

Clinical Studies Confirm Superior Tattoo Clearance with PicoSure

By Jeffrey Frentzen, Executive Editor

Tattoo removal has graduated from the days of non-selective ablation using carbon dioxide and continuous wave lasers to selective photothermolysis using Q-switched lasers. "The first breakthrough in tattoo treatments came 20 years ago, with the development of these Q-switched nanosecond lasers," explained Jeffrey S. Dover, M.D., F.R.C.P.C., a dermatologist in Chestnut Hill, Mass., who also



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conducted one of the clinical studies used in the PicoSure™ laser's FDA approval process. "These billionth of a second pulse duration devices achieved scarless tattoo removal for the very first time."

Q-switched lasers release high-powered pulses in the range of nanoseconds, which causes the formation of acoustic waves and photothermal

effects that ultimately destroy the tattoo ink particles. These destroyed ink molecules are then absorbed by macrophages and removed from the

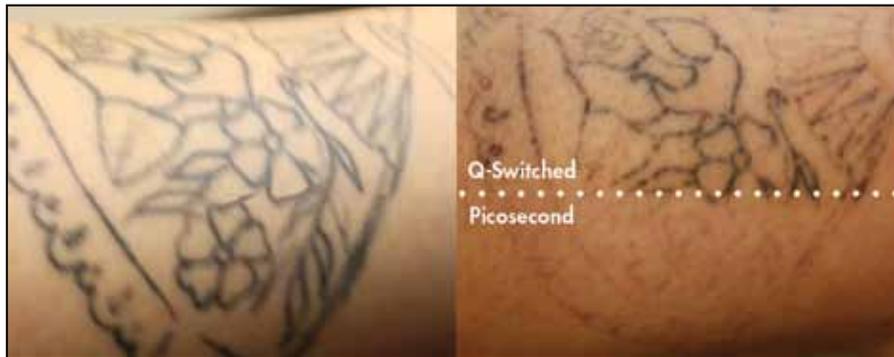
"This is a picosecond domain device, producing pulse durations in the trillionth of a second; therefore, the pulses are 100 times shorter than the Q-switched laser."

body via the lymphatic system. The decades-old, original study of tattoo removal via Q-switched lasers demonstrated near complete clearance of professional tattoos in around six treatments, Dr. Dover reported. "However,

these results have not been borne out in practice. To obtain this sort of clearance, it usually takes a lot more than six treatments. Generally at least 12 are needed, and often as many as 18 or more are required."

Despite the much improved Q-switched devices, and more sophisticated treatment modalities, cosmetic results for tattoo removal have remained inconsistent in terms of time and treatment sessions required for complete removal. PicoSure, from Cynosure Inc. (Westford, Mass.), features revolutionary picosecond technology and was recently FDA cleared for the removal of tattoos and benign pigmented lesions. According to clinical investigators, this system is a major evolutionary leap in terms of treating tattoos, as well as benign epidermal pigmentary lesions. "This is a picosecond domain device, producing pulse durations in the trillionth of a second: 10 to the power of -12; therefore, the pulses are 100 times shorter than the Q-switched laser," Dr. Dover explained. "Studies done over the past 20 years have suggested that these shorter pulse durations would achieve better clearance of tattoos than nanosecond devices."

After being in development for nearly a decade, PicoSure is being introduced as the first safe and effective picosecond aesthetic laser specifically designed to treat tattoos and pigmented lesions. This innovative 755 nm alexandrite laser delivers ultra short pulse bursts of energy to the skin in trillionths of a second. Picosecond lasers enable significant photomechanical stresses rather than photothermal action to damage the



Before Tx

Photos courtesy of Cynosure, Inc.

Comparison of tattoo treated with Q-switched vs. picosecond technology one month after three treatments

targets. In addition, nanosecond lasers may only produce a small fraction of the power generated by a picosecond laser.

In addition to performing tattoo removal, the PicoSure treats benign pigmented lesions, which are caused when skin cells produce too much melanin in a localized region.



Before Tx



After three PicoSure treatments
Photos courtesy of Cynosure, Inc.

Though some lesions are present at birth, most develop with sun exposure or age. When the pigment is located in the epidermis, light brown spots occur, such as freckles, cafe-au-lait birthmarks and sun spots. When the

pigment is found deeper in the skin, dark brown spots can result, such as Nevus of Ota or other moles.

