# 3 Month Clinical Results Using the CoolGlide Long-Pulse Nd:YAG Laser for Hair Removal

Suzanne L. Kilmer, M.D.
*Director, Laser and Skin Surgery Center of Northern California*

This paper reports the 3-month results of a study intended to determine the safety and efficacy of a long-pulse high-power Nd:YAG laser for the removal of unwanted pigmented hair in subjects with Fitzpatrick skin types I-V. This system operates on the principle of selective photothermolysis,[1] which makes it possible to selectively target and treat multiple hairs simultaneously in a non-invasive manner.

The first detailed studies of laser hair removal were published in 1996 based on the results obtained from the use of a 694 nm pulsed ruby laser.[2] This and subsequent studies have shown that short term removal and a long term reduction in hair count can be achieved. Since that time, the trend in long-pulse hair removal lasers has been towards longer wavelengths. Ruby lasers were followed by alexandrite lasers at 755 nm, diode lasers at 810 nm, and now the CoolGlide long-pulse Nd:YAG laser with a wavelength of 1064 nm. By continuing the trend towards longer wavelengths, this laser takes advantage of the corresponding decrease in melanin absorption. The advantages of less melanin absorption include reduced epidermal heating and damage, the ability to treat a wider range of patients (darker skin types as well as light), and the ability to use higher fluences. Additional advantages of the longer wavelength are reduced scatter and deeper penetration of the light so that more energy is delivered to the target. While the decreased melanin absorption of longer wavelengths is an advantage in terms of epidermal heating and damage, it also means that the melanin in the desired target has less absorption. This decreased absorption at the target is overcome by the use of higher fluences and by taking advantage of the reduced attenuation and scatter of the laser light as it passes through the epidermis.

Nd:YAG lasers with a wavelength of 1064 nm have been shown to selectively target melanin in the dermis. Q-switched versions of these lasers are currently used for the treatment of Nevus of Ota, and it has been shown that, with sufficient fluences, they can also be used for hair removal in which the target chromophore is the melanin in the hair follicle and shaft.[3] While the Q-switched (with 2 to 20 ns pulse widths) Nd:YAG laser has been shown effective in targeting melanin, it is not well suited to hair removal. The Q-switch pulse width is too short to optimally target the hair structure, so commercial Q-switched hair removal lasers require the complete removal of the hair and the introduction of an exogenous carbon chromophore to absorb the light energy. Even with these additional procedures, these systems do not achieve the permanency seen with other hair removal systems.

A long-pulse, high-energy Nd:YAG laser, with pulse widths that correspond to the thermal relaxation time of hair, will be able to directly target the melanin in the hair structure and should provide more efficacious hair removal results with minimal epidermal injury.

## Study Description

The performance of the Cutera CoolGlide laser system is being evaluated in a prospective, controlled, single-center clinical study in 25 subjects, with 50 control sites and 100 treatment sites, to investigate the safety and effectiveness for hair removal. This report includes the results through 3 months following a single laser treatment.

The study is being conducted at the Laser and Skin Surgery Center of Northern California. The principal investigator is Suzanne L. Kilmer, MD; and the co-investigators are Vera Chotzen, MD; Marla McClaren, MD; Jacqueline Calkin, MD; and Susan Silva, MD.

The device under investigation is a long-pulse Nd:YAG laser utilizing fluences up to 60 J/cm$^2$ with epidermal contact cooling and a laser spot size of 1 square centimeter per pulse.

Subjects with Fitzpatrick skin types I-V were enrolled and each subject received treatment on two body areas selected from the face, arms, legs, axilla, bikini line, and back. On each body area selected, three sites were identified. One to serve as a control and two to receive treatment. Each study site was shaved and received either no treatment, a treatment with a fluence of 60 J/cm$^2$ at a pulse width of 30 ms, a treatment of 50 J/cm$^2$ at 30 ms, or a treatment of 50 J/cm$^2$ at 15 ms. Treatment and control areas were located with a template and stamped for identification. Epidermal response was assessed and digital photographs were taken pre-operatively and at visits 1 day, 1 month, and 3 months after the treatment.

The enrollment for the study consisted of 9 subjects with skin type II, 8 subjects with skin type III, 4 subjects with skin type IV, and 4 subjects with skin type V. There were 19 females and 6 males. Each subject had 4 laser treated sites and 2 control sites, resulting in 100 treated sites and 50 control sites.

Efficacy was determined from hair counts made by an independent observer using digital photographs printed at a high magnification (6.4x), as well as a blinded side-by-side aesthetic evaluation of the pre-treatment and 3 month post-treatment photographs. The aesthetic side-by-side evaluation consisted of an independent evaluator choosing the better aesthetic appearance of the pre-treatment and 3 month post-treatment photographs. The evaluator for this comparison, as well as for the hair counts, was unaware of the visit at which each photograph was taken.

