

## Editor's Choice

# Increased Tattoo Fading in a Single Laser Tattoo Removal Session Enabled by a Rapid Acoustic Pulse Device: A Prospective Clinical Trial

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**Background and Objectives:** The ability to provide improved tattoo fading using multiple laser passes in a single office laser tattoo removal session is limited. In part, this is due to the loss of laser effectiveness caused by epidermal and dermal vacuole “whitening” generated during the initial laser pass at the tattoo site. The Rapid Acoustic Pulse (RAP) device generates acoustic shock wave pulses that clear epidermal and dermal vacuoles to enable multiple laser passes in a single office laser tattoo removal session. The objectives of this study were to determine if the RAP device, when used as an accessory to the 1064 nm Nd:YAG Q-switched (QS) laser can enable delivery of multiple laser passes in a single office laser tattoo removal session, and therefore result in increased tattoo fading compared to the clinical standard single-pass QS laser tattoo removal session.

**Study Design/Materials and Methods:** The RAP device was evaluated in a single-center (SkinCare Physicians), prospective, IRB approved study. A total of 32 black ink tattoos, from 21 participants, were divided into three zones and treated with either multiple QS laser passes, each followed by 1 minute of RAP device application (Laser + RAP) in zone one and single-pass QS laser treatment (Laser-Only) in zone two, separated by an untreated control zone. The treatment sites were assessed for the number of laser passes and adverse events immediately, 6 weeks, and 12 weeks following the treatment session. Photographs of the treatment sites were assessed for percent fading at 12 weeks post-treatment by three blinded reviewers.

**Results:** When the RAP device was applied as an accessory to the QS laser in a multi-pass laser tattoo removal treatment, an average of 4.2 laser passes were delivered in a single session, with no unexpected or serious RAP device-related adverse events. At the 12-week follow-up, tattoos treated with Laser + RAP showed a statistically significant increase in average fading (44.2%) compared with tattoos treated with Laser-Only (24.8%) ( $P < 0.01$ ). Additionally, a significantly higher overall proportion of tattoos treated with Laser + RAP (37.5%) had a response of >50% fading compared with

tattoos treated with QS Laser-Only (9.4%) ( $P < 0.01$ ) as well as a response of >75% fading from Laser + RAP treatment (21.9%) compared with Laser-Only treatment (3.1%) ( $P < 0.05$ ).

**Conclusions:** The RAP device, applied as an accessory to the 1064 nm Nd:YAG QS laser, safely enables multiple QS laser treatments in a single office laser tattoo removal session by clearing the whitening caused by the previous QS laser pass. Enabling multiple QS laser passes results in a statistically significant increase in tattoo fading in a single office laser tattoo removal session compared to the clinical standard single-pass QS laser tattoo removal session. © 2019 The Authors. *Lasers in Surgery and Medicine* Published by Wiley Periodicals, Inc.

**Key words:** tattoo removal; Q-switched laser; acoustic pulse; acoustic shock wave

## INTRODUCTION

The number of people with tattoos has grown steadily in recent years, as has the demand for tattoo removal [1,2]. The most common method for removal is the use of a short-pulse, high fluence laser such as a 1064 nm Nd:YAG Q-switched (QS) laser [3]. The QS laser has a limited ability to affect the tattoo ink pigment particles in each treatment session due to shielding of the pigment

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**Conflict of Interest Disclosures:** All authors have completed and submitted the ICMJE Form for Disclosures of Potential Conflicts of Interest and none were reported.

**Ethical approval:** This human clinical trial was prospectively registered on clinicaltrials.gov identifier NCT02877667.

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Fig. 1. Single-pass laser “whitening” (left), untreated black tattoo (right).

particles caused by both the agglomeration of the pigment particles and laser-induced epidermal and dermal vacuoles known as “whitening” [4,5] (Fig. 1). Following single-pass laser treatment of the tattoo, the resulting laser-induced epidermal and dermal vacuoles inhibit any additional passes of the laser from effectively reaching the tattoo pigment agglomerations due to optical scattering [4]. As a result, use of the QS laser often requires 10 or more single-pass office sessions to achieve acceptable fading results [6].

