

Acoustic Shock Waves Associated with Lasers to Accelerate Tattoo Removal Procedures: A Real-World Study

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Abstract

Background: The combination of lasers and acoustic shock waves has shown promising results in accelerating tattoo removal.

Objective: To assess the effectiveness of treatments combining lasers and shock waves regarding the number of sessions required for successful tattoo removal.

Methods: A prospective, observational, real-world, single-center study including adults (>18 years) with \geq one professional tattoo of any color on any body part, excluding the head, partially removed or not. Devices were the QS laser RevLite[®] SI (Cynosure Lutronic, USA), the picosecond laser PicoWay[®] (Candela, USA), the CO₂ laser DUOglide[®] with a SCAR 3 scanner (DEKA M.E.L.A. srl, Italy), and the GENTLE Pro[®] shock waves system (Zimmer MedizinSysteme GmbH, Germany). Treatment protocols consisted of QS/picosecond laser passes alternated with shock wave passes (three each) (classic protocol) and one QS/picosecond laser and one shock wave pass, a QS/picosecond second laser pass, and a final fractional CO₂ laser pass (reinforced protocol). Sessions were performed at two-month intervals.

Results: We included 22 patients (68.2% women and 68.2% Fitzpatrick phototype III) with a mean (range) age of 42 (22–68) years and 25 tattoos in total. Most tattoos were black (92.0%) and were removed using the picosecond laser (80.0%) and following the classic (40.0%) and the reinforced (60.0%) protocols in a total of 66 treatment sessions. In 22 tattoos undergoing more than one session, results were good or excellent in 68.2% of them after 2–4 sessions, with no adverse effects.

Conclusion: Acoustic shock wave therapy constitutes a safe adjuvant treatment to accelerate laser-based tattoo removal.

Keywords: acoustic shock wave therapy, picosecond laser, Q-switched laser, laser CO₂ fractional, tattoo removal

Introduction

As the popularity of tattoos has increased, so has the number of individuals requesting their removal, resulting in a growing need for effective tattoo removal methods.^{1,2} Professional tattoos are applied by deep, dense injections of ink composed of organometallic dyes and are difficult to remove.³ Lasers are the mainstay method for tattoo removal by selective photothermolysis, resulting in the fragmentation of ink particles.³ Traditional quality-switched (QS) lasers, including the ruby, Nd:YAG, and alexandrite lasers, produce pulses lasting nanoseconds and have been used for decades to remove various tattoo types.⁴ More recently, the picosecond lasers emitting pulses in the picosecond range have emerged as a more effective alternative and are becoming the laser of

choice.^{4,5} These lasers may be combined with ablative laser systems, such as fractional carbon dioxide (CO₂).^{6,7}

Treatments with traditional QS lasers and picosecond lasers induce epidermal and dermal vacuoles filled with gas, known as “whitening” or “popcorn effect.” The vacuoles scatter the laser beam, preventing further laser passes from reaching the tattoo pigment.^{8–10} Moreover, ink particles agglomerate, further limiting the ability of the laser to fragment ink particles in each treatment session.¹⁰ The whitening effect disappears within 24 h, leaving the tattoo with a brighter appearance that gradually fades over one to one and a half months. Therefore, tattoo fading assessment requires a long-term follow-up. Consequently, laser treatments typically require at least 8–10 single-pass sessions at 7- to 8-week intervals to ensure ink and vacuole clearance, resulting in long, cumbersome treatments.¹¹

In this scenario, new methods enabling multiple laser passes in one session may increase the efficacy of tattoo removal techniques, accelerating tattoo removal. The approaches tested to date, including the R20 protocol, consisting of four passes with 20-min interval between passes to allow gas vacuoles to disappear, and the perfluorodecalin patch, enable multi-pass sessions, but dermal vacuoles remain between passes, preventing the laser beam from reaching the ink particles underneath.^{12–14} Recently, innovative methods using acoustic radial shock waves, known as radial shock wave therapy (rSWT), have been developed to accelerate tattoo removal.

