ORIGINAL PAPER

UROLITHIASIS

Renal and ureteral temperatures changes during ureteroscopic pulsed thulium: YAG laser lithotripsy: an *in vitro* analysis

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Introduction Promising studies have shown a high stone-free rate achieved with the pulsed solid-state thulium YAG laser. However, studies on its safety concerning temperature effects during activation remain limited. The aim of this study was to characterize temperature variations during laser activation.

Material and methods This *in vitro* experimental study utilized a high-fidelity uretero-renal simulation model to assess temperature changes during intracorporeal laser lithotripsy. Temperatures reached after laser activation at 15, 20, and 30 seconds were recorded. The flow rates used were 10 ml/min and 20 ml/min. The maximum allowed temperature was set at 43°C, given its association with thermal tissue damage. A linear logistic regression model was used to analyze variations and project temperature behavior over time.

Results In the renal model, temperature increases were correlated with the applied energy. With a 10 ml/min flow rate, no laser configuration exceeded 43°C at 15 seconds; at 20 seconds, only the 30 W (2.5 J/20 Hz) configuration exceeded this temperature. By 30 seconds, all 30 W configurations exceeded 43°C, except for 0.4 J/75 Hz. With a 20 ml/min flow rate, no laser configuration exceeded 43°C. The 20 ml/min flow rate decreased renal temperature by 1.96°C ($p = 0.01$). In the ureteral model, the temperature increase was not proportional to the applied energy, but in no scenario the temperatures reach the 43°C.

Conclusions The temperature variations observed in this study with the use of the pulsed solid-state thulium YAG laser should be considered to avoid potential renal and ureteral thermal damage.

Key Words: radical cystectomy ‹› emergency department ‹› readmission ‹› bladder cancer

INTRODUCTION

The increasing case volume of ureteroscopy (URS), particularly flexible ureteroscopy (f-URS), over shock wave lithotripsy (SWL) globally [1] may be attributed to the widespread adoption of the Holmium:YAG (Ho:YAG) laser since its introduction for endoscopic lithotripsy in 1992 [2]. Urologists currently face fierce competition in developing superior lasers, prompting manufacturers to produce high-power devices, often without fully assessing associated risks. In recent years, newer platforms such as the Ho:YAG with pulse modulation and the thulium fiber laser (TFL) have been compared mainly based on their stone-free rates [3, 4]. However, increased power carries potential risks, including elevated temperatures during laser activation, which could impact renal and urinary tract tissues [5–7]. Recently, the new pulsed solid-state thulium YAG (p-Tm:YAG) laser has been added to the lasers already mentioned above. This laser has already shown reliable results in both *in vitro* and *in vivo* studies, proving to be effective even on hard stones [8, 9] which is likely determined by an adjustable power peak (1000–2000 W, PP) that is higher than that of the TFL (≤ 500 W). In terms of initial clinical experience with this new device, stone-free rates close to 80% have been demonstrated, placing it in a very good position compared to its competitors [10], even more it has been rated as "a safe and effective compromise between Ho:YAG laser and TFL for endoscopic lithotripsy" [11]. However, studies on its safety regarding temperature effects during its activation remain limited. In 2023, our group studied the temperature effects on the areas surrounding the activation site of the Ho:YAG laser Moses 2.0, detecting that several combinations of parameters commonly used could exceed the temperature deemed risky for generating thermal damage [12]. This study aimed to evaluate temperature variations generated by the p-Tm:YAG laser in the sectors surrounding the laser fiber tip using different parameters combinations while a flexible ureteroscopy is performed in a simulated bench model

MATERIAL AND METHODS

The experimental setup replicated our prior high-fidelity simulation bench model [12]. For this study, we employed the same equipment: a flexible disposable ureteroscope (Lithovue, Boston Scientific, Marlborough, MA, USA) passed through a 36 cm, 11/13 Fr access sheath (Navigator HD, Boston Scientific). We utilized irrigation with 3 l saline bags at 23°C, suspended by gravity to achieve inflow rates of 10 ml/min and 20 ml/min. The p-Tm:YAG laser (Tm:YAG, Dornier MedTech Laser GmbH, Wessling, Germany) was employed in the experiment, utilizing a new laser fiber of 270 μm. For intrarenal temperature measurement, a thermocouple (Leaton R Digital Thermometer) was positioned 5 mm proximal to the stone phantom (T-IR). For ureteral temperature measurement a second thermocouple recorded 5 mm distal to the stone (T-UR) (Figure 1). Before each measurement, the distal transparent part of the laser fiber tip was removed using standard scissors. Laser parameters were set according to the pre-setting recommendation (pulse modulation). For the "Dusting" pre-setting, the following parameters were selected: 0.3 J/25 Hz, 0.5 J/50 Hz, and 0.4 J/75 Hz. For the "Flex Long Pulse" pre-setting, the evaluation included: 0.3 J/100 Hz, 1 J/15 Hz, 1.5 J/20 Hz, and 2 J/15 Hz. The selection of the parameters was based on those commonly used in clinical practice with this laser.

