SAFETY OF SOFTLIGHT® TOPICAL SUSPENSION ASSISTED Q-SWITCHED Nd:YAG LASER HAIR REMOVAL

Experience With 100,000 Treatments

By

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Is laser hair removal safe? Does it damage the skin in any way? These questions are frequently asked by our clients and patients. Their concern is understandable and their input to our study of this issue is appreciated.

Photo-epilation is an emerging science, with evolving concepts and questions. Both the safety and efficacy of the various technologies need frequent update and review. The early reports of melanin-targeting technologies show similar types and frequencies of complications, in some contrast to the study of the SoftLight® process that follows.

Grossman, et al, studied the effects of a normal-mode ruby laser on 13 subjects with white skin and dark hair and observed hypopigmentation in 16%, and hyperpigmentation in 24% of treated sites, with hyperpigmentation in one patient persisting longer than 6 months.[1] Another ruby laser used with cooling gel caused blistering and mild hypopigmentation in an unreported number of patients studied by Nestor.[2] Connolly and Paolini reported that 20% of sites treated with an alexandrite laser exhibited crusting, in spite of topical cooling.[3] Data for the incoherent flash-lamp reported by Gold, et al, included blistering in 11 % and hyperpigmentation in 3% of treated subjects.[4] These findings appear typical when melanin is used as the target chromophore even when treatment is limited to lighter skin colors.

Instead of melanin, the SoftLight process uses a nanophase carbon particle activated by a low-energy Nd:Y AG laser to damage hair follicles. It carries no restriction as to hair or skin color. A histologic review and statistical summary of complications from the SoftLight process demonstrates the inherent safety of this approach.

HISTOLOGICAL ASSAY OF THE IMPACT OF THE SOFTLIGHT HAIR REMOVAL PROCESS ON ALL SKIN TYPES

Over 800 biopsy sites on 230 subjects were studied to determine the potential impact of the ThermoLase SoftLight Hair Removal Process on human skin. In this study, we used the SoftLight Q-switched Nd: YAG (1.06 micron) laser at a fluence of 2.5 J/cm^2 together with a topically applied carbon lotion.[5] Four-millimeter punch biopsies were taken from each subject at one, three, and six weeks or more after treatment. Of the 230 subjects, 69 with Fitzpatrick Skin Types I through VI were further studied and their representative biopsy results are described below.

Figure 1, for Fitzpatrick Skin Type IV is representative of the biopsies observed for all Skin Types after lasing. The two figures on top are controls and show the skin prior to lasing. The two figures on the bottom depict biopsies harvested seven days after treatment. The figure at the bottom left, at low magnification, shows extensive damage to the hair bulb region. In particular, there is extensive damage to the hair matrix as well as the dermal papilla. The epidermis is noted to be relatively unaffected.

The figure on the bottom right is a close-up of the epidermis at high magnification after lasing. It demonstrates a normal stratum corneum, a normal stratum spino sum and basal layer. In addition, the melanocytes are normal in appearance after lasing. There is no disruption of the dermal-epidermal junction or changes in the staining pattern of the superficial papillary dermis.

Figure 2 shows biopsies of the epidermis for all six Skin Types after lasing. Similar to the example above on Skin Type IV, there is no damage to the epidermis after lasing. All six Skin Types demonstrate a normal stratum corneum, stratum spinosum and basal layer. In addition, the melanocytes have not been affected by the Nd:Y AG laser. This is true even for Skin Type VI, which is from the darkest, and highest pigmented individual. The data in this figure is representative of five people of Skin Type 1,28 of Skin Type II, 9 of Skin Type ill, 22 of Skin Type IV, 4 of Skin Type V, and 1 of Skin Type VI.

Figure 3 shows the status of the sebaceous and sweat glands after lasing. Each of these structures has a normal appearance.

