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Clinical Report

Photodamage Therapy Using an Electro-Optic Q-Switched Nd:YAG Laser

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Background and Objective: Q-Switched Nd:YAG lasers produce photoacoustic effects in addition to photothermal effects which may allow for greater tissue collagen production. The objective of the study is to determine the effectiveness and tolerability of an Electro-Optic (EO) Q-switched Nd:YAG laser with Single Pulse and novel Double Pulse (DP) options in the treatment of photodamaged skin.

Materials and Methods: Sixteen subjects with photoaging were enrolled in this prospective, randomized, split-faced study. Subjects received 6 bi-weekly laser treatments. One half of the face was treated with a Single Pulse while the other half was treated with energies divided into a DP. Blinded investigators and subjects assessed improvement after the sixth treatment for wrinkles, coarseness, pigmentation, redness, laxity, comedones, pore size, and overall skin condition. Subjects also rated the tolerability of the treatments.

Results: For the Single Pulse side of the face, the investigators rated 33% of the patients as having a good to excellent (51% or greater) improvement in the overall condition of the skin while 47% of the subjects reported these levels. On the DP side, the overall improvement was good to excellent at a 27% rate by the investigators and 54% by the subjects. Distributions of improved ratings among investigators and subjects were similar for both sides of the treatment area. The majority of stinging/burning sensations during treatment were reported as mild on the DP side (62.8%) and moderate (63.8%) on the Single Pulse side. The chance of reporting none or only mild stinging/burning sensation during treatment was four times greater on the side of the face treated with the DP ($P<0.0001$).

Conclusions: Results have shown that treatment with the EO QS Nd:YAG laser provides a safe and effective method of skin rejuvenation with the additional benefit of significantly lower patient discomfort during use of the DP mode. Lasers Surg. Med. 42:699–705, 2010.
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Key words: collagen remodeling; non-ablative laser therapy; photorejuvenation; photoacoustic; photothermal

INTRODUCTION

Clinical signs of photoaging include coarse skin texture, irregular pigmentation, and laxity of skin tone, as well as the appearance of fine lines and wrinkles. The clinician has a variety of laser choices for the treatment of photodamage. A laser approach which was commonly used is laser skin resurfacing with a CO_2 or Erbium laser. The clinical improvement achieved is, at times, significant, however, it can be associated with an extended recuperation period and an increased risk of side effects including persistent pigmentary changes and scarring. As such, investigation and development into other laser approaches and technologies for the treatment of photoaging continues to be a significant challenge. Fractional non-ablative and ablative laser therapy has produced clinical benefit with a reduction in both immediate and long-term side effects [1–5]. There still remains the potential for procedural discomfort and significant immediate post-procedural erythema and edema even with the non-ablative systems. The ablative fractional systems have in addition greater pain and post-operative exudation. These systems also are associated

Conflict of Interest: Laser made available by manufacturer for the study.

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with persistent erythema, prolonged hyperpigmentation and scarring.

Non-ablative, non-fractional laser procedures, as with the non-ablative, fractional approaches, induce a mainly dermal healing action with relative sparing of the epidermis. Although the typical response to this type of treatment is modest clinical improvement in mild to moderate facial rhytides, non-ablative therapy has gained in popularity over the past few years for photoaging therapy because of its little to no downtime. Laser systems which have been traditionally used for this approach rely on thermal induction for tissue change. Introduction of Q-switched laser systems have added a photoacoustic element to the dermal response. The Q-switched Nd:YAG laser has been shown to improve photodamage changes [6]. With this laser system, relatively lower laser energies are needed resulting in mild immediate side effects. We wish to report the use of an Electo-Optic (EO) Q-switched Nd:YAG laser with both a Standard Single Pulse (SSP) and a novel Double Pulse (DP) mode for the treatment of facial photodamage changes.

