

Hair Removal for Tanned Patients & Wide Range of Skin Types with the Cutera Nd:YAG CoolGlide Laser – Study Results

For the Treatment of Tanned Patients, Skin Type I - IV

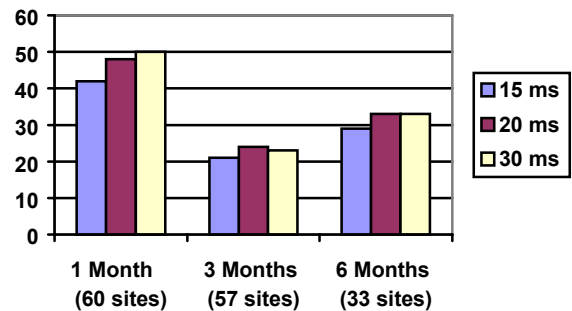
Summary of data presented by Melanie Grossman, MD at the American Society for Dermatologic Surgery Meeting in Denver, CO, November 2000. Studies conducted by Melanie Grossman, MD, Marisol Edward, RN, and Roy Geronemus, MD, at the Laser and Skin Surgery Center of New York.

Two prospective, controlled studies were conducted to determine the safety and efficacy of the Cutera CoolGlide aesthetic laser for the removal of unwanted hair in tanned patients of skin type I – IV with brown or black hair. Enrollment for the initial study was 20 tanned subjects. Each subject received a single treatment on three test areas, and an untreated control site, of 3 cm by 5 cm each and was followed at 1, 3 and 6 months to evaluate epidermal response and hair counts. These safety results were further confirmed in the second study in which larger areas, up to 15 cm by 15 cm, were treated on 38 tanned subjects and followed for 1 month. Treatments were performed on arms, legs, backs, shoulders, abdomens and bikini lines. The actual enrollment in the two studies consisted of skin type II (31%), skin type III (24%) and skin type IV (45%) patients. Immediate post-treatment reaction included erythema and edema. No blistering or purpura were seen. The treatments for the first study were performed at 15, 20, and 30 ms pulse widths using the 10 mm spot size and pre-cooling handpiece of the CoolGlide system. The fluence was determined by the investigator for each patient with an average fluence of 63 J/cm² (range of 50 to 70 J/cm²).

Side Effects – Both Tan Studies

- Month 1 – 94 sites on 54 subjects
 - 1 site: Mild hyperpigmentation (clear by mo. 3)
 - 93 sites: Clear
- Month 3 – 57 sites on 19 subjects
 - 1 site: Mild hyper and hypo-pigmentation
 - 56 sites: Clear
- Month 6 – 33 sites on 11 subjects
 - All 33 sites clear

Hair Count Reduction (%): 1 Treatment



For the Treatment of Skin Types I - V

Summary of data presented by Suzanne Kilmer, MD at the American Society for Laser Medicine and Surgery Annual Meeting in Reno, Nevada, March 2000 and in clinical white papers.

This prospective, controlled study was conducted to determine the safety and long-term efficacy of the Cutera CoolGlide aesthetic laser for the removal of unwanted hair in 25 subjects with Fitzpatrick skin types I – V and brown or black hair. At the 3 month follow-up visit, half of the treatment sites received a second treatment. All epidermal observations after the 1 day visit were rare and transient, having all cleared. Shown below are the combined results (median hair count reductions compared to baseline) for all treatments performed at 50J/cm² fluence and 15 ms pulse width, and 60 J/cm² fluence and 30 ms pulse width.

	Month 3	Month 6	Month 9	Month 12	Month 15
1 Treatment (1 st Treatment performed at Month 0)	27% (68 sites)	27% (34 sites)	30% (33 sites)	39% (34 sites)	45% (36 sites)
2 Treatments (2 nd Treatment performed at Month 3)	---	50% (32 sites)	47% (31 sites)	52% (35 sites)	50% (37 sites)
Control Sites	6% (42 sites)	12% (39 sites)	15% (38 sites)	13% (42 sites)	15% (44 sites)