Both thermocouples recorded temperatures at 15, 20, and 30 seconds after laser activation, and only the maximum temperature reached in each test (in Celsius degrees) was recorded. The temperature for each power and irrigation combination was recorded three times. A rest period of 30 seconds was allowed to equilibrate the temperature for each new irrigation pressure before each run. To determine the influence of the flow rate of physiological solution, measurements were conducted with 10 and 20 ml/min. For all trials, we considered 43°C as the threshold temperature because it is associated with

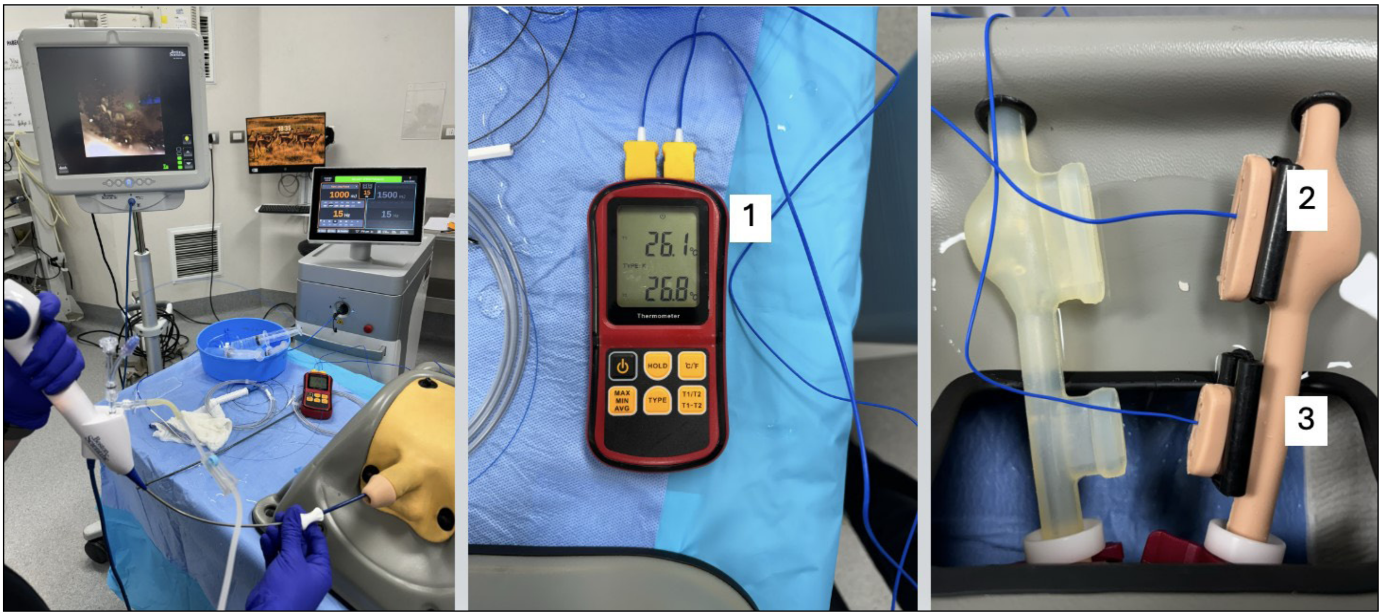

Figure 1. *Experimental setup: 1 – thermometer, 2 – thermocouple at renal pelvis, 3 – thermocouple at proximal ureter.*

denaturation of proteins [13]. Statistical analyses and graphics were performed using RStudio software version 2023.03.0+386. A linear logistic regression model was performed to compare the variation of renal and ureteral temperature according to laser configuration. The level of statistical significance was set at $p < 0.05$.