COMPLICATIONS

Table 1 summarizes the complications noted during clinical studies and those reported from commercial treatments at Spa Thira salons. The first column of Table 1 lists complications noted in 230 subjects who participated in clinical studies at the ThermoLase R&D center in San Diego. The number and rate of complications seen are not statistically significant. The second column of the table shows the complications that have been reported from the commercial Spa Thira salons where over 100,000 treatments have been performed. In all cases, the incidence of complications is expressed as a percentage of the total number of treatments.

In the R&D clinic there have been no complications of scarring, atrophy, infection, blistering, scabbing or tattooing. The incidence of induration and folliculitis is less than 1%; the latter being related to waxing which is no longer part of the treatment protocol. The incidence of hyperpigmentation is less than 1.5%, and has not ever been seen in Types I-ill subsequent to SoftLight treatment. The incidence of complications in over 100,000 treatments performed in the commercial Spa Thira salons parallels the experience in the research clinic. All complications have been transient, resolving in a matter of days or weeks instead of months as reported for melanin targeting technologies.[1,2,3]

Recently in Japan, 78 individuals with Asian skin were treated in a clinical study. In this study, there has been 0% incidence of hyper- or hypopigmentation.[6]

RESIDUAL CARBON AND THE ABSENCE OF TATTOOING

It is interesting to examine what happens to the carbon during and after the lasing process. Some physicians have inquired about the possibility of permanent tattooing of the skin with the carbon particles after laser treatment.

Laser propulsion of carbon into the follicle by means of vaporization is an essential part of this hair removal procedure. High pressure gradients generated by the first nanosecond laser pulses force the superficial carbon chromophore deeper into the hair follicle. An instantaneous pressure rise, due to vaporization of carbon, can reach hundreds of atmospheres over a time period of less than one millionth of a second (one microsecond). The carbon is heated and vaporized by subsequent laser pulses. It is the heating process that causes significant damage to the hair bulb and other follicular structures.

In order for visually perceptible tattooing to be produced, the individual carbon particles, or their aggregates, must be at least 0.5 microns in size. Since individual particles are nominally 0.1 micron in size, they would not be visible even if the skin is observed with an optical microscope. Larger size aggregates of the particles, which may form in the lotion prior to lasing, are effectively broken down by the enormous agitation created during laser illumination.

A histological study to evaluate the possibility of tattooing after laser propulsion was performed. Microscopic carbon particles could reach the stratum granulosum in less than 1% of the cases, but deeper penetration was never observed. In these cases, carbon particles that were invisible to the naked eye were noted to be sparsely scattered in the superficial epidermal layers. The study demonstrated that the pressure shock wave was not powerful enough to accelerate carbon particles through the stratum corneum and epidermis into the papillary dermis. These residual carbon particles have been observed to be expelled completely within several days after the propulsion treatment through the natural process of desquamation.(7) Residual carbon particles are vaporized by the multiple laser passes of the SoftLight process and are therefore not seen subsequent to the procedure.(5)

It is important to note that not a single incidence of tattooing has been reported in the course of over 100,000 treatments in the Spa Thira salons.

The hair root canal is another site where residual carbon could possibly accumulate. Laser propulsion is designed to force the carbon lotion deeply into the hair follicle, where it would normally be vaporized. Indeed, histological examination reveals residual carbon has not been observed inside the hair follicle following laser vaporization.

Several hypothetical situations that could possibly lead to tattooing should be considered. Assume that the technique has been carried out improperly and that a fluence lower than 2.5 J/cm^2 had been used. Alternatively, assume that the laser fluence is significantly attenuated by high scattering resulting in absorption inadequate to completely vaporize all the carbon. In either case, the residual carbon would be excreted from the follicle within a few weeks. In the event that carbon particles were propelled into the surrounding dermis, their small size would render them invisible to the naked eye. It should be noted that to our knowledge, none of these hypothetical scenarios has occurred.

