Introduction
Unwanted hair is a significant and common cosmetic problem.\(^1\) In addition, removal of unwanted pubic hair is also becoming increasingly popular among younger women. According to research at Indiana University, 60% of American women between 18 and 24 reported hair removal, and almost half of 25-29 year olds reported the same.\(^2\)

Literature supports the use of laser systems for photoepilation, including red-light ruby lasers, infrared-light systems (alexandrite, diode and Nd:YAG), and Intense Pulsed Light (IPL).\(^3\) The spot sizes and repetition rates offered are crucial factors in terms of penetration depth, treatment speed, and efficacy.\(^4\)

Diode lasers are considered efficient light sources well-suited for clinical uses, including laser hair removal.\(^5\) The use of longer pulse durations are accompanied by effective thermal damage to the hair follicle while preserving the epidermis in lighter skin types (Fitzpatrick skin types I-III). It is, however, a challenge is to avoid unwanted thermal damage to the epidermis in darker skin tones (Fitzpatrick skin types IV-VI) while still obtaining the same intensity of thermal destruction to the hair follicle.\(^5,6\)

Recently, diode lasers, combined with contact cooling, have emerged as a primary modality for hair removal for both skin types. Clinical studies demonstrated that longer pulse durations combined with contact cooling may provide a greater safety margin in treating darker skin types.\(^5,6\)

The purpose of this study was to demonstrate the hair reduction capabilities of an 808nm high-power, long-pulse diode laser with contact cooling system (STNE Laser System by ST Laser Co., Ltd., Beijing, China).

The STNE delivers long pulse durations up to 400ms to effectively damage the hair follicle. When combined with high power, a repetition rate up to 10 Hz to deliver energy quickly, and contact cooling system to reduce thermal discomfort, the device can target the hair follicle without causing epidermal damage.

This paper reports on the safety and efficacy of the STNE Laser System for the reduction of unwanted hair in two subjects—one with Fitzpatrick lighter skin type and the other with a darker skin type. Two case reports from results of this study are presented.

Methods
Both subjects provided informed consent to participate and have photographs taken in this post-market trial.

The study was open to subjects with Fitzpatrick Skin Types I-IV, aged 18 years or older, who desired treatment for unwanted pigmented axillary and/or bikini line hair, and met study inclusion/exclusion criteria. Subjects who had undergone laser/IPL treatments, electrolysis or waxing in the designated treatment area within six weeks were excluded from participation.

Subjects were prepared for laser treatment in accordance with acceptable medical practice. Enrolled study patients received a total of three (3) laser treatments, spaced approximately one month apart, over the affected areas with the Nice Epilator Laser, using standard and established hair removal settings accordance. Treatment fluence ranged between 36 and 48 J/cm\(^2\) in the axilla and 30-36 J/cm\(^2\) in the bikini line with pulse widths up to 370ms.

Subjects were given verbal and written post-treatment skin care instructions to gently clean the skin with warm water and a mild cleanser, and to avoid direct sun exposure for the
duration of the study. Subjects were also instructed not to shave, wax or pluck hair within the treatment area for the duration of the study. Standard, digitalized, high-resolution photographs were taken of the treatment area at baseline and again after the third laser treatment/final follow-up visits. The photographs were taken by a professional clinical photographer.

Subject discomfort (stinging/burning sensations, etc.) during the laser procedure was recorded using the following four-point scale:

0 = None  
1 = Mild  
2 = Moderate  
3 = Severe

After the treatment was performed, the treating investigator was asked to record any clinical observations (i.e., the severity of anticipated treatment response/side effects of the treatment with regard to any erythema, scaling and dryness, edema or blistering, etc.) as well as any adverse/unanticipated events (whether treatment related or not). If an expected side effect noted above (erythema, edema, etc.) was severe in nature and/or lasted more than 30 days, it was considered an adverse event.

The investigator noted the estimated or average total time for each treatment in minutes.

Success of the treatment was based on clinical improvement/clearance of unwanted hair after treatment using baseline and follow-up photographs assessed separately by the subject and the study investigator using a quartile rating scale as follows:

1=<25% = Mild Improvement  
2=25-50% = Moderate Improvement  
3=51-75% = Good Improvement  
4=76%-100% = Excellent Improvement

Case Study Results

Subject #1 (D-ALK-001): 42 year-old Caucasian female with Fitzpatrick Skin Type III and unwanted medium texture, medium density, dark brown axillary hair.

Subject underwent three (3) monthly treatments to the right and left axilla lasting approximately five minutes each with the Nice Epilator laser. Transient-expected mild to moderate erythema and follicular edema were noted immediately after treatment. During the laser sessions, subject discomfort ratings remained at a score of 2 (moderate) or less. Both investigator and subject assessments taken after the third treatment revealed excellent improvement (76-100%). No adverse events were reported. Figure 1 (A-B) depicts an example of treatment results.

Subject #2 (D-DDS-002): 47 year-old Caucasian female with Fitzpatrick Skin Type IV with unwanted medium texture, medium density, dark brown hair in the right and left axilla and bikini line.

Subject underwent three (3) monthly treatments with the SNTE laser. Both the bilateral axilla and bikini line were treated. Duration of treatment was approximately 10 minutes per laser session for the right and left axilla and 15-20 minutes per laser session for the bikini line. In all treated regions, the subject experienced anticipated transient post treatment response of mild to moderate erythema and follicular edema. Subject reported only mild (1) discomfort (stinging/burning) during the treatments. At study end, the investigator rated the subject’s improvement as good (51-75%) in the axilla and excellent (76-100%) in the bikini line area. The subject rated her improvement as excellent (76-100%) for all body areas treated. No adverse events were reported. Figures 2 (C-D) and 3 (E-F) show examples of treatment results.

Discussion

In this study we used the STNE laser, which is an 808nm diode laser, currently marketed in the United States, which combines longer pulse widths and a repetition rate of up to 10 Hz enabling the clinician to treat larger areas more rapidly. Its longer wavelength and skin cooling system (sapphire cooling tip) cools the skin and keeps it at a constant temperature of 5° C, thus increasing patient tolerance, eliminating the need for topical anesthetic, and minimizing damage to the epidermis while delivering high energy safely, even in darker skin.

Results from the current study demonstrate that the STNE laser can provide safe and effective treatment for unwanted hair in both lighter and darker skin types. Both of the cases presented here demonstrate successful and significant hair reduction with treatment responses rated as good or excellent improvement following three (3) laser treatments, which lasted 20 minutes or less for the bikini line and 10 minutes or less for bilateral axilla.

Both subjects reported only mild to moderate stinging/burning during treatment, without use of topical anesthetics. No adverse events were reported in this study.

Conclusion

Results of two case reports from this study demonstrate treatment with the STNE Laser System® is an effective solution for unwanted hair. The skin cooling system reduces the degree of discomfort during treatment to mild to moderate. There is also an overall absence of pigmentation complications and other untoward side effects.
Figure 1  Subject #1 {D-ALK-001} female with Fitzpatrick Skin Type III. Left axilla before treatment (A) and 11 days after third treatment (B) with the STNE diode laser using 45J/cm² and 150ms pulse duration.

Figure 2  Subject #2 {D-DDS-002} female with Fitzpatrick Skin Type IV. Left axilla before treatment (C) and 11 days after third treatment (D) with the SNTE diode laser using 54J/cm² and 180ms pulse duration.

Figure 3  Subject #2 {D-DDS-002} female with Fitzpatrick Skin Type IV. Right side bikini line before treatment (E) and 11 days after third treatment (F) with the STNE diode laser using 54J/cm² and 180ms pulse duration.
References


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