Currently, the global market for the removal of pigmented lesions is roughly twice as large as the market for tattoo removal. Whether the treatment is for benign lesions or tattoos, the ability of the shorter picosecond pulses to break up the targeted pigment, without damaging surrounding areas or forming rough edges, is proving to be vital for skin treatments.

“We have known that if we can get a shorter pulse to break up these pigments more readily, the outcomes should be better.”

In 1982 the first glimmer of the picosecond laser occurred when an M.I.T. scientist created a device that could generate short pulses in the picosecond and femtosecond ranges. The picosecond laser, which is also known as the ultrafast laser or ultra short pulse laser, operates at a millionth of one millionth of a second. A laser with such extremely short pulse durations produces pulses that achieve a very high peak power and can focus that energy onto a small volume of space, in order to ablate material from the

surface quickly and cleanly without damaging the underlying areas. Picosecond lasers have created a niche in medicine, both for developing biomedical devices and in performing sensitive procedures such as corneal surgery. “The picosecond is a technology that has been talked about for years. In tattoo removal, the question has always been, when will we have something that works a little bit better?” advised Kenneth A. Arndt, M.D., a dermatologist in Chestnut Hill, Mass.

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these pigments more readily, the outcomes should be better,” Dr. Arndt continued. “Tattoo ink particles are extremely small, though, so optimally one needs a very short pulse to break them up. The way PicoSure works is twofold: first, the mechanical or acoustic effect simply breaks up the pigment; and second is a thermal effect. When the energy is absorbed, it induces heat, which also plays a part. With lower fluences, the beam is both shorter and uses less energy. Even though the device is very powerful, the skin’s reaction to it – the wound healing, etc. – is better than with other devices. Now that a picosecond laser is available, it is very exciting because it does indeed seem

to work better. There are a lot of people with tattoos and lesions that will benefit from this technology."

Unlike previous energy-based systems used to remove tattoos, the PicoSure laser deposits so much energy so fast that the target material, such as tattoo ink, experiences significant photomechanical effects leading to a break-up of the ink or pigment particles. Since the thermal relaxation time of tattoo pigment particles and

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melanosomes is less than ten nanoseconds, this means energy delivery in the picosecond range is effective, according to clinical results that were used in two pivotal trials. Dr. Dover feels, "the new picosecond laser is the first significant improvement in the treatment of tattoos in over 20 years. I believe it will be a huge improvement to existing technology. Who wouldn't want their

tattoo cleared in half the number of treatments and half the time, with no increase of side effects?"

Dr. Dover and Dr. Arndt were involved in a single center prospective study¹, which took place at SkinCare Physicians, a dermatology clinic in Chestnut Hill, Mass. In this clinical study 15 patients with darkly pigmented tattoos were treated using the PicoSure system to



Before Tx



Three months after four PicoSure treatments

Photos courtesy of Kenneth A. Arndt, M.D. and Jeffrey S. Dover, M.D., F.R.C.P.C.

investigate the effect of therapy on targeted and surrounding tissues, and how many treatments were needed to eradicate the tattoo ink.

Treatment efficacy was based on the level of tattoo clearance in standard 2D photographs, which were assessed by a blinded physician

evaluator, as well as a measure of physician and patient satisfaction. Twelve patients completed the study, with all of them obtaining greater than 75% clearance and nine observing greater than 75% clearance after two to four sessions. On average, four applications were needed to achieve 75% clearance, with all 12 patients satisfied or extremely satisfied with the treatment. There was minimal subsequent downtime and patients reported low to moderate pain, on average. Only two patients received topical 30% lidocaine (applied over the treatment area for 30 minutes prior to treatment). These patients reported low pain scores. Any noted pain subsided immediately after therapy, according to the study, whereas swelling and blistering resolved within one week. Some hypopigmentation and hyperpigmentation were reported at the three month follow-ups.

In these trials, the adverse effects reported for PicoSure were roughly equivalent to what patients have reported after treatments using Q-switched and other lasers. Dr. Arndt noted minimal blistering and some crusting was seen, as well some alteration in pigmentation. "This is just a byproduct of the thermal effects and the impact effect of strong laser pulses, which goes hand in hand with any laser treatment," he reported.

Dr. Dover concurred that there was minimal hyper- and hypopigmentation after treatments. "Those effects were transient in all cases. The picosecond device appears to clear tattoos about twice as fast as

the Q-switched nanosecond domain devices with no increased risk of side effects."