Occasionally, an examination with an optical microscope of sebum from a lased follicle has shown the presence of dark brownish discoloration. The dark brown material was microscopically determined to be remnants of intrafollicular cellular material destroyed by the laser treatment. No permanent mark has ever been observed from this substance.

CONCLUSION

The ThermoLase SoftLight hair removal process is safe, virtually free of complications, and there have been no reported cases of tattooing in over 100,000 treatments.

The explanation for the virtual absence of complications with the low fluence (2.5 J/cm^2) Q-switched Nd:YAG laser as compared to other hair removal procedures, which use melanin as their chief chromophore, is due to at least two factors: 1) at the Nd: YAG 1.06 micron wavelength, the absorption by carbon is several orders of magnitude higher than that of melanin or any other innate cutaneous chromophore, and 2) the procedure uses a fluence that is ten to twenty times lower than that used in other laser or incoherent light source hair removal procedures. The combined effect of these two factors leads to a safety margin approximately 1000 times greater than those which utilize melanin as the chromophore and primary target for laser assisted hair removal.

TABLE 1. COMPLICATIONS IN SKIN TYPES I-VI

COMPLICATION	OCCURRENCE IN CLINICAL TRIALS %	COMMERCIAL SPA THIRA SALONS %
Scarring	0	0
Hypopigmentation	0	<1
Hyperpigmentation	<1.5	<1
Atrophy	0	0
Induration	<1	0
Folliculitis	<1	<1
Other Infections	0	0
Blistering, Scabbing	0	0
Tattooing	0	0

References

(1) 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,* December 1996.

(2) Laser Hair Removal: Clinical Results and Practical Applications of Photo thermolysis, Nestor M, *Skin & Aging,* January 1998.

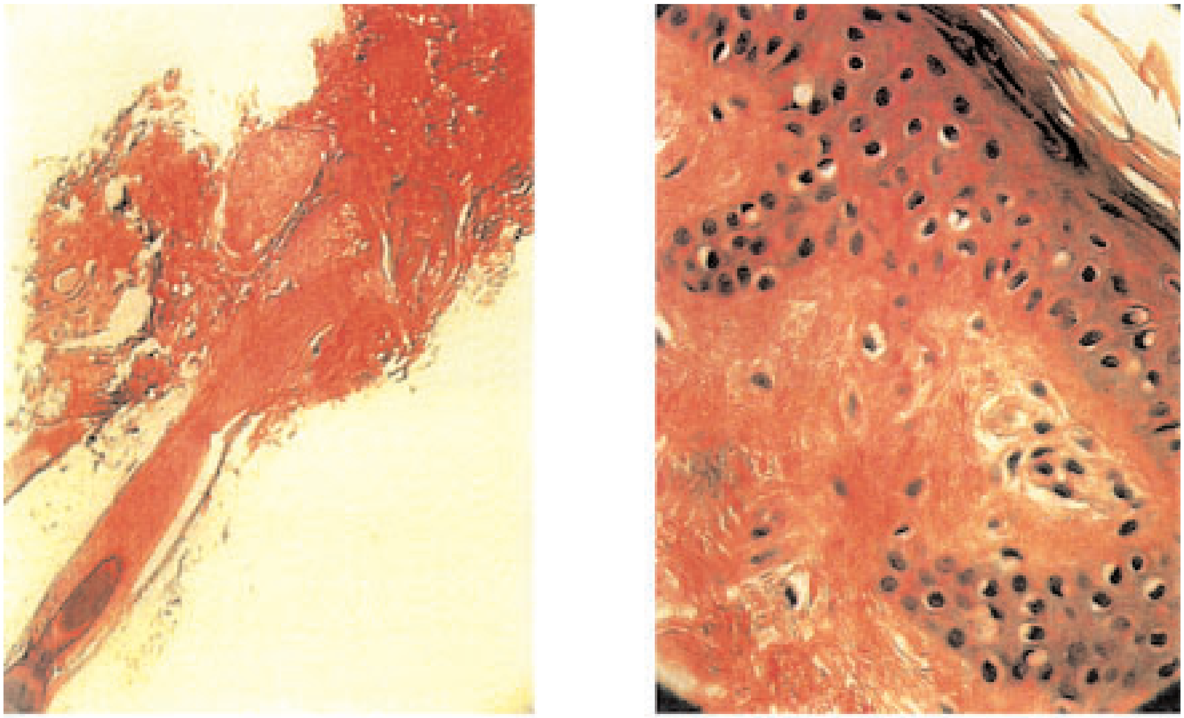
(3) Connolly C, Paolini L, Study Reveals Successful Removal Of Unwanted Hair With LPIR Laser, *Cosmetic Dermatology* Vol. 10, No. 12 December 1997.

