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# F1 Diode Laser™ thirty-six-month clinical study

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Despite the impressive clinical results that have been reported with the use of laser hair removal systems, long-term comparative studies have been scarce. The purpose of this study was to evaluate over a thirty-six-month period the lasting effects of the *F1 Pulsed Diode Laser*™ System on hair reduction.

With a wavelength of 810 nm, the *F1 Diode Laser*™ offers excellent follicular melanin absorption without the need for increased fluence, and can safely treat a wide range of skin types (I-VI), with minimal pain. Moreover, its long-pulse duration (15-40 msec) ensures deep follicular destruction. Results from the *F1 Diode Laser*™ twelve-month clinical study were previously presented at the ASLMS (American Society for Laser in Medicine and Surgery) meeting in Reno, Nevada, in April 2000 by Dr. Barolet (Barolet D. [Comparison of two infrared laser systems for hair removal](#), *Lasers Surg Med.*, Supp. 12, 2000, p.20). Herein, the thirty-six-month clinical study (1999-2002) clearly demonstrates permanent hair reduction following treatments with the *F1 Diode Laser*™, assessing both security issues and overall efficacy of the device, up to three years after treatment.

## I. Protocol

IRB Services (FDA approved independent ethical review committee) reviewed the ethical aspects of the study. A total of seventeen (17) patients were recruited and informed consent was obtained after explanation of study design and potential risks involved.

Patient pretreatment evaluations included medical checkup, review of enrolment inclusion/exclusion criteria, and determination of skin type (Fitzpatrick scale I-VI).

- Large 2 x 3 cm test sites (13) were mapped on the upper back (male) and posterior aspect of thigh (female) of N=17 patients, with skin type I-V (fair to dark-skinned) and any hair color. Each test site was shaved before laser exposure and treated for 1, 2, 3 or 4 times at one-month intervals, with 15, 20 and 25 Joules/cm<sup>2</sup> fluence energy, using an 810 nm diode laser.
- Test sites were on the back or posterior aspect of the thighs based on similar uniformity, density and hair growth cycle duration (5-8 months) of terminal hairs.
- Sites were irradiated with an 810 nm diode laser, with the exception of one adjacent shaved control site. Laser pulses were given in a contiguous, non-overlapping pattern that covered the entire test site.
- Baseline and subsequent regrowing terminal hair characteristics were obtained from each site and analyzed over 36 months from each site. A digital image of each treatment site was taken at the initial visit. A CCD video camera was used to project the image of the treatment site onto a computer screen providing high resolution hair imaging. Hair parameters were analyzed using a sophisticated software designed for precise measurements of hair count, hair diameter and hair luminance (color).

### Patient Risks:

Risks estimated for this study were similar to those expected when undergoing any dermatological laser treatment. Identified risks were: blistering, edema, erythema, and mild to moderate local pain. A lesser possibility existed for dyspigmentation, scarring, and/or infection.