To improve the efficacy of current tattoo removal techniques and reduce the number of office sessions required to achieve tattoo removal success, methods have been introduced to use multiple laser passes in a single treatment session (multi-pass laser treatments). One published approach is the R20 Method [7], which involves facilitating up to four laser passes in a single session by waiting for approximately 20 minutes between passes to let the laser-induced epidermal vacuoles naturally subside [8]. More recently, to overcome the time required to perform the R20 Method, a silicone dressing that contains perfluorodecalin (PFD) (Describe<sup>®</sup> Transparent PFD Patch; Merz, Raleigh, NC) has been introduced. According to one published report, the first mechanism of action of the PFD Patch is the direct absorption of the gas from the bubbles that comprise epidermal whitening [9]. This permits repeated passes of a 755 nm QS Alexandrite laser.



Fig. 2. The Rapid Acoustic Pulse device components.

In a series of animal studies (unpublished data) undergoing laser tattoo-removal treatment sessions, laser-induced vacuole whitening was not only formed in the epidermis (targeted by the R20 method or PFD Patch), but also in the dermis directly above dermal ink pigment clusters at depths up to 2 mm. These dermal vacuoles persist up to 48 hours post-treatment, and shield the remaining dermal ink underneath from being reached by additional laser passes. An effective modality that would meaningfully reduce the number of treatment sessions would be valuable to both patients and clinicians.

The Rapid Acoustic Pulse (RAP) Device (Soliton, Inc., Houston, TX) is an accessory to the QS laser designed to enable multi-pass laser tattoo removal treatments on the arms, legs, and torso in Fitzpatrick Skin Type I–III individuals. The RAP device uses repeated acoustic shock waves with rapidly rising pressure pulses to both disrupt pigment laden cells (i.e., macrophages and fibroblasts), and importantly, provide clearing of both the epidermal and dermal vacuoles generated during the prior laser pass [4]. The RAP device produces acoustic shock waves through electrohydraulic (EH) discharge at a rate of 100 Hz. In prior unpublished experiments in a porcine model, histologic evaluation demonstrated optimal clearance of epidermal and dermal vacuoles at a rate of 100 Hz (vs. 25 and 50 Hz). The RAP device is composed of three parts: the Console, the Hand Piece and a disposable Cartridge (Fig. 2). The Console houses the power supply used to provide high voltage to the electrodes that are housed in the Cartridge, which can be replaced when the electrodes wear out. Additionally, the Console contains a fluid management system that circulates saline through the Cartridge for cooling. The Cartridge is snapped in and out of the Hand Piece for quick replacement.

Other acoustic pulse devices on the market are often known as Extracorporeal Shock Wave Therapy (ESWT) devices similar to kidney stone lithotripsy devices. These often have reflectors that focus the pressure pulse into small areas about 2–3 mm in diameter at very high pressures, with risk for adjacent tissue damage and pain [10]. Other similar devices, often considered Therapeutic Massagers, usually have slow pressure rise times, low peak pressures, and relatively low pulse rates of 10–20 per second.

In comparison, the RAP device generates planar acoustic shock wave pulses across the entire 1.3 inch diameter treatment window allowing treatment of larger areas at once, using a fast pulse rate of 100 per second, resulting in shorter treatment times. Additionally, the RAP pulses are very short in duration (100–200 nanoseconds) with fast rise and fall times to relatively high peak pressures and minimal negative pressures (some other devices have large negative pressures during each pulse cycle that cause cavitation bubbles resulting in pain [10]). This combination allows fast and efficient dispersion of whitening vacuoles and ink particles without discomfort or adjacent tissue damage. Figure 3 shows the Hand Piece in use during application in a Laser + RAP tattoo removal session. With RAP vacuole clearing, the loss of laser



Fig. 3. Hand Piece of Rapid Acoustic Pulse device being applied for 1 minute after a laser tattoo removal treatment to dissipate the laser whitening and allow an additional laser pass.

efficacy due to optical scattering is minimized, which should result in more effective multi-pass QS laser tattoo removal in a single office treatment session (Fig. 4).

The objectives of this study were to determine if the RAP device, when applied as an accessory to the 1064 nm QS Nd:YAG laser (MedLite IV; Cynosure, Westford, MA), could enable the safe delivery of multiple QS laser passes in a single office laser tattoo removal session, and therefore result in increased tattoo fading during one office tattoo removal session compared with the clinical standard single-pass QS laser tattoo removal session. There was no intent within this study to completely remove a tattoo.