Shock waves are short duration (i.e., pulses), high-pressure sound waves generated extra corporally that deliver energy to tissues inside the body. High-energy extracorporeal shock wave therapy (ESWT) was introduced in 1980 to disintegrate kidney stones.¹⁵ However, regenerative effects in the surrounding soft tissues receiving low-energy shock waves were also observed, leading to the development of focused ESWT (fESWT) to treat musculoskeletal disorders.¹⁶ To this end, specific devices that focus the shock waves 4–6 cm under the application point on the skin were introduced. Since their first use to treat calcific tendinitis in 1991,¹⁷ fESWT has been used in multiple musculoskeletal conditions. ESWT technology was further developed in the 2000s with the introduction of devices that use ballistic pressure waves to deliver energy onto the skin in rSWT. These shock waves are lower energy waves that propagate radially from the tip of the applicator and have superficial penetration, a lower peak pressure, and a considerably longer rise time.¹⁸

In rSWT, the pressure field produces mechanical shear forces that are transmitted into the target tissue. This mechanical stimulation induces specific signaling pathways in targeted cells through mechanotransduction, stimulating regenerative processes such as proliferation of connective tissues, angiogenesis, vasculogenesis, and remodeling, leading to different biological effects.¹⁸ rSWT has analgesic, anti-inflammatory and anti-edema effects and has been shown to improve local metabolism, increase collagen production, and strengthen muscles and connective tissue, among other effects.¹⁸ Consistently, the indications for rSWT are expanding, and they are currently used to treat muscular/tendon conditions, such as radial epicondylitis, tendonitis, chronic tendinopathy of the Achilles tendon, plantar fasciitis/heel spurs, and myofascial trigger point treatment (neck and back), among others, and urological conditions (i.e., erectile dysfunction).¹⁸ Moreover, rSWT is indicated for dermatological conditions, such as scars, hypertrophic lesions, chronic wound healing, and post-burn fibrosis,¹⁹ and has cosmetic applications, such as cellulite, stretch marks, and rejuvenation.^{20,21} Despite the observed benefits, rSWT has contraindications, such as vascular diseases, open wounds, infections, tumors (benign or malignant), and muscle and tendon ruptures in or near the application area, and is not recommended for patients using a pacemaker, during pregnancy and breastfeeding, patients receiving anticoagulants or local cortisone or with specific conditions such as bleeding/coagulation alterations (due to disorders or treatments), disturbances of the vasomotor system, and generalized pain syndrome.¹⁸ Unlike ESWT, rSWT is less painful and does not require anesthesia.²² Nevertheless, it has been associated with short-term, local side effects, such as bruising,

hematoma formation, irritation and redness, transient pain intensification, petechiae, and swelling.¹⁸

Application of rSWT during laser tattoo removal increases lymphatic drainage, accelerating the clearance of ink fragments, and simultaneously induces the instantaneous clearance of epidermal and, more importantly, dermal vacuoles generated by laser passes.^{8–10,23} Therefore, adjuvant rSWT completely eliminates the interference of the laser-induced whitening effect within minutes, enabling multi-pass sessions. The radial shock waves avoid damage to surrounding tissues, with good tolerance and short recovery times.

Tattoo removal protocols combining lasers, whether traditional QS or picosecond, and acoustic radial shock waves have been recently introduced, and studies assessing its effectiveness in the real-world setting are still scarce. This prospective, real-world study aimed to assess the effectiveness of tattoo removal treatments combining lasers and radial shock waves regarding the number of sessions required for successful tattoo removal and, secondarily, to assess its safety.