The contact cooling feature of the handpiece was used to provide epidermal protection and to act as an anesthetic for the treatment in most subjects. However, for 6 of the 25 subjects, a cooling gel was used instead of contact cooling for comparison purposes. Topical anesthesia, such as EMLA®, was not used for this study as the treatments were well tolerated by the subjects.

## Safety

Subjects were assessed at 1 day, 1 month, and 3 months after the single treatment. The epidermal response at 1 day following treatment included erythema, edema, and infrequent blistering. The occurrence of these responses was slightly greater in the sites that were cooled with the gel as compared to the contact cooling, however the difference was not significant. The responses in the laser treated sites at 1 day and 3 months after treatment are shown below. All 25 subjects were assessed on the day following treatment. 21 of the 25 subjects returned for the 1 month and 3 month visits.

**Safety data 1 day after treatment**
(100 laser treated sites evaluated)

| | None | Mild | Moderate | Severe |
|---|---|---|---|---|
| **Erythema** | 39 | 50 | 11 | 0 |
| **Edema** | 85 | 9 | 6 | 0 |
| **Blistering** | 97 | 2 | 1 | 0 |
| **Bruising** | 100 | 0 | 0 | 0 |
| **Hyperpigmentation** | 100 | 0 | 0 | 0 |
| **Hypopigmentation** | 100 | 0 | 0 | 0 |

**Safety data 3 months after treatment**
(84 laser treated sites evaluated)

| | None | Mild | Moderate | Severe |
|---|---|---|---|---|
| **Erythema** | 84 | 0 | 0 | 0 |
| **Edema** | 84 | 0 | 0 | 0 |
| **Blistering** | 84 | 0 | 0 | 0 |
| **Bruising** | 84 | 0 | 0 | 0 |
| **Hyperpigmentation** | 79 | 5 | 0 | 0 |
| **Hypopigmentation** | 84 | 0 | 0 | 0 |

At the 1 month and 3 month follow-up visits, the only observation was minimal hyperpigmentation that was present in 5 sites of 3 subjects at the 3 month follow-up. It was observed on 3 of the 16 skin type IV laser treated sites, and on 2 of the 16 skin type V laser treated sites. This minimal hyperpigmentation was not aesthetically significant and was only noticeable under close scrutiny of the sites. No unexpected observations were noted in the subjects.

## Efficacy

Efficacy was determined by demonstrating a significant reduction in hair count at 3 months post-treatment in the laser-treated sites, as compared to the control sites; and a statistically improved overall appearance (with respect to hair reduction) of the laser treated sites as compared to the control sites when evaluated by an independent, blinded, photographic rater (comparing paired baseline and 3-month photographs).

Half of the sites on each subject were treated with a fluence of 50 J/cm$^2$ and a pulse width of 15 ms. The other half of the treatments were performed with a pulse width of 30 ms. Of these, 70% were treated with a fluence of 60 J/cm2 and 30% were treated with a fluence of 50 J/cm2.

The hair counts indicate that two of the three treatment parameters were effective for the removal of hair. The median hair count reduction three months after a single treatment was 32% for the treatment parameters of 60 J/cm$^2$ and 30 ms, and 24% for the treatment parameters of 50 J/cm$^2$ and 15 ms. By contrast, the median hair count reduction at the shaved control site was 6% at three months. These results compare favorably with results obtained with other types of hair removal lasers after a single treatment.

The aesthetic side-by-side evaluation consisted of an independent evaluator choosing the better aesthetic appearance of the pre-treatment and 3 month post-treatment photographs. For all three sets of treatment parameters, the 3 month post-treatment photographs were preferred over the pre-treatment photographs. For the two treatment parameters determined to be effective based on hair counts, the 3 month post-treatment photographs were preferred approximately 3 to 1. For the treatment parameter not deemed effective based on hair counts, 50 J/cm$^2$ at 30 ms, the 3 month post-treatment photographs were still preferred, by a margin of 2 to 1. For the control sites, the pre- and post- "treatment" photographs were selected in equal numbers, as expected.