## MATERIALS AND METHODS

The RAP device was evaluated in a single-center (SkinCare Physicians, Chestnut Hill, MA), prospective study. The use of the investigational device had been determined by the overseeing Institutional Review Board (Quorum Review IRB, Seattle, WA) to present a non-significant risk in accordance with 21 CFR 812.3 for the intended use in this study. The study also conformed to US Federal Policy for the Protection of Human Subjects.

Inclusion criteria for study participants included healthy individuals between the ages of 22 to 65 with Fitzpatrick skin type I to III, having at least one tattoo

that met the following criteria: black ink only tattoo located on arms, legs, and torso measuring approximately 1" × 3" with at least 30–50% of the treatment area containing black tattoo ink. Of note, other ink colors were permitted, but the areas of black ink within the tattoo had to meet inclusion criteria. All tattoos must have been professionally applied. Selected exclusion criteria for the participants included: pregnancy or plans to become pregnant during the duration of the study, past medical history of immune deficiency or other condition affecting wound healing, an electronic, metal, or plastic implant in the area of the tattoo site, prior tattoo removal procedures performed at the site, or history of excessive tanning at the tattoo site.

Treatments were administered during a single office laser tattoo removal session following completion of screening, enrollment, and obtaining informed consent from each participant. All participants received a follow-up phone call 5 days post-treatment, and were clinically followed at 6 and 12 weeks post-treatment for serial photographs and evaluation of adverse events (AEs) at the tattoo site.

Each tattoo was divided into three approximately equal areas including: a clinical standard single QS laser pass treatment area (Laser-Only), a multiple QS laser pass tattoo removal treatment area utilizing a minimum of three consecutive laser passes alternating with one minute of pulsed acoustic shock wave applications from the RAP device (Laser + RAP), separated by an untreated middle zone. The middle area between the treated areas remained untreated to avoid overlap between the treatment zones and to provide a visual control site for side-by-side comparison of untreated versus treated tattoo (Fig. 5). The Laser + RAP area was treated first to avoid the possibility of the RAP device affecting the Laser-Only treated area due to the proximity of the two areas. No RAP device application was administered after the final laser pass. Each RAP device application was delivered for one minute, however, if the investigator felt that the whitening was insufficiently cleared, an additional one minute of RAP device treatment was delivered.

Lidocaine HCl 1% with or without epinephrine 1:100,000 was injected at all treatment sites prior to any laser treatments. Due to the wide variation in tattoos resulting from different ink composition, application technique, tattoo age, and skin type, all QS laser passes were optimized before treatment delivery to both the Laser + RAP and the Laser-Only areas. This was done using "test spots" in the corner of the tattoo while



Fig. 4. (A) Pre-treatment, (B) laser whitening, and (C) whitening resolved by 1 minute of Rapid Acoustic Pulse application.

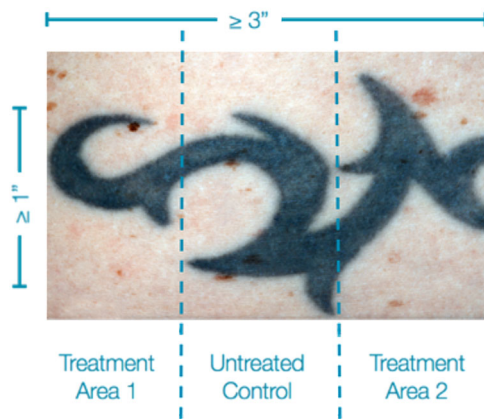


Fig. 5. Example of a suitable tattoo treatment area layout within a tattoo.

adjusting the laser spot size and fluence settings. Sufficient fluence for tattoo removal was indicated by epidermal whitening without clinically apparent blister formation or spot bleeding, and/or an audible “snap” caused by laser energy absorption by the tattoo ink. For the Laser + RAP treatments, laser fluence was increased, and when necessary, spot size was decreased and the laser was again tested on a test spot until each successive laser pass was optimized to account for the reduced amount of ink in the tattoo and the amount of whitening clearance accomplished by the RAP application. Spot size and fluence adjustment with spot testing was repeated before each subsequent Laser + RAP laser pass until there was no noticeable whitening or snap, at which time, the procedure was complete. The spot size and fluence of each laser pass as well as the number of laser passes performed during the Laser + RAP treatment were recorded. To allow sufficient heat dissipation during laser treatment delivery, a pulse rate of 1 Hz was used. In order to further remove heat buildup from subsequent QS laser passes, the skin was cooled with forced chilled air throughout the QS laser treatments using a Cryo 6 chiller (Zimmer Aesthetics, Irvine CA).