As Dr. Arndt explained, the PicoSure laser works optimally on black inks, as well as blues and greens. "With a hundred times shorter pulse than the current nanosecond devices, the picosecond laser will be more effective in treating colors – yellows, oranges, purples and blues – that historically are not well absorbed," he advised.

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dermatology at New York University Medical Center, led the second PicoSure clinical study². "I was involved with the clinical development of the first lasers for tattoo and pigmented lesions almost 23 years ago, which included the Q-switched ruby, alexandrite and Nd:YAG lasers," he shared, adding that his active cosmetic laser and dermatology practice sees many patients for tattoo and pigmented lesion removal. After he and colleagues put PicoSure through its paces he confirmed, "the picosecond laser's shorter pulse duration erases tattoo pigment more efficiently, leading to a higher level of patient satisfaction and improved results compared with current technology."

Using the PicoSure system, Dr. Geronemus and colleagues described the successful and rapid treatment of ten patients with 12 tattoos containing blue and/or green pigment that were either previously untreated and multicolored, or recalcitrant to previous



Before Tx



After three PicoSure treatments

Photos courtesy of Roy G. Geronemus, M.D.

treatment. "PicoSure dramatically improved outcomes with blue and green pigment, and showed faster response with black ink," he stated.

One patient had two untreated multicolored tattoos, and one patient had two recalcitrant tattoos. Recalcitrant tattoos were defined as those with

clinically apparent pigment after at least ten previous treatments. The age range of the patients was 23 to 39 years, with Fitzpatrick skin types ranging from II to IV. In both clinical trials, most of the tattoos were located on the upper back, shoulder, leg, thigh, abdomen or arm. Ink colors included black, white, yellow, red, orange and purple. In the Geronemus

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study, the average age of untreated tattoos was 9.5 years, with one patient's recalcitrant tattoos aged 13 and 15 years old.

Investigators found that the procedure was well tolerated by patients, who reported minimal subsequent downtime. Patients described low pain, on average, although one patient noted blistering. The remaining patients reported only a formation of crust, with a few signs of post-inflammatory pigmentary alteration appearing.

"We are seeing faster healing and less blistering with PicoSure," said Dr. Geronemus. "Patient satisfaction was quite high, especially for those who did not have a viable option for blue and green colors." Additionally, subsequent follow-up visits revealed no scarring or residual pigmentary alteration.

"11 of the 12 treated tattoos had achieved greater than 75% clearance of the blue and/or green pigment after only a single treatment, with greater than two-thirds of those approaching closer to 100% clearance."

During the follow-up interviews, it was found that 11 of the 12 treated tattoos had achieved greater than 75% clearance of the blue and/or green pigment after only a single treatment, with greater than two-thirds of those approaching closer to 100% clearance. The remaining patient's green-only tattoo required two treatments to achieve a comparable

rate of clearance. Both of the tattoos that had been recalcitrant to prior treatments achieved over 75% clearance of the green and blue pigments after a single session. In addition, Dr. Geronemus assessed, "Black inks responded faster with PicoSure than with the Q-switched lasers."



Before Tx



After three PicoSure treatments

Photos courtesy of Kenneth A. Arndt, M.D. and Jeffrey S. Dover, M.D., F.R.C.P.C.

Dr. Geronemus explained; when using PicoSure to treat benign lesions, "it works more quickly on lentigines versus Nd:YAG, except in skin type V. PicoSure actually improves skin texture, including hypertrophic and atrophic scars. However, we

did see some hyperpigmentation in darker skin types."

In the clinical trials conducted at SkinCare Physicians, investigators also used the PicoSure system to treat benign lesions. "We did some lentigines and as you would expect PicoSure worked well on a large variety of pigments and lesions," Dr. Arndt pointed out. "It should work well on pigment problems in the epidermis or even lower in the dermis, and while nanosecond lasers have been pretty effective for treating many pigmentary issues and lesions, the picosecond laser should be even more effective for treating those as well."

In Dr. Dover's opinion, the future of PicoSure may not be limited to tattoo removal and treating lesions. "I suspect that eventually it will also be used for laser skin tightening and toning, mild textural improvements, and perhaps even the treatment of striae, fine lines, wrinkles and acne scarring." ■

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