(4) Gold M. Bell M. FosterT. Street S. Long-Term Epilation Using the EpiLight Broad Band. Intense Pulsed Light Hair Removal System, *American Society for Dermatologic Surgery,* Inc 1997:23:909-913.

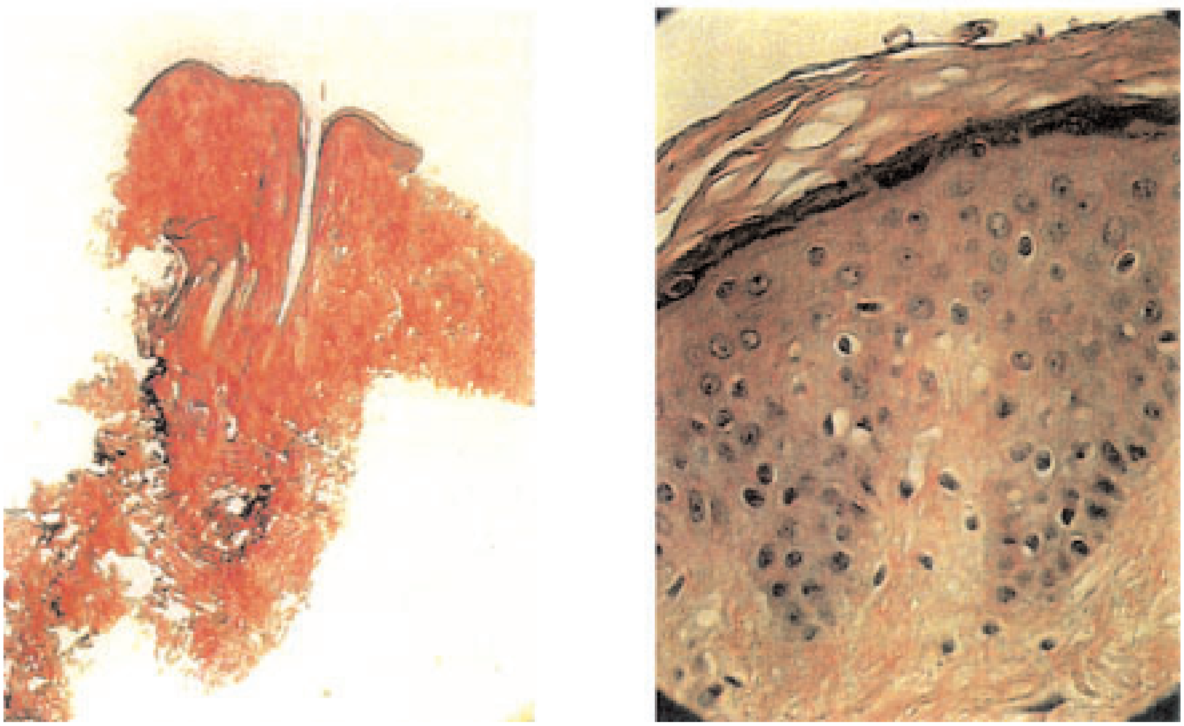
(5) N. Tankovich MD, Ph.D., V. Kolinko PhD, C. Littler MD, H. Branstetter BS, RN, A. Cole BS, M. Lefebvre MS, R. Van Osdel BS, T. Andjus MS, G. Anderson BS, D. Fine Ph.D., Destruction of Hair Follicles Using a Carbon Lotion and A Q-Switched Nd: Y AG Laser, ThermoLase Corporation April 1998.