High-intensity acoustic shock waves are generated by the RAP device when an electric potential is applied for 100 to 200 nanoseconds across electrodes immersed in circulating saline contained in the Cartridge enclosure. When an arc discharges between the electrodes, a plasma and gas bubble rapidly expands and then contracts creating an acoustic shock wave that propagates through the saline and is reflected off the paraboloid acoustic reflector of the Cartridge as a single planar wave front that passes through the Cartridge’s acoustically transparent window at a rate of 100 times per second at an average peak pulse pressure ranging from 1 to 5 MPa. The outer surface of the window is coupled to the skin with an ultrasound hydrogel pad (2nd Skin Moist Burn Pads; Spenco, Waco TX) allowing the acoustic shock wave front to penetrate the skin to a depth of about 3 mm, which corresponds with the greatest typical depth of tattoo ink

[11]. The 1-mm thick hydrogel pad also aids in cooling the skin during QS laser treatment by thermal conduction, to reduce the potential for thermal damage as well as to suppress laser plume and smoke.

Assessment for safety and AEs were made by the investigators after the treatment session and at each follow-up. All AEs were followed to resolution. Photographs were obtained prior to treatment, and at the 6- and 12-week follow-up visits using non-polarized flash and cross-polarized flash images (Nikon D610 with 60 mm Micro Nikkor lens; Nikon USA, Melville NY, and custom fabricated flash polarizer). Assessment of the percentage fading for each Laser + RAP and Laser-Only treated tattoo was conducted by visual examination of the photographs. The 12-week post-treatment follow-up session photographs were compared to those from the start of the study as well as the untreated control site by three reviewers, unaffiliated with the study, who were blinded to the treatment received. The amount of fading was recorded as a percentage (0–100%) and subsequently converted to the following 1–5 point scale and response grading: 1 = 0% (poor); 2 = 1–25% (fair); 3 = 26–50% (good); 4 = 51–75% (very good); 5 = 76–100% (excellent).

Statistical analysis of the data collected during this study were presented using descriptive statistics. Analysis of before and after treatment differences of tattoo fading was performed with Student’s *t* tests using the statistical software R (R Foundation for Statistical Computing, Vienna, Austria). *P* values < 0.05 were considered statistically significant.

## RESULTS

A total of 22 participants with 34 professionally applied tattoos met all inclusion and exclusion criteria and were enrolled. A total of 32 tattoos were evaluated through the final follow-up visit, as one participant with two tattoos was lost to follow-up. In three participants, a large tattoo was divided into two separate tattoo sites, and eight participants had more than one distinct tattoo treated. Of the participants, 19 were female and 3 were male (age range: 23–58). Only skin types I–III were enrolled.

Laser treatment parameters for the Laser + RAP sites included an average laser spot size of 4.1 mm (range: 4–8 mm). The average laser fluence used was 5.22 J/cm<sup>2</sup> (range 1.5–8.3 J/cm<sup>2</sup>). At the Laser-Only treated sites, a single laser pass was administered using a laser spot size of 4 mm at an average laser fluence of 3.9 J/cm<sup>2</sup> (range: 3.0–4.6 J/cm<sup>2</sup>). The average number of delivered laser passes at all Laser + RAP sites was 4.16 with a minimum 3 and a maximum of 5 passes delivered. Post-laser treatment reactions included erythema, edema, and crusting, and all were reported as mild or moderate. No unexpected or severe adverse events were identified, and no RAP device-related adverse events occurred.

