patients with type V and VI skin.

Therefore, with respect to skin types V and VI, the published literature paints a far different picture from the prevailing impression that long-pulsed infra-red lasers offer effective epilation with minimal side-effects. Even a study using very long pulses (20-200 ms) at 800 nm describes dyschromia as the most common side

effect and reported epidermal damage (blistering) in skin type VI (ECT) at the lowest fluence tested-15 joules/cm^2 with a 100 ms pulse.[12] The study also confirms that both the efficacy and risk of side effects is directly proportional to the fluence used. It recommends very long pulse durations to allow all skin types to tolerate high fluences and suggests that pulse durations longer than 100 ms maybe required for the darkest skin types. There are very few infrared laser systems capable of delivering these very long pulses. In addition these long pulse durations are still associated with epidermal damage and dyschromia, although the exact incidence is not reported.[12] The same study warns that caution is required when using very long pulse widths to treat areas with dense hair, because of thermal conduction between closely adjacent hair follicles.[12] Epilation with combined RF and optical energy in 10 subjects with the darkest skin types was associated with a zero rate of dyschromia or pigment change. Our preliminary study suggests that this method of treatment substantially reduces and could eliminate the expected risks of photoepilation in type V and type VI skin.

The overall rate of side-effects for red light at pulse durations of <10 ms and a Q-switched Nd:YAG laser varies from 1-9% for skin types I to III and rises significantly from 10-37% for skin types IV and V.[5] Most of these systems are unsuitable for black skin. Infrared lasers with longer pulses reduce the overall risks of photoepilation for darker skin types, but the incidence of epidermal damage and dyschromia is still of concern. The Aurora DS™ system may offer a better therapeutic margin of safety for the treatment of pigmented skin.

Integrated radio-frequency and optical energy offers a new approach for the treatment of unwanted hair, and pseudo-folliculitis in patients with Fitzpatrick skin types V and VI. It provides effective hair loss without any apparent adverse effects and raises the safety profile for patients with pigmented skin to an unexpected level. The absence of adverse effects brings the treatment of the darkest skin into the same comfort zone as Fitzpatrick type I or the lightest skin color.

References

1. Dierickx CC, Grossman MC, Farinelli WA, et al. Permanent hair removal by normal-mode ruby laser. Arch Dermatol 1998; 134:837-842.
2. Laughlin SA, Dudley DK. Long-term hair removal using a 3-millisecond alexandrite laser. Journal of Cutaneous Medicine and Surgery 2000; 4:83-88.
3. Grossman MC, Dierickx CC, Farinelli BX, et al. Damage to hair follicles by normal-mode ruby laser pulses. J Am Acad Dermatol 1996; 35:889-894.
4. Campos VB, Dierickx CC, Lin T-YD, et al. Long-term efficacy of normal-mode 694 nm ruby laser and 800 nm diode laser for hair removal. Laser Surg Med 1999; 11(Suppl):22.
5. Campos VB, Dierickx CC, Farinelli WA, et al. Hair removal with an 800-nm pulsed diode laser. J Am Acad Dermatol 2000; 43:442-447.
6. Nanni CA, Alster TS. Laser-assisted hair removal: Side effects of Q-switched Nd:YAG, long-pulsed ruby, and alexandrite lasers. J Am Acad Dermatol 1999; 41: 165-171.
7. Alster TS, Bryan H, William CM. Long-pulsed Nd:YAG laser-assisted hair removal in pigmented skin. Arch Dermatol 2001; 137:885-889.
8. Olsen EA. Methods of hair removal. J Am Acad Dermatol 1999; 40:143-154.
9. Chan HH, Ying SY, Ho WS, et al. An In Vivo study comparing the efficacy and complications of diode laser and long-pulsed Nd:YAG laser in hair removal in Chinese patients. Dermatol Surg 2001; 27: 950-954.
10. Lorenz S, Brunnberg S, Landthaler M, et al. Hair removal with the long-pulsed Nd:YAG laser: a prospective study with one year follow-up. Lasers in Surgery and Medicine 2002; 30:127-134.
11. Lou WW, Quintana AT, Geronemus RG, Grossman MC. Prospective study of hair reduction by diode laser (800 nm) with long-term follow-up. Dermatol Surg 2000; 26: 428-432.
12. Battle EF Jr, Suthamjariya KK, Alora MB, Palli K, Anderson RR. Very long-pulsed (20-200ms) diode laser for hair removal on all skin types. Lasers Surg Med 2000; 26(suppl 12):85.