Material and Methods

Study design and population

This prospective, observational, real-world, single-center study included adult patients (>18 years) with at least one professional tattoo of any color on any body part, excluding the head. Patients with tattoos partially removed before inclusion in this study, requiring finalization, were also included. Patients entered the study at different points in their treatment journey in the participating center or at other centers and, therefore, differed in terms of their tattoo status. The study was conducted at the Dermo Laser Office in Verona, Italy, between November 2023 and December 2024. Exclusion criteria were participation in a clinical trial assessing another device or drug within six months before study inclusion; history of allergic reactions to tattoo pigments; malignant tumors in the treated areas; chronic skin conditions with known Koebner phenomena (e.g., psoriasis, vitiligo, lichen ruber planus); keloid or hypertrophic scarring; and other atypical or delayed scarring responses. Pregnant patients and those with blood coagulation disorders, pacemakers, or electro stimulators were also excluded. Patients were recruited until October 2024, and follow-up visits were scheduled to match tattoo removal treatment sessions, which were performed at average intervals of two months until the fading of the tattoo was considered satisfactory. Data (i.e., images) were collected before the first session and during subsequent study visits.

The study was conducted following the principles outlined in the current revised version of the Declaration of Helsinki, Good Clinical Practice (GCP), and in compliance with all applicable laws and regulatory requirements relevant to the use of devices in Italy. After meeting the inclusion criteria, all patients provided their written informed consent to participate in the study and for publication.

Tattoo removal devices and settings

The medical devices used in this study included lasers and a low-energy radial shock wave generator. Different wavelengths should be used to remove different tattoo colors: Nd:YAG (1064 nm) for black, Nd:YAG with frequency doubling (532 nm) for red, and Alexandrite laser (755 nm) for blue,

violet, and green. Lasers used in this study were the traditional nano QS laser RevLite[®] SI (Cynosure Lutronic, Westford, MA, USA), the picosecond laser PicoWay[®] (Candela, MA, USA), and the CO₂ laser DUOglide[®] with a SCAR 3 scanner (DEKA M.E.L.A. srl, Calenzano, FI, Italy). The lasers settings are summarized in Table 1.

For treatment with radial shock waves, we used the GENTLE Pro[®] system (Zimmer MedizinSysteme GmbH, Germany). Settings were 90 mJ and 22 Hz with a 39 mm applicator. The maximum energy flux density was 0.191 mJ/mm² (corresponding to 22.62 MPa). Effective penetration depth for radial shock waves is approximately 35 mm, depending on tissue composition. Each session involved 1500–2200 shocks, depending on patient response and tattoo size. This device is equipped with a water-cooled shock wave generator that enhances durability (referring to generator lifetime) and with minimal noise, as well as an applicator head that allows the targeted introduction of energy.

Tattoo removal procedures

Patients' tattoos were removed using two different protocols: the classic protocol and the reinforced protocol. The classic protocol consisted of one pass with the QS or the picosecond laser followed by shock wave passes until the whitening effect disappeared each time (usually 1 to 2 min). This sequence was repeated three times. The reinforced protocol consisted of one first pass with the QS or the picosecond laser and one shock wave pass for a maximum of 5 min, followed by a second pass with the QS or the picosecond laser and a final pass with the fractional CO₂ laser. Therefore, unlike conventional laser treatments, the two protocols consisted of multi-pass sessions. The investigator chose the treatment protocol according to his criteria based on tattoo characteristics, previous treatment approaches, and responses. Hence, tattoos with an optimal previous response to conventional treatment were preferentially treated following the classic protocol to avoid overtreatment and maintain progressive fading. Patients reporting adverse effects from previous treatment received the classic protocol to minimize discomfort and promote faster recovery. Conversely, tattoos with slower fading and more treatment resistance (i.e., dense pigment) received the reinforced protocol, a more aggressive protocol with additional fractional CO₂ laser passes, which enhance laser penetration. Patients starting on the classic protocol may be switched to the reinforced protocol if fading plateaus. The two protocols were applied regardless of patients' age.