Comparative analysis of tattoo fading for each pair of treated areas of the tattoos showed that 93.8% (30/32) of the Laser + RAP treated sides of the tattoos had greater fading than the Laser-Only treated side. One pair had

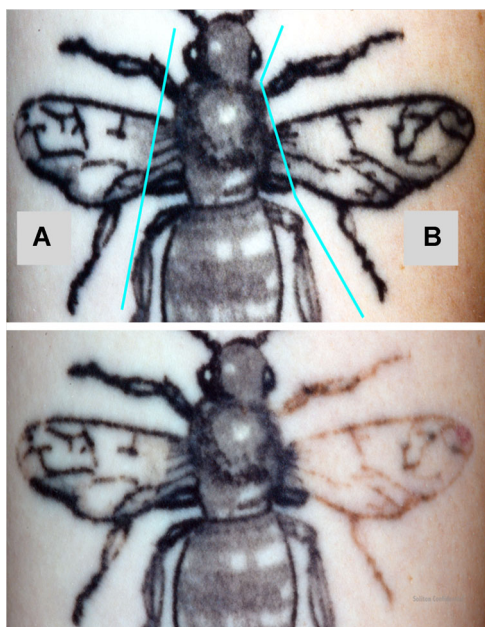


Fig. 6. Before treatment (top picture) and 12 weeks after treatment (bottom picture). (A) Laser-Only and (B) Laser + RAP. RAP, Rapid Acoustic Pulse.

equivalent fading and one Laser + RAP treated tattoo had less fading than that of the Laser-Only treated tattoo (5% fading vs. 7% fading). Representative cross-polarized flash photographs of three participant's tattoo before treatment and 12 weeks after one treatment session are shown in Figures 6–8.

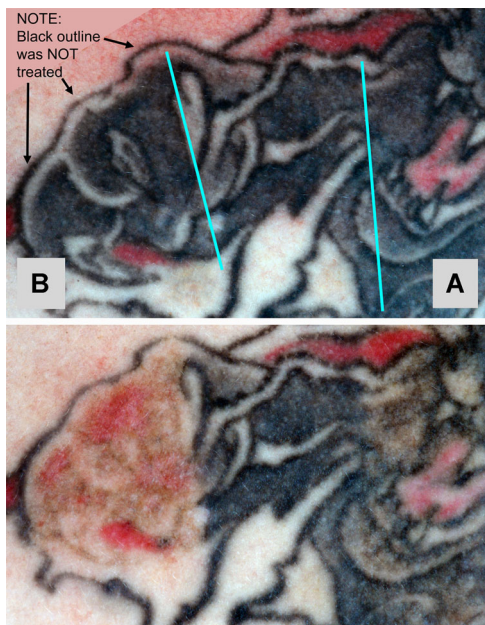


Fig. 7. Before treatment (top picture) and 12 weeks after treatment (bottom picture). (A) Laser-Only and (B) Laser + RAP. Tattoo “outline” of paw not treated with Laser + RAP. RAP, Rapid Acoustic Pulse.



Fig. 8. Before treatment (top picture) and 12 weeks after treatment (bottom picture). (A) Laser-Only and (B) Laser + RAP. RAP, Rapid Acoustic Pulse.

Overall, a significantly higher number of tattoos in the Laser + RAP group (37.5%) achieved greater than 50% fading after a single office laser tattoo removal session compared to the Laser-Only (9.4%) group ( $P < 0.01$ ). Similarly, a significantly higher proportion of tattoos in the Laser + RAP group (21.9%) achieved greater than 75% fading compared with the Laser-Only group (3.1%) ( $P < 0.05$ ) (Fig. 9).

Averaged blinded assessment of percent fading by three independent dermatologists of all 32 tattoos assessed is shown in Figure 10. Overall, there was increased fading of tattoo sites treated with Laser + RAP with 22/32 (69%) scored as 3, 4, or 5 vs. 10/32 (31%) scoring 1 or 2; compared

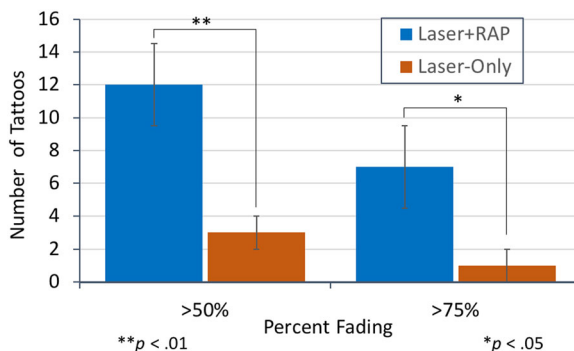


Fig. 9. Tattoo fading distribution at 12 weeks post-treatment in a single office laser tattoo removal session. Tattoos treated with Laser + RAP achieved higher percentages of fading than Laser-Only treated tattoos. RAP, Rapid Acoustic Pulse.