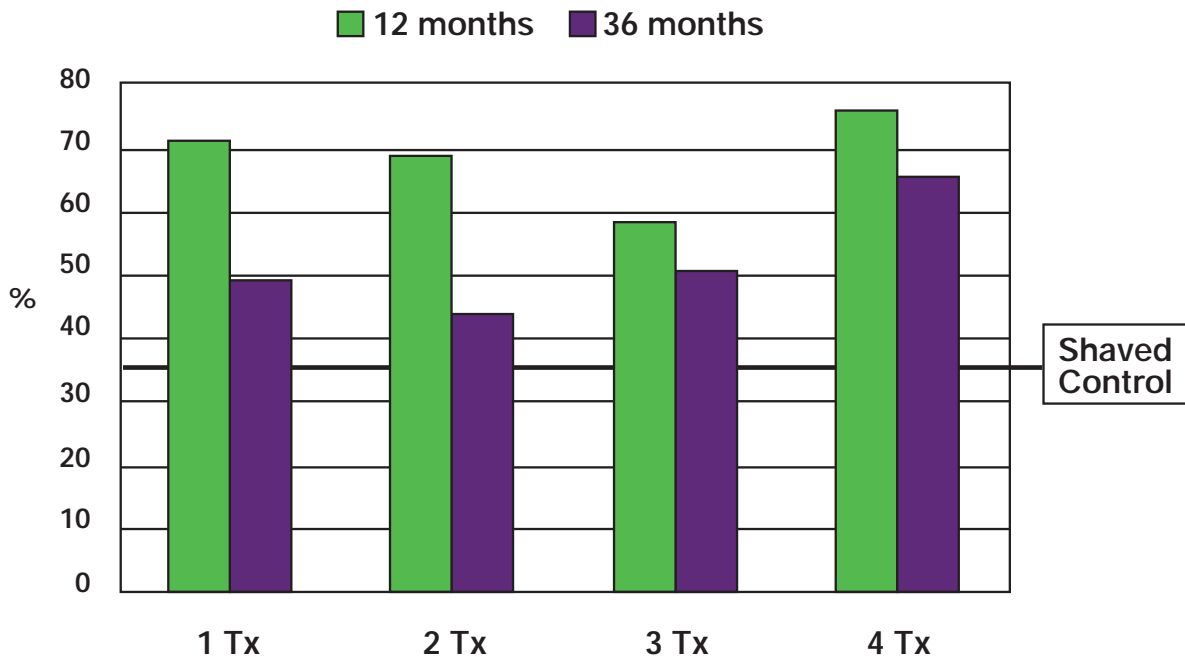
## II. Results

After 4 consecutive monthly treatments (25 J/ cm<sup>2</sup> fluence), sustained hair reduction is demonstrated at 12 and 36 months post-treatment with respective hairiness reduction values reaching 72% and 65%. All subjects exhibited thinner and lighter hair regrowth. The hairiness score (**HS**) was calculated using three hair parameters measured at specific intervals during the study:

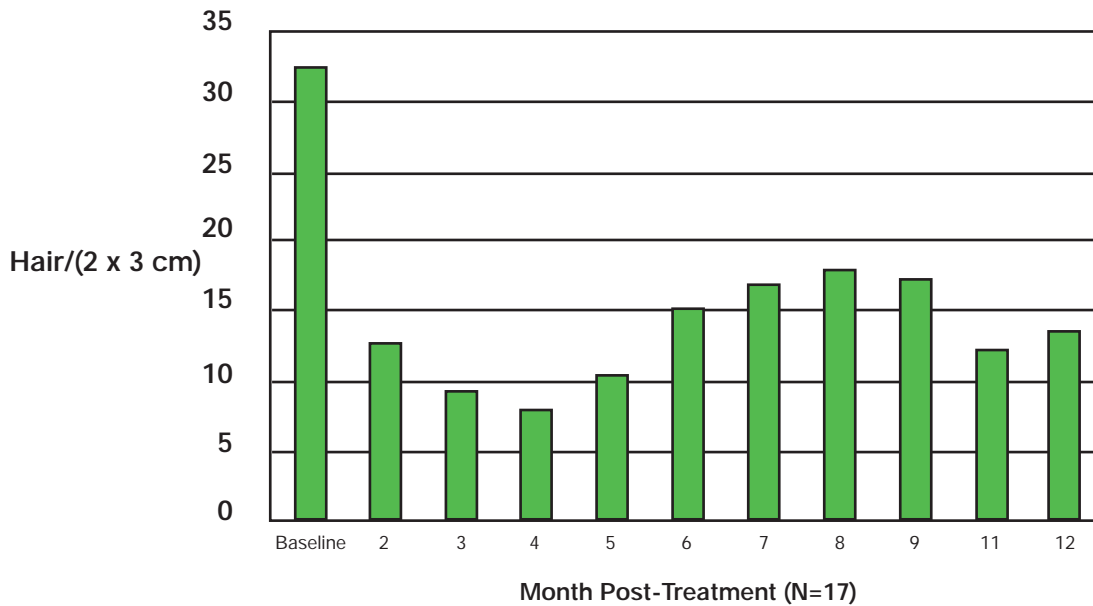
$$\text{HS} = \frac{\text{Hair count} \times \text{Hair diameter} \times \text{Hair color (luminance)}}{\text{Surface}}$$

Minimum side effects were observed. Some partial and temporary reddening of the treated area was seen. Transient pigmentary changes were observed. There was neither incident of scarring nor long-term side effects.

## Long-Term Hairiness Reduction (25 J/cm<sup>2</sup>/Tx) Maintained at 12 and 36 Months



## Long-Term Hair Count Reduction After 4 Treatments at 25 J/cm<sup>2</sup>



### III. Conclusion

- The long pulse *F1 Diode Laser*<sup>TM</sup> can affect both structural recovery (size of hair) and follicular pigmentation (hair absorption coefficient) even with low fluence energy (up to 25 J/cm<sup>2</sup>).
- The response is wavelength-dependent with a cumulative effect after multiple treatments.
- Permanent hair reduction (after a complete hair cycle at 7 months) has been shown at 810nm (*F1 Diode Laser*<sup>TM</sup> System) and maintained over a 36-month period (>5 hair growth cycles later).
- The clinical efficacy previously established for 12 months is maintained over a 36-month-period, based on following rigorous software hairiness analysis.
- Results clearly show that the *F1 Diode Laser*<sup>TM</sup> System is safe and efficacious for permanent hair reduction.