Evaluations

Images were acquired at different time points during the treatment journey using a digital camera, SONY Model DSCRX10M3 (Japan), including images from tattoos treated with conventional treatments that were later switched to combined treatment. Tattoo fading was evaluated after each session and before performing the next session by visual inspection of the images to assess how much the tattoo had faded in between sessions (either with conventional or combined treatment). For the included tattoos that had received previous treatment with conventional methods, the evaluation focused on assessing how much the tattoo lightened after the session with associated shock waves compared with the conventional methods. At the end of treatment, images were evaluated primarily by the dermatologist, who graded the procedure results as poor, fair, good, or excellent, whereby good and excellent results were considered successful tattoo removal. Two nurses further validated these results independently. Only tattoos receiving at least one treatment session and assessed at the two-month follow-up visit were considered evaluable. Dermoscopy was performed on selected tattoos.

Regarding safety, the treating physician evaluated treatment side effects after each session by examining the tattoo area to rule out side effects other than those occurring upon routine treatments performed over seven years in the participating center.

Data analysis

Tattoo fading was evaluated visually and graded on a four-point scale (poor, fair, good, excellent). Three independent evaluators (dermatologist + two nurses) assessed images; in case of discrepancy, the average grade was used. Data were analyzed and presented descriptively: qualitative variables as absolute and relative frequencies, and quantitative variables as the mean and range.

Ethics and patient consent statement

The techniques performed in this study are routinely used and comply with all applicable laws and regulatory requirements relevant to the use of devices in Italy and with the ethical standards of the National Institutional Research Committee, the Helsinki Declaration (Fortaleza, Brazil, 1975), and GCP. All patients provided their informed consent before inclusion in the study.

TABLE 1. LASER SETTINGS USED IN THIS STUDY

	QS RevLite [®] SI ^a	PicoWay ^{®a}		DUOglide [®] CO ₂ ^b
Tattoo color	Black	Black	Blue/light blue	All colors
Wavelength (nm)	1064	1064	785	10,600
Pulse width	2–5 ns	450 ps	300 ps	1500 μs
Spot diameter (mm)	3–6	3–6	2–4	—
Fluence (J/cm ²)	2–9	1–4	1–4	0.19

^aAs tattoo ink was progressively removed, fluences were progressively increased, requiring smaller spot diameters.

^bAdditional settings: spacing 500 μm, deep pulse, smart stack 2, energy per microbeam ("energy per point/dot") 58.80 mJ, and 11% fractional laser density, defined as the point/dot density, which represents the percentage of the surface area covered by the laser.

Results

Study population and tattoo and treatment characteristics

We recruited 22 patients, 15 (68.2%) women and 7 (31.8%) men, with a mean (range) age of 42 (22–68) years and 25 tattoos. Most patients had Fitzpatrick phototype III (68.2%) (Table 2). The tattoos were mostly black (92.0%) and were primarily removed using the picosecond laser (80.0%). The protocols for tattoo removal were the classic protocol for 10 (40.0%) tattoos and the reinforced protocol for 15 (60.0%). Of the 25 tattoos, 20 previously received conventional treatment. A total of 66 sessions were performed for the 25 tattoos. Three tattoos received only one treatment session, as patients missed the corresponding two-month follow-up visit, precluding evaluation, and did not receive the second treatment session. Hence, they were considered not evaluable, resulting in 22 evaluable tattoos. Four tattoos underwent dermoscopy.

Efficacy and safety outcomes

Of the 22 evaluable tattoos, over two-thirds achieved good or excellent (68.2%) results and were therefore successfully removed. Overall, the results were poor in 2 (9.1%) tattoos, fair in 5 (22.7%), good in 9 (40.9%), and excellent in 6 (27.3%).

Figure 1 shows examples of tattoos graded with good and excellent results after the classic and reinforced protocols. Patients in Figure 1A and B had incomplete tattoo removal after eight and six sessions of picosecond and fractional CO₂ laser treatment before study inclusion. They achieved good results with only two and three additional sessions following the classic and the reinforced protocols with the picosecond laser, respectively. Figure 1C shows a patient

who received five sessions with the picosecond and fractional CO₂ laser before study inclusion and achieved excellent results after three sessions with the reinforced protocol with picosecond laser.