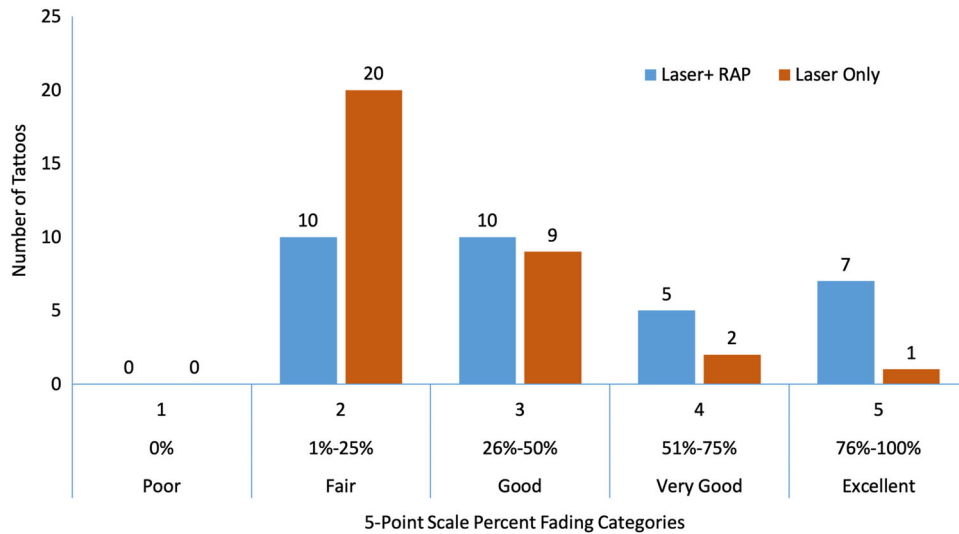


Fig. 10. The number of tattoos that were greater than 50% faded from a single office laser tattoo removal session was significantly greater for Laser+RAP than for Laser-Only with  $t=2.77$  ( $df=50.87$ ,  $P<0.01$ ), and the number that were greater than 75% faded was significantly greater for Laser+RAP than for Laser-Only with  $t=2.33$  ( $df=41.65$ ,  $P<0.05$ ). RAP, Rapid Acoustic Pulse.

with tattoos treated with Laser-Only with 12/32 (38%) scored as 3, 4, or 5 vs. 20/32 (63%) scoring 1 or 2.

Average percent fading for Laser+RAP (44.2%) and Laser-Only (24.8%) treated tattoo sites are shown in Figure 11, overlaid with a scatterplot of the actual percent fading value for each of the 32 study tattoos. Laser+RAP was associated with significantly greater tattoo fading compared with Laser-Only treatment ( $P<0.01$ ).

## DISCUSSION

During the tattoo application process, tattoo ink pigment particles are driven into the dermis by

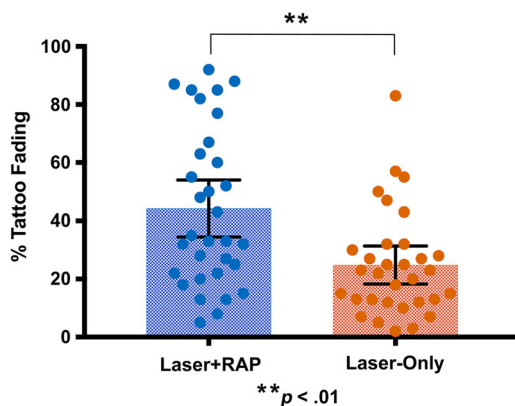


Fig. 11. Average percent tattoo fading scores from three blinded reviewers 12 weeks after a single office laser tattoo removal session (shown as columns) overlaid with scatter plots of the average percent fading for each tattoo evaluated. Laser+RAP was associated with significantly greater tattoo fading than Laser-Only with  $t=3.38$  ( $df=54.30$ ,  $P<0.01$ ). RAP, Rapid Acoustic Pulse.