**Hair count reduction at 1 and 3 months (compared to baseline) after single treatment**

| | **60J/cm$^2$ @ 30ms** | **50J/cm$^2$ @ 15ms** | **60 J/cm$^2$ @ 30ms & 50 J/cm$^2$ @ 15ms** | **Control** |
|---|---|---|---|---|
| **1 Month Reduction** | **35%** | **44%** | **43%** | **8%** |
| N at 1 month follow-up | 30 | 41 | 71 | 42 |
| p-value[1] | .007 | <0.0001 | <0.0001 | --- |
| | | | | |
| **3 Month Reduction** | **32%** | **24%** | **27%** | **6%** |
| N at 3-month follow-up | 27 | 41 | 68 | 42 |
| p-value[1] | 0.1240 | 0.0531 | 0.0324 | --- |

Note: p-value determined from student's T-test comparing the treatment group to the control group.

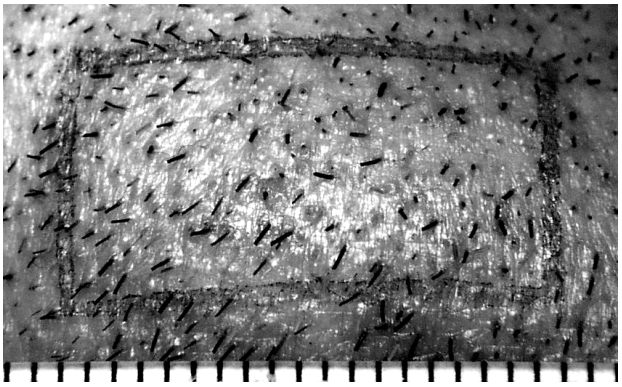
**Aesthetic side by side evaluation 3 months (compared to baseline) after single treatment**

| | **60J/cm$^2$ @ 30ms** | **50J/cm$^2$ @ 15ms** | **Control** |
|---|---|---|---|
| **3 Month Photo Preferred** | **76%** | **74%** | **49%** |
| Pre-op Photo Preferred | 24% | 26% | 51 |
| p-value | 0.0071 | 0.0018 | 0.8774 |

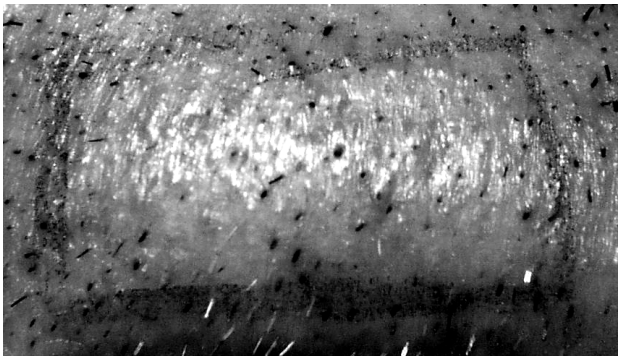
Note: p-value determined from chi-square test to determine if the percent preferring Month 3 is significantly larger than 50%. Subject sites scored as "same" counted as ½ for pre-op and ½ for month 3.

## Photos

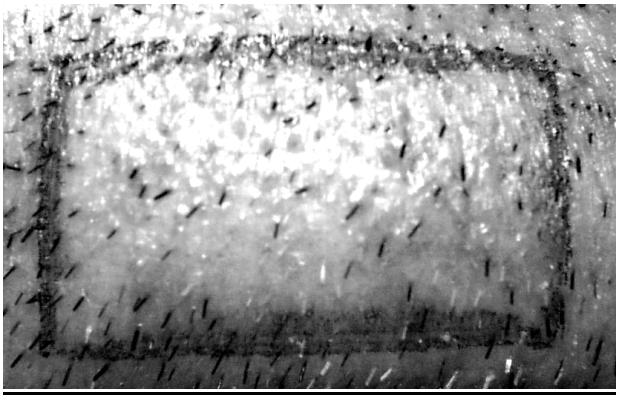
The before and after photos of the chin of a female subject that received a single treatment with a fluence of 60 J/cm2 at a pulse width of 30 ms are presented below. Based on the results of the hair counts, the reduction at 1 month is 56% and the reduction at 3 months is 35%.



**Pre-treatment**



**1 Month post-treatment**



**3 Months post-treatment**

## Summary

Results from this study show that the CoolGlide laser hair removal system is system is safe and effective for the removal of unwanted pigmented hair in subjects with Fitzpatrick skin types I-V.

## References


[1] Anderson RR, Parish JA. Selective photothermolysis: precise microsurgery by selective absorption of pulsed radiation. Science 1983; 220:524-7.

[2] Grossman MC, Dierickx C, Farinelli W, Flotte T, Anderson RR. Damage to hair follicles by normal-mode ruby laser pulses. Journal of the American Academy of Dermatology 1996;35:889-894.

[3] Kilmer SL, Chotzen V, Calkin J. Hair removal study comparing the Q-switched Nd:YAG and long pulse ruby & alexandrite lasers. American Society for Laser Medicine and Surgery Abstracts 1998;Supplement 10:43.