METHODS

Subjects

As shown in Table 1 below, 16 subjects (13 female and 3 male) were enrolled in this IRB-approved study at three sites. Patients ranged in age from 31 to 68 years, with an average age of 51 and all had visible evidence of photodamage. Patients agreed to refrain from other laser or intense pulsed light (IPL) treatment, microdermabrasion or chemical peels for the duration of the study. Those patients using photosensitizing drugs, topical retinoids/retinol within 4 months or oral retinoids within 6 months, or who had undergone laser/IPL treatments, microdermabrasion or chemical peels within 4 months and those patients with type I or II diabetes were excluded from participation in the study. All subjects gave informed consent for treatment and photographs.

Treatment Protocol

Subjects in this prospective, randomized, split-face study received a total of six laser treatments, one treatment every 2 weeks. The study was designed to evaluate the amount of visible improvement in photodamaged skin after laser treatment, and to compare clinical improvement and tolerability between the SSP mode and the DP mode of the laser. The entire face was treated at each session: half of the face received treatment in the SSP mode, and half of the face received treatment with the DP option. Subjects were randomized as to the side of the face to be treated with the DP option, as well as to the order of treatment (left to right vs. right to left).

TABLE 1. Subject Baseline Characteristics ($N = 16$)

Average age (range) years	51 (31–68)
Female %	72%
Skin type	
I	31%
II	44%
III	25%
Not reported = 1	
Wrinkle class	
I	19%
II	44%
III	31%
Not reported = 1	

In the Single Pulse mode, treatment parameters were set at 1,064-nm, 10 Hz, 6 mm spot size at an average of 3.2 J/cm^2, 2–3 passes, at a pulse duration of 5–7 nanoseconds. In the DP mode, the two pulses were delivered automatically consecutively in <0.3 milliseconds, with each pulse remaining at a 5–7 nanoseconds pulse duration. The complete energy density was distributed within the two pulses. The first 12 subjects received treatment with an 8 mm spot size, with other parameters being identical to the Single Pulse mode. The last four subjects enrolled in this study received treatment in the DP mode with a 6 mm spot size at an average of 5.7 J/cm^2. All other parameters remained constant. Male subjects were allowed to opt out of treatment in the beard area to avoid potential hair loss. Some investigators used topical anesthesia on the entire face pre-treatment. Subjects were provided with verbal and written post-treatment skin care instructions to gently clean the skin with warm water and a mild cleanser no more than 2–3 times a day, to use oil-free, water-based, non-comedogenic cosmetics and moisturizers, to remove cosmetics at night and to apply an oil-free sun block with an SPF of 30 or higher on a daily basis.

Photographs were taken pre- and post-treatment. Patients and investigators who were blinded to the randomization assignment and were not involved in the performance of the laser treatments were asked to complete a questionnaire that assigned a percentage of improvement for the following clinical criteria: wrinkles, coarseness of skin texture, irregular pigmentation, facial redness, skin laxity, closed and open comedones and the appearance of pore size. Blinded investigators compared photographs to assess the percentage of improvement. Each study center had a blinded evaluator. The post-treatment improvement scale assigned the percentages as follows: 0% = no improvement, 1–25% = poor improvement, 26–50% = fair improvement, 51–75% = good improvement, $>76\%$ = excellent improvement. Assessments of improvement were completed immediately after Treatment 6. Subjects were asked to record the amount of downtime they experienced after each treatment, as well as the tolerability of the SSP and DP modes of treatment. In those patients who did not receive topical pre-treatment anesthesia, stinging/burning sensations were recorded on a 4-point scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe. After each half of the treatment was performed, treating investigators were asked to record the effects of the treatment with regard to any erythema, scaling/dryness, edema, or blistering. These effects of treatment were judged on a 5 point scale: 0 = none, 1 = minor, 2 = mild, 3 = moderate, 4 = severe.