Figure 2 shows a treatment-resistant high-density ink tattoo with minor fading after two conventional laser sessions despite combining picosecond and fractional CO₂ lasers. The tattoo showed a remarkable response to treatment following the reinforced protocol.

Dermoscopy images show how the shock waves effectively removed the vacuoles generated by the laser treatment (i.e., whitening effect) and progressively cleared ink particles in only one treatment session (Fig. 3).

No adverse effects were reported. Moreover, patients experienced less edema, erythema, and epidermal crusting compared with conventional treatments, suggesting an analgesic effect of the shock waves and faster skin healing.

Discussion

This prospective, observational, real-world, single-center study showed that adjuvant acoustic shock wave therapy enables multiple laser passes in one session, resulting in satisfactory tattoo removal in over two-thirds of patients in fewer sessions than conventional laser methods. The treatment was safe and well tolerated, with no adverse effects reported, and patients perceived accelerated healing of treated areas.

Our study showed very good results in a few treatment sessions using a protocol combining the traditional QS laser or picosecond laser with acoustic shock waves, with and without fractional CO₂ laser treatment. Adjuvant treatment with the fractional CO₂ laser in the reinforced protocol resulted in better results than the classic protocol, even on high-density ink tattoos. These observations were expected, considering the previously reported improved tattoo clearance upon combined treatment with QS lasers and fractional CO₂.^{6,7} Nevertheless, adjuvant shock wave therapy further increased the effectiveness of tattoo removal using QS and fractional CO₂ lasers, supporting the superiority of the method assessed in this study. Similarly to this study, a previous clinical trial reported good results using protocols consisting of alternating laser and shock waves for three passes per session, with a favorable safety profile.¹⁰

Acoustic shock wave therapy has been shown to increase lymphatic drainage, metabolic activity, and local blood circulation, contributing to the clearance of fragmented ink particles.^{20,24} Shock waves stimulate the production of vascular endothelial growth factor, promoting lymph angiogenesis.^{25,26} Improved clearance of fragmented ink particles helps the laser beam access target skin layers in subsequent passes, intensifying its effects. Moreover, shock waves facilitate the clearance of epidermal and dermal vacuoles, eliminating their effect on scattering the laser beam.⁸ The dermoscopy images confirmed that radial shock waves effectively cleared laser-induced vacuoles (whitening effect), allowing additional passes in the same session and enhancing pigment clearance.

Radial shockwave therapy is considered a noninvasive procedure. Adverse effects are rare and typically limited to mild, transient erythema or edema. Under the rSWT conditions used in this study, the risk of vascular damage is virtually absent, except in patients with blood coagulation disorders, which remain contraindications. The safety profile of the

TABLE 2. CHARACTERISTICS OF PATIENTS' SKIN, TATTOOS, AND TREATMENTS

	n (%)
Patients' characteristics, n = 22	
Fitzpatrick phototype	
II	5 (22.7)
III	15 (68.2)
IV	2 (9.1)
Tattoos characteristics, n = 25	
Color	
Black	23 (92.0)
Blue	1 (4.0)
Light blue	1 (4.0)
Treatment characteristics, n = 25	
Laser	
Pico	20 (80.0)
Nano	5 (20.0)
Protocol	
Classic	10 (40.0)
Reinforced	15 (60.0)
Number of sessions/tattoo (n), n = 25	
1 (not evaluable)	3
2	6
3	9
4	7
Dermoscopy	
Yes	4 (16.0)



FIG. 1. Examples of tattoos during laser removal procedures: A tattoo with good results after applying the classic protocol (A), a tattoo with good results after applying the reinforced protocol (B), and a tattoo with excellent results after applying the reinforced protocol (C).

protocols assessed in this study was satisfactory, with no adverse effects reported. Similarly to previous studies, shock wave therapy showed no associated adverse effects and produced an analgesic effect.^{10,23} Moreover, patients reported that shock wave therapy was not painful or troublesome and was almost comfortable. The application of shock waves is noninvasive, user-friendly, and well-tolerated, representing a valuable adjuvant treatment for patients undergoing laser tattoo removal. The effectiveness and tolerability of the combined treatment support its suitability for tattoo removal in multi-pass sessions.