reciprocating needles, and these particles are then phagocytized by dermal resident macrophages. After the skin has healed, these “pigment laden macrophages” (PLMs) permanently reside in the dermis and remain visible through the epidermis. In order to remove an established tattoo, one must disrupt the PLMs and break down the size of the pigment particles. This is currently accomplished by irradiating the tattoo with high fluence lasers. The QS laser energy is differentially absorbed by dark pigment leading to disruption of the PLM’s cell membrane, and fragmentation of the pigment particles [12]. Laser irradiation and consequent heating of the pigment particles lead to the generation of gas vapor and steam bubble expansion resulting in epidermal and dermal vacuoles (i.e., whitening) [4]. The formation of these vacuoles scatters the laser light so that insufficient laser energy reaches the pigment particles (laser shielding) after the initial laser pulse absorption. As a result, performing multi-pass laser treatments on tattoos in a single session is largely ineffectual [4].

This study confirms the feasibility of using the RAP device to enable safe multi-pass QS laser treatments in a single office laser tattoo removal session. The observed mean number of laser passes in the Laser+RAP treated participants was 4.16. The RAP induced clearance of the epidermal and dermal vacuoles allowed the use of smaller spot sizes and higher fluences to irradiate the remaining tattoo particles with each subsequent pass. Earlier animal studies by the authors (unpublished data) showed that use of the RAP device alone resulted in disruption of the PLMs and dispersal of the released ink particles. The dispersed particles are more exposed to a subsequent laser pass by having less “self-shielding” than clustered

ink particles would have. It is believed that in addition to the ability to deliver multiple passes in a single treatment session, ink particle dispersal further augments RAP's ability to increase tattoo fading during multi-pass laser tattoo removal.

Multi-pass QS laser treatment in a single session will of course deposit more heat energy into the skin than a standard single-pass procedure. It is therefore important to use as much skin surface cooling as possible. The 2nd Skin hydrogel comprises about 95% water, which provides much better cooling of the skin surface than room air [13] and water has little absorption of the 1064 nm wavelength of the QS laser [14]. While there is some reflection and scattering of the laser from the gel surface, the small loss was not an issue as the fluence and spot size of all laser passes for both Laser + RAP and Laser-Only passes were optimized before each treatment for whitening production on a test spot, and then both sites were treated by passing the laser through the hydrogel pad as described in the Materials and Methods section.

This study was limited to the use of the 1064 nm QS laser on black ink tattoos in a limited range of Fitzpatrick skin types I–III. Further clinical studies will be performed to investigate the broader applicability of the RAP device as an accessory device to reduce the number of laser tattoo removal sessions for other tattoo ink colors in a broader range of skin types. This study was also limited to Fitzpatrick skin types I–III to exclude possible confounding effects resulting from an increase in adverse events such as hyper- or hypopigmentation during laser tattoo removal treatments in skins of color due to increased epidermal melanin content [15]. While there are no differences in the effects of the RAP device in skins of color, future studies in Fitzpatrick skin types IV–VI will limit the laser fluence and/or number of laser passes used for multi-pass laser tattoo removals due to the increased melanin content in these skin types.

Preliminary results from treating colors other than black in a porcine tattoo model have shown that the RAP device will clear vacuoles caused by other wavelength lasers that produce whitening on interaction with a complementary ink in the same way it clears whitening caused by the use of a QS laser on black ink. We, therefore, believe resolution of the whitening in the laser treatment of any color tattoo ink should allow additional laser passes in a single treatment session and lead to increased fading, as has been shown for black ink tattoos in this trial. Future clinical trials will be required to verify this hypothesis.

## CONCLUSION

The RAP device, applied as an accessory to the 1064 nm Nd:YAG QS laser, safely enables multiple QS laser treatments in a single office laser tattoo removal session by clearing the whitening caused by the previous QS laser pass. Enabling multiple QS laser passes results in a

statistically significant increase in tattoo fading from a single office laser tattoo removal session compared to the clinical standard single-pass QS laser tattoo removal session. As a result, a lower total number of office visits will likely be required for complete tattoo removal leading to improved convenience and efficiency as well as increased satisfaction for both patients and clinicians.

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