Binomial outcomes were assessed using chi-square statistical tests of the hypothesis that the response rates

TABLE 2. Investigator Assessed Improvement at Last Treatment ($N = 15$) for SSP Side

	SP									
Investigator assessment at last treatment ($N = 15$)	Total	Rating 4: excellent, >75% improvement		Rating 3: good, 51–75% improvement		Rating 2: fair, 26–50% improvement		Rating 1: minimal, <25% improvement		No improvement	
	N	N	%	N	%	N	%	N	%	N	%
Amount of wrinkles	14	0	0	2	14	8	57	4	29	0	0
Wrinkle depth	15	0	0	2	13	6	40	7	47	0	0
Skin texture	15	0	0	6	27	4	40	6	27	1	7
Pigmentation	15	0	0	4	27	5	33	3	20	3	20
Redness	15	0	0	2	13	4	27	5	33	4	27
Laxity	15	1	7	1	7	4	27	8	53	1	7
Pores	15	0	0	3	20	5	33	5	33	2	13
Closed comedones	12	1	8	0	0	1	8	6	50	4	33
Open comedones	12	1	8	0	0	0	0	6	50	5	42
Overall skin condition	15	0	0	5	33	5	33	5	33	0	0

are the same in each sample category. If the assumptions associated with the chi-square distribution were not met, the non-parametric median test was employed to test the null hypothesis that the medians of the populations from which two samples were drawn were identical. Univariate analysis with Fisher's Exact t-test was employed to analyze dichotomous outcomes such as the procedural and safety endpoints. Polynomial and ordinal outcomes were assessed in a logistic regression environment using cumulative logits in a proportional odds model. Correction for continuity and exact probabilities were computed where appropriate. Significance levels were set 0.05 for all tests.

RESULTS

Of the 16 enrolled subjects, 1 subject withdrew from the study after the completion of 4 laser treatments. Fifteen subjects underwent the full series of six treatments, for a total of 90 treatments performed. The majority of the patients were treated during the Spring months and a few in the Fall. Nearly 200 clinical criteria assessments were made by both blinded investigators and subjects.

Blinded Investigator Assessment of Improvement

Tables 2 and 3 depict the percentage of improvement by pulse modality, as assessed by the blinded investigators after the final laser treatment. A statistically significant proportion of patients were rated having a cumulative percentage of improvement $>25\%$ ($P<0.0001$) (Figs. 1 and 2). The distributions of improved ratings among investigators were similar for both the Single Pulse and DP treated sides of the face; the probability of the investigator making an assessment of an improvement of $>25\%$ was comparable for both pulse modes.

TABLE 3. Investigator Assessed Improvement at Last Treatment ($N = 15$) for DP Side

	DP									
Investigator assessment at last treatment ($N = 15$)	Total	Rating 4: excellent, >75% improvement		Rating 3: good, 51–75% improvement		Rating 2: fair, 26–50% improvement		Rating 1: minimal, <25% improvement		No improvement	
	N	N	%	N	%	N	%	N	%	N	%
Amount of wrinkles	14	0	0	2	14	7	50	5	36	0	0
Wrinkle depth	15	0	0	1	7	6	40	8	53	0	0
Skin texture	15	1	7	2	13	7	47	4	27	1	7
Pigmentation	15	1	7	1	7	7	47	3	20	3	20
Redness	15	1	7	1	7	5	33	5	33	3	20
Laxity	15	1	7	0	0	3	20	10	67	1	7
Pores	15	2	13	1	7	4	27	6	40	2	13
Closed comedones	12	1	8	0	0	2	17	5	42	4	33
Open comedones	12	1	8	0	0	1	8	5	42	5	42
Overall skin condition	15	1	7	3	20	5	33	6	40	0	0

