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Editor's Note: Canadian, Ted Molczan, A consultant in the energy conservation industry, first became interested in hair removal technology in the 1980's, as a satisfied electrolysis consumer. When laser entered the picture in 1995, Ted closely followed its development via the Internet. When he concluded that the reality of laser fell far short of the hype, Ted became an activist, using the Internet to warn fellow consumers.

Permanent Hair *Reduction* - A Legal Pandora's Box

by Ted Molczan

On 22 July 1998, Palomar Medical Technologies, Inc., announced that it had received FDA clearance to market its Epilaser for "permanent hair reduction" of treated hairs. Most people understand permanent hair *removal*, but what is permanent hair *reduction*? I believe that laser promoters will come to regret this confusing new terminology as much as consumers.

Confusing New Term Defined

Here is Palomar's exact wording of the Epilaser's new *Indications for Use*, cleared by FDA:

"The Epilaser is intended to effect temporary hair reduction in skin types I through IV. The Epilaser is also intended to effect stable, long-term or permanent hair reduction, in skin types I through IV, through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after treatment regime."

As I read it, this means that Epilaser results are either "temporary", "long-term" or "permanent", and "permanent" actually means "long-term." Confused? So was I, but I obtained some clarification in a conversation with Mr. Richard Felten, FDA's senior reviewer of medical lasers:

"the definition that is being used is basically a stable, long-term hair reduction, following a treatment regime, and the period of time that observations occur that are used to support the claim is a period of time long enough to have included at least one full hair growth cycle, for hairs in that site, which can vary from 3 to 6 months, depending on where the sites are."

Felten also disclosed that Palomar provided clinical trial data from two separate studies, which followed patients one to two years after treatment. He stressed that, "they cannot claim permanent hair removal, or permanent elimination of hair. What they've demonstrated is that for that period of time, there has been a reduction in the number of hairs in the treated site."

This appears to have been a compromise that allowed FDA to deny having approved “permanent hair *removal*”, while allowing Palomar to use the word “permanent” in its advertising. Perhaps this was a win-win for FDA and Palomar, but I believe consumers will *lose*, because promoters are likely to emphasize “permanent” and leave out the part about *reduction*, which I believe is likely to be minimal.

Weak Clinical Basis

One of the two clinical studies mentioned by Felten, appears to have been the 13 subject pilot study carried out at Massachusetts General Hospital in September 1994, under the direction of Dr. R. Rox Anderson. It appears to be the only study old enough to have allowed two years of follow-up prior to Palomar’s new FDA-application. Strangely, Palomar’s original Epilaser FDA-application was supported by data from that study, which FDA found insufficient, leading it to deny clearance to market for hair removal in July 1996.

The pilot study also was the basis for the Epilaser’s patent, and *two* papers published in peer-reviewed journals.^{1,2} The earlier paper,¹ by Grossman et al, reported generally complete regrowth within 6 months, except for four pre-shaved test patches, treated at the highest fluence, 60 J/cm², in which less than 50 percent of the hair had regrown after six months. The hair count on two of those patches had not changed during the final three months of observation, which appears to have been the basis for the claim of “apparently permanent hair removal in some cases.” But this claim appeared only in the abstract, and was ignored in the body of the article, suggesting that the observation was insignificant.

However, following an additional 18 months of observation, a new paper² by Dierickx et al, appeared in the July 1998 issue of Archives of Dermatology, trumpeting “Permanent Hair Removal.” But, its actual conclusions fall somewhat short:

“Permanent, nonscarring alopecia can be induced by a single treatment with high-fluence ruby laser pulses. Miniaturization of the terminal hair follicles seems to account for this response.”

Dierickx et al argued that miniaturized follicles seen after ruby laser pulses are similar to androgenetic alopecia (male baldness), “characterized by a proportional reduction in size of the papilla and the matrix”, leading to the claim:

“Therefore, the terminal follicles are gradually transformed to velluslike follicles. "Loss" of hair in androgenetic alopecia only relates to the loss of terminal hairs and is similar to "loss" of hair after ruby laser treatment. The follicles are not actually lost but produce hairs that are shorter, finer, and less pigmented.” They seem to admit that there is no real hair loss!