Results from this study should be interpreted in the context of limitations associated with the measures used to evaluate tattoo fading, which were subjective. However, three people independently evaluated results to compensate for this potential bias. Additional limitations include the small sample size, which may have limited the representation of certain tattoo colors and skin phototypes. Thus, the tattoos were primarily black, and colored tattoos were therefore poorly represented in our study sample. In this regard, multi-colored tattoos may be more challenging to remove. Likewise, the study sample did not represent all skin types, with most patients being



FIG. 2. A high-density ink tattoo resistant to conventional treatments and excellent results after applying the reinforced protocol.

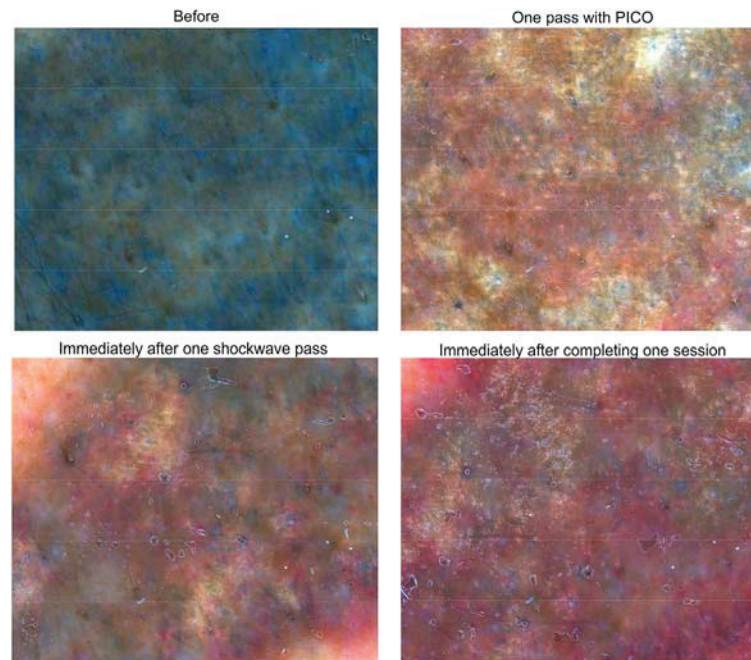


FIG. 3. Dermoscopy images showing vacuoles and ink clearance in one treatment session.

Fitzpatrick phototypes II and III. Given that laser tattoo removal in patients with darker skin color (Fitzpatrick phototypes V and VI) may result in hypo- or depigmentation, further studies including this patient profile are needed to investigate this undesired effect upon combined treatment.⁴ Moreover, melanin may interfere with laser penetration, decreasing treatment effectiveness.⁴ Future studies may include a larger sample size to ensure representation of different tattoo colors and skin phototypes. Despite these limitations, this study provided valuable, real-world evidence for acoustic shock wave therapy as an adjuvant treatment to laser tattoo removal regarding its suitability for multi-pass sessions and accelerating tattoo removal. The need for fewer tattoo removal sessions represents an advantage for patients, who may avoid lengthy and expensive tattoo removal treatments.

Conclusions

Acoustic shock wave therapy was a safe and effective adjuvant treatment to accelerate tattoo removal procedures based on laser treatments in this real-world cohort. Future studies with larger and more diverse populations are warranted to optimize these combined protocols, confirm long-term outcomes, and assess results in multicolored tattoos.

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Authors' Contributions

G.S. contributed to conceptualization, data curation, formal analysis, investigation, methodology, project administration, resources, validation, visualization, and writing—review and editing.

Consent for Publication

All subjects enrolled in the study have given their consent to publish the results for scientific and research purposes.

Data Sharing Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Disclosure Statement

The only conflict of interest to declare is that Zimmer-Italy provided the GENTLE Pro[®] shock waves system equipment free of charge to conduct the study.

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