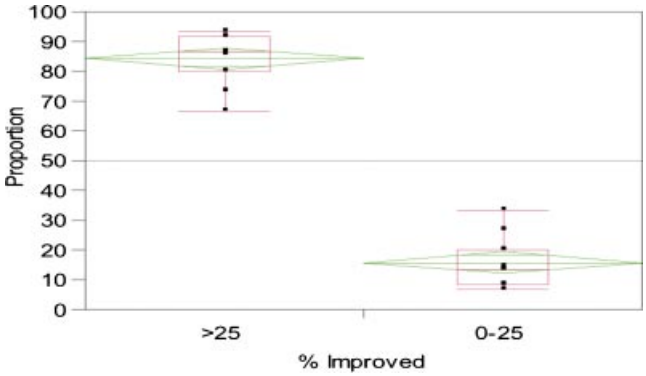


Fig. 1. Investigator assessment, one-way analysis of proportion by % improved. Independent of the pulse mode and clinical criteria, the plot above illustrates the proportion of assessments made by the investigators which estimated the percent of improvement to be $>25\%$ versus the proportion of assessments which estimated the percent of improvement to be 0–25%. The median proportions were 86.7 and 13.3 where the estimated percent of improvement was $>25\%$ versus the estimated percent of an improvement of 0–25%, respectively. The non-parametric median test resulted in a chi-square approximation of 39.0, $df=1$, $P<0.0001$. This statistic would suggest a statistically significant difference in proportions.

Subject Assessment of Improvement

Subject ratings were similar to the investigator ratings and did not differ significantly by pulse modality. Figure 3 illustrates the proportion of subjects who estimated their percent of improvement to be $>25\%$ after the final treatment, versus those who estimated their percent of improvement to be 0–25%, independent of pulse mode. The median proportions were 63.3 and 33.3 for subjects who estimated their percent of improvement to be $>25\%$ versus subjects who estimated their percent of improvement to be 0–25%, respectively. The non-parametric median test resulted in a chi-square approximation of 21.2, $df=1$, $P<0.0001$. This statistic would suggest that a significantly larger proportion of subjects scored their improvement as "Fair" or better ($>25\%$) in contrast to rating their improvement as "Poor" ($\leq 25\%$). Independent of clinical criteria and pulse modality, a statistically significant proportion of subjects rated the cumulative percentage of improvement to be $>25\%$ ($P<0.0001$) (Fig. 4a,b).

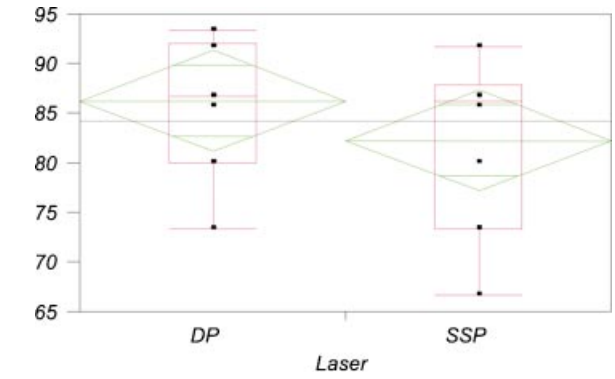


Fig. 2. Investigator assessment, one-way analysis of proportion by laser mode. Independent of condition when contrasting laser modes (Standard Single Pulse vs. Double Pulse) for the investigator assessment of improvement, it was found that the median proportion of assessment of $>25\%$ was 86.7 for the DP option and 86.7 for the SSP mode. The difference between these proportions was found to be non-significant ($P=0.568$). One could conclude that (independent of condition treated), the probability of the investigator making an assessment of improvement of $>25\%$ was comparable for both pulse modes.

Treatment Tolerability

Subject tolerability of the treatment is shown in Figure 5. Overall, the majority of stinging and burning sensations during treatment were reported as mild on the DP treated side (62.8%) and moderate (63.8%) on the SP treated side. Most subjects reported no stinging/burning sensations post-treatment (DP 69.2%, SP 74.6%). A statistically significant association was detected ($P<0.0001$), allowing the conclusion that the odds of reporting no sensation or minimal stinging/burning sensation during treatment was 4.1 (95% CI 2.2, 7.6) times greater for the side treated with the DP option as compared to the side treated in the SP mode.