Amazingly, the claim of alopecia is based on 3 mm biopsies, taken from a single subject, pre-treatment and 1 year post-treatment. Those two biopsies represented about 2 percent of the area of the 2 x 3 cm test site from which they were taken. Both contained 4 hairs, so there was no actual hair reduction!

The pre-treatment biopsy had 3 terminal hairs, and 1 vellus hair. This was reversed in the post-treatment biopsy, which had 1 terminal hair, and 3 vellus hairs. The change in ratio

between terminal and vellus hairs was the basis for claiming laser-induced alopecia! How can two biopsies, representing a mere 2 percent of the treated area be considered significant?

Criticism by Peers

Interestingly, the same issue of Archives of Dermatology includes a lengthy editorial³ by Drs. Tope and Hordinsky, critical of this and other research into laser hair removal. On the use of biopsies:

“The applicability of biopsies in analyzing the effects of phototricholysis may be limited to establishing specific patterns of follicular injury rather than an accurate population view of an entire treatment site. Herein lies a very real criticism of the article by Dierickx et al, who conclude that the permanent hair removal they observed resulted from conversion of terminal hairs to nonpigmented velluslike hairs. While they cite an inversion of the terminal-velluslike hair ratio and decreased average hair diameter from pretreatment to 1 year after treatment, these findings are based on 8 hair follicles counted in 2 biopsy specimens taken from a single patient. In our opinion, these are too few hairs upon which to hang one's hat.”

Perhaps FDA should have consulted with Tope and Hordinsky before ruling in Palomar's favour!

Tope and Hordinsky provided a detailed critique of the generally poor quality of published peer-reviewed laser hair removal research, and offered many suggestions for improvement. Most importantly, they recommended that “discerning clinicians should look for studies incorporating rigorous design to produce believable data and conclusions.” However, they added this note of despair:

“Unfortunately, appropriately rigorous studies may be difficult to perform in the face of existing FDA market clearance of many hair removal systems.”

Clearly, Tope and Hordinsky saw the FDA's rather minimal clinical trial requirements as a hindrance to rigorous research. As a consumer, I say Bravo! Perhaps this will spark a much needed public debate on this issue.

A Legal Poison Pill

In my opinion, “permanent hair *reduction*” may turn out to be more of a liability than a help to laser promoters, based in part on this statement made to me by FDA's Richard Felten:

“They [Palomar] were required, as part of the labeling in the application, which was the information that was used as the labeling for that device, to include the actual clinical trial data summaries, as part of their labeling. So there are tables in the document, which is part of their labeling, that actually give the percent of hair reduction for various fluences used to treat different patients, and [in] some cases this also includes patients who received more than one treatment - usually two treatments. And that table includes the percentage hair reduction that was observed at each of those levels. And what you would notice, or what is obviously there, is that there appears to be little or no effect

below 30 J/cm², and as you go up towards 50 J/cm², the percent of hair reduced actually increases.”

I believe this may prove to be the one saving grace of FDA’s otherwise ill-advised decision, for it places real clinical results in the hands of physicians. Based on previously published data, we know that most patients experience rapid and nearly complete hair regrowth, but now clinics will not be able to claim blissful ignorance. This creates a difficult dilemma. If they disclose the FDA-mandated clinical data, customers are likely to be turned off. If they conceal it, they leave themselves wide open to be sued by patients who expected “permanent hair *reduction*” to mean “permanent hair *removal*.”

1. Grossman MC, Dierickx C, Farinelli W, Flotte T, Anderson RR. Damage to hair follicles by normal-mode ruby laser pulses. *J Am Acad Dermatol* 1996 Dec;35(6):889-894
2. Dierickx CC, Grossman MC, Farinelli WA; Anderson RR. Permanent Hair Removal by Normal-Mode Ruby Laser. *Arch Dermatol*. 1998;134:837-842
3. Tope WD, Hordinsky MK. A hair's breadth closer? *Arch Dermatol* 1998 Jul;134(7):867-869