(6) Spa Thira Japan, Data on file.

(7) Wheeland R, Review Series Article: Clinical Uses of Lasers in Dermatology, *Lasers in Surgery and Medicine* Volume 16, No.1, 1995.



BEFORE LASING



AFTER LASING

Figure 1. Skin type IV before and after lasing.

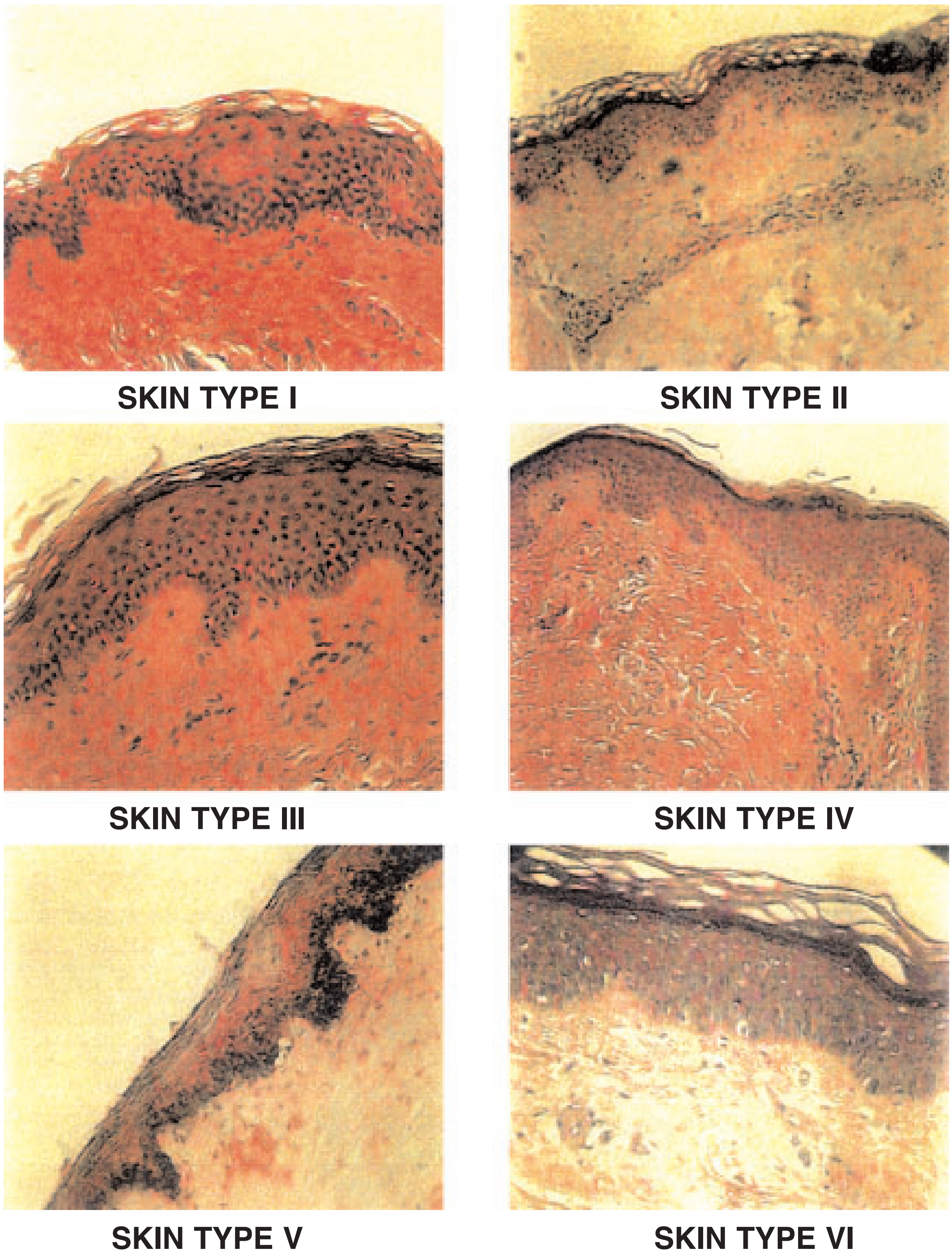
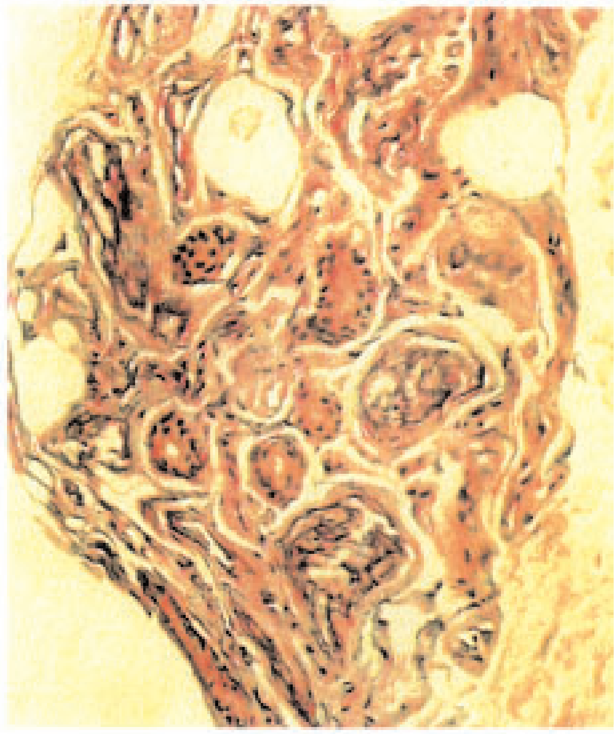
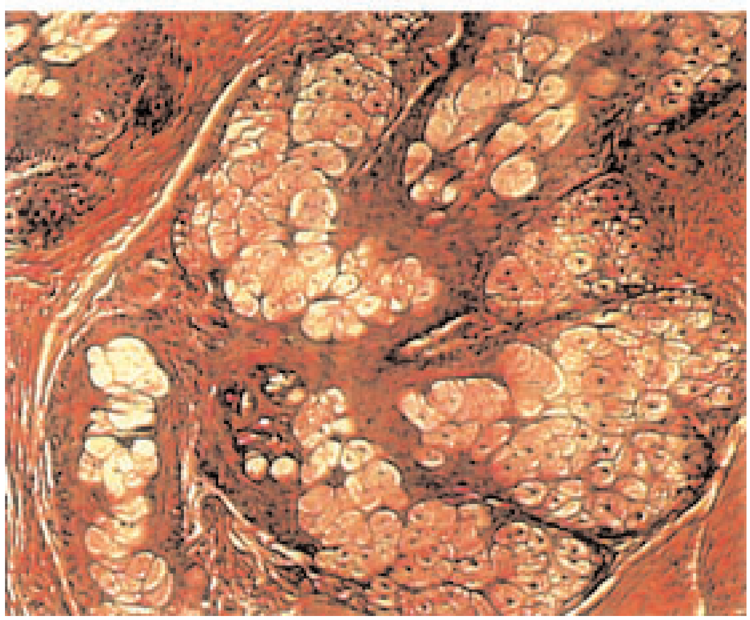


Figure 2. Skin types I through IV after lasing.



SWEAT GLAND



SEBACEOUS GLAND

Figure 3. Sebaceous and sweat gland after lasing.