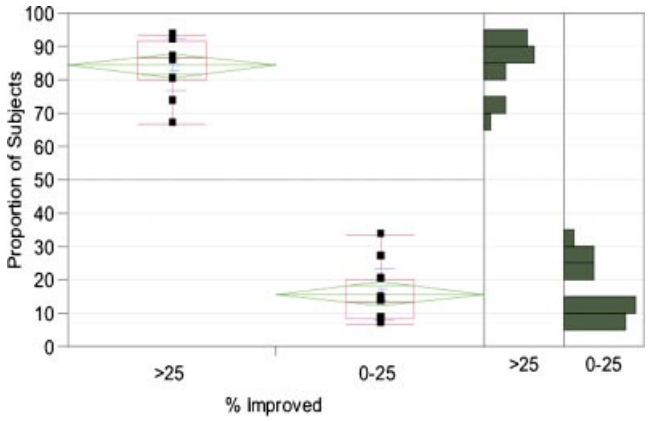


Fig. 3. Subject assessments, one-way analysis of proportion by % improved. When analyzing percent improvement as an ordinal response variable, the cumulative logits function was modeled by performing ordered logistic regression using the proportional odds model. The probability of no improvement was compared to the probability of having 1–25% improvement and the probability of having $>25\%$ improvement for both pulse modes. The proportional odd assumption was supported as a result of a non-significant score test. As a consequence, the overall odds of having a $>25\%$ improvement was 2.2 times greater than having 1–25% improvement in the DP mode ($P=0.041$). The odds of having some improvement was 6.2 times greater than having no improvement with the DP option ($P<0.0001$). When contrasting treatment modes (SP vs. DP), the probabilities of improvement were not significantly different ($P=0.980$).

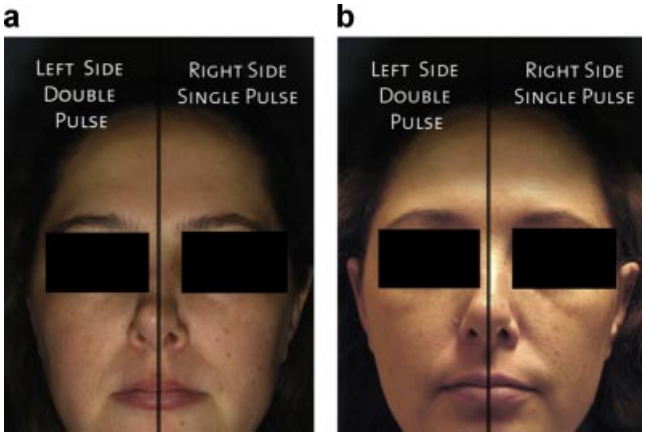
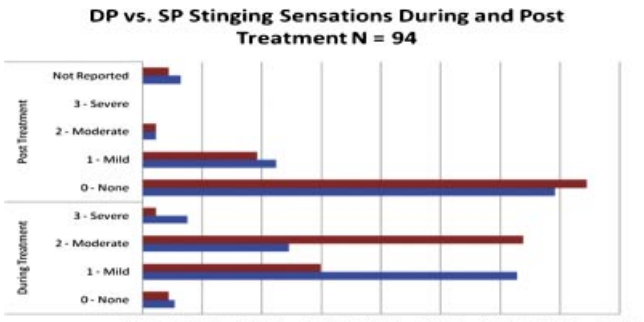


Fig. 4. **a**,**b**: Subject at baseline (a) and after 6 bi-weekly laser treatments (b). The subject rated her overall improvement as "good" on the side treated with the DP option, and as "fair" on the side treated with the Single Pulse.

Effects of Treatment

Close to 700 expected treatment effects were assessed immediately following treatment. The most prevalent effect was erythema ($n = 600$; 86%), though only once was this rated as "moderate," with the most frequent rating being "minor" (57%; $n = 344$) and another 43% ($n = 255$) of the incidents rated as "mild." Edema was reported in 8% of the cases ($n = 53$), with the majority of occurrences rated as "minor" (83%; $n = 44$). The investigators documented scaling/dryness in 20 cases and all but one incident were rated as "minor." There were no significant differences in the expected effects ratings between the SP and DP modes.



	During Treatment				Post Treatment				
	0 - None	1 - Mild	2 - Moderate	3 - Severe	0 - None	1 - Mild	2 - Moderate	3 - Severe	Not Reported
Single Pulse	4.26%	29.79%	63.83%	2.13%	74.47%	19.15%	2.13%	0.00%	4.26%
DP	5.32%	62.77%	24.47%	7.45%	69.15%	22.34%	2.13%	0.00%	6.38%

Fig. 5. Tolerability of treatment. For this analysis, outcome categories were collapsed to create 2×2 contingency table. The "none" and "mild" categories were collapsed into one category (i.e., none–mild) and the "moderate" and "severe" categories were collapsed into second outcome category (i.e., moderate–severe). This facilitated testing the null hypothesis of no association between intervention and outcome.

Adverse Events

There were three adverse events reported during this trial. Two developed an upper respiratory infection and one had an eye infection. One subject complained of pain and burning and experienced a small, first-degree burn to the right upper forehead, within minutes of the onset of the fourth laser treatment. It was later discovered that the subject did have a microdermabrasion (a procedure which the patients were advised to avoid during the study) 5 days prior to the laser treatment. The burn resolved without sequelae. There were no reports of any downtime following the laser treatments.

DISCUSSION

Non-ablative laser therapy remains a very advantageous therapeutic approach for skin rejuvenation. The potential of inducing beneficial textural and pigmentary changes to sun damaged and aged skin without the need of ablation, will result in dramatically less post-operative undesired immediate and long-term effects. Various laser and intense light systems have been used in a non-ablative approach [7–10]. These approaches have resulted in collagen production and subsequent dermal thickening with a reduction of surface textural changes. In addition, both pigmentary and erythematous changes can be improved. All of this with minor immediate post-operative effects generally limited to transient erythema and edema. Long-term undesired effects such as fibrosis, scarring, or persistent pigmentary changes have been remarkably diminished relative to ablative procedures.

Infrared non-ablative systems have included wavelengths at 980, 1,072 [7], 1,320 [8], 1,450 [9], 1,540 nm [10] and IPL broad wavelength emissions [11]. The light may be delivered in a homogenous or fractionated pattern. All accomplish their effects following chromophore light absorption by induction of thermal events producing collagen, reducing vessel caliber and correcting pigmentary content. The final clinical outcome is dependent on the absorption selectivity of the intended targets and the amount of thermal damage and tissue repair. Therefore, such parameters as wavelength and pulse duration will affect tissue response and clinical outcome.

The Nd:YAG laser at 1,064 nm has been used in a non-Q-switched long pulsed mode for non-ablative laser therapy [12–17]. Its wavelength which is absorbed by melanin and hemoglobin is not as well absorbed by water, which allows for deeper tissue penetration and thermal diffusion. Therapeutic outcome has been beneficial and in some cases better than other evaluated wavelengths. There are also reports of having an additive effect when used in combination with shorter wavelengths [14,15]. A limiting factor has been the necessary heat production. Although an important outcome of light tissue interaction, too much generated heat will induce both epidermal and dermal undesired effects. Both atrophy and fibrosis can occur while hypo- and hyperpigmentation may result. As such, epidermal cooling and long pulse durations have been instituted to protect the epidermis and limit the thermal dermal damage.

At the desired 1,064 nm wavelength, the Nd:YAG laser has been evaluated in the microsecond pulse duration range [18,19]. This shorter pulse duration has allowed for reduction in applied energy densities and with exposure monitoring, elimination of epidermal cooling. The thermal events produced by the microsecond Nd:YAG have produced collagen production and a reduction in the clinical vascular presentation.

As an Electro-Optic Q-switched apparatus, the Nd:YAG effect on the tissue produces photoacoustic events in addition to the photothermal [6,20–22]. Very high power densities contained within the 5–10 nanoseconds pulse durations of these lasers will produce tissue events including tissue repair. Also, the system evaluated in this study, introduced the capability of delivering the pulses in a Standard Single and novel DP mode.

Early pioneering work by Goldberg and Silapunt [6] in analyzing general Q-switched Nd:YAG effect on tissue response revealed a spared epidermis with improvement in solar elastosis and a mild desired thickening of the upper papillary collagen zone and organization of collagen fibrils. Later, Friedman et al. [20] elicited clinical textural improvement using a Q-switched Nd:YAG reporting mild to moderate pain with therapy and pinpoint petechiae. Both of these laser systems did not have the available pulsing of the newer system.

In a report using the Single Pulse mode of the Q-switched Nd:YAG used in this study, Lee et al. [21] studied its effect on skin rejuvenation in Asian patients with or without exogenous topical carbon solution application. They were able to demonstrate clinical improvement in several parameters but did not elicit any enhancement of efficacy using the topical carbon solution. Berlin et al. [22] used the same system in the DP mode and reported on both light and electron microscopic findings. As was found in the earlier work, evidence of wound repair with new collagen deposition was present. There was an increase in the amount and diameter of the collagen fibrils with a reduction in elastosis. It was suggested that both photoacoustic and photothermal effects contributed to the histological findings.

In this study both the SSP and DP modes were evaluated. Both had demonstrated significant clinical improvement in many categories with there being a higher number of "excellent" ($>75\%$) improvement ratings evidenced on the DP side of the treatment area. Although there is both erythema and mild edema with this Q-switched Nd:YAG laser, there were no cases of petechiae as were seen with the earlier Q-switched Nd:YAG systems. In addition, an important exhibited difference between the SSP and the DP modes is the reduction in patient discomfort during laser treatment in the DP mode. In our trial, 62.8% of subjects rated the stinging/burning sensations during treatment in the DP mode as "mild" versus the similar number (63.8%) who reported "moderate" on the Single Pulse side of the face. This significant difference may be attributable in part to lower peak powers reached with the DP mode. A similar total energy dose is divided over two pulses instead of being contained in just a single pulse.

Initially, an 8 mm spot size was used with the DP mode at similar energies as the SSP mode. With more experience with the laser system, a 6 mm spot size was initiated in a few cases with the DP mode at a compensated higher energy density. Patient tolerance was similar and there was a trend toward even higher subject-perceived improvement scores in the categories of skin laxity and amount/depth of wrinkles. The DP mode using higher energies may portend to a method which will increase effectiveness while maintaining safety. Further study is warranted.

CONCLUSION

The EO Q-Switched Nd:YAG laser has exhibited the ability to achieve clinically desirable improvement in many parameters of skin rejuvenation. Remarkably, this has occurred with a very acceptable adverse effect profile and, as importantly, patient tolerance and acceptability. The production of photoacoustic events in conjunction with photothermal effects may have contributed to the desirable clinical outcome while reducing discomfort and immediate petechiae especially with the gentler DP mode. Not only was there less discomfort with this mode but there was a trend to a better clinical outcome. It is anticipated that the EO Q-switched Nd:YAG laser may achieve even greater benefit with further study into various laser parameters, Skin Types and clinical applications such as tattoo removal, hair reduction, and vascular changes. Also, as is generally experienced with non-ablative laser therapies, over the ensuing months after therapy, there is more dermal remodeling and collagen production. As such, it is anticipated that the studied patient pool clinical outcome may improve over the next several months post-procedure.

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