RESULTS

In the renal model test (T-IR), temperature increases correlated with energy applied. In the subgroup using 30 W, the setting of 0.3 J/100 Hz (Flex Long Pulse) reached the highest temperatures: 46.3°C at a flow rate of 10 ml/min and 41.4°C at a flow rate of 20 ml/min, both within 30 seconds. At a flow rate of 10 ml/min, no laser configuration exceeded 43°C at 15 seconds; at 20 seconds, only the 30 W configuration (2.5 J/20 Hz) exceeded 43°C, recording 44.8°C. By 30 seconds, all 30W configurations exceeded 43°C, except for 0.4 J/75 Hz. At a flow rate of 20 ml/min, no laser configuration exceeded 43°C. Table 1 presents the results obtained. Using a linear logistic regression model, the temperature behavior was projected up to 60 seconds (Table 2). It was observed that the 7.5 W and 15 W configurations would not exceed 43°C at a flow rate of 10 ml/min (Figure 2). At a flow rate of 20 ml/min, only the 30 W configurations would exceed 43°C (Figure 3). Compared with the 15 W configuration, it was observed that at a flow rate of 10 ml/min, the 30W configuration (0.4 J/75 Hz) showed the highest temperature rise per second ($p < 0.01$). At a flow rate of 20 ml/min, the 30 W configuration (0.3 J/100 Hz) exhibited the highest temperature rise per second ($p < 0.01$). The 20 ml/min flow rate resulted in a decrease in renal temperature of 1.96°C ($p = 0.01$) (Table 2). In the tests of the ureteral model (T-UR), it was observed that the temperature increase was not

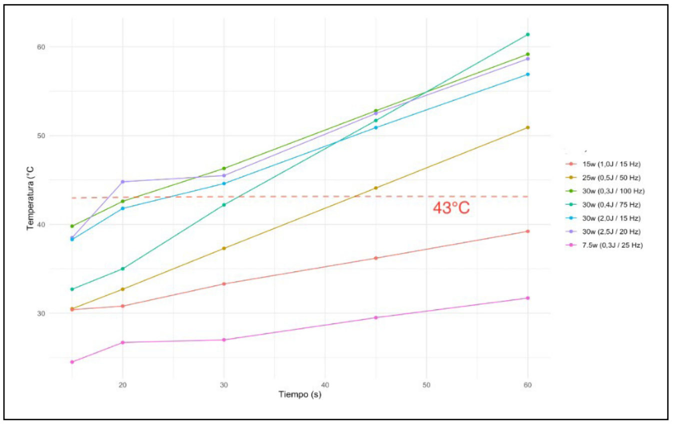

Figure 2. *Projected renal temperature with laser activation over 60 seconds at a flow rate of 10 ml/min.*

Table 1. *Renal and ureteral temperature*

Power		Renal temperatures					
	Flow rates		10 ml/min			20 ml/min	
	Firing times	15 s	20 s	30 s	15 s	20 s	30 s
7.5 W (0.3 J/25 Hz)		24.5	26.7	27	25.5	25.8	26.5
25 W (0.5 J/50 Hz)		30.5	32.7	37.3	34.3	34.4	35.5
30 W (0.4 J/75 Hz)		32.7	35	42.2	33.5	37	41.1
30 W (0.3 J/100 Hz)		39.8	42.6	46.3	33.7	37.2	41.4
15 W (1.0 J/15 Hz)		30.4	30.8	33.3	29.6	30.4	31.9
30 W (1.5 J/20 Hz)		38.5	44.8	45.5	35.6	37	39.4
30 W (2.0 J/15 Hz)		38.3	41.8	44.6	35.5	38.5	40.3
Power		Ureteral temperatures					
	Flow rates		10 ml/min			20 ml/min	
	Firing times	15 s	20 s	30 s	15 s	20 s	30 s
7.5 W (0.3 J/25 Hz)		22.6	22.6	22.8	24.5	25	25
25 W (0.5 J/50 Hz)		23.5	23.6	25.4	24.5	26	26
30 W (0.4 J/75 Hz)		23.2	24.8	25.6	25	26	27.5
30 W (0.3 J/100 Hz)		23.2	25.2	26	25.4	26	27.5
15 W (1.0 J/15 Hz)		25.4	25.2	25.4	26.4	25.5	26.1
30 W (1.5 J/20 Hz)		26.5	25.6	26.2	28.8	33.8	36.3
30 W (2.0 J/15 Hz)		24.6	25	26	29	27.5	30.6

proportional to the applied energy. The configuration of 2.5 J/20 Hz recorded the highest temperatures: 26.5°C with a flow rate of 10 ml/min at 15 seconds and 36.3°C with a flow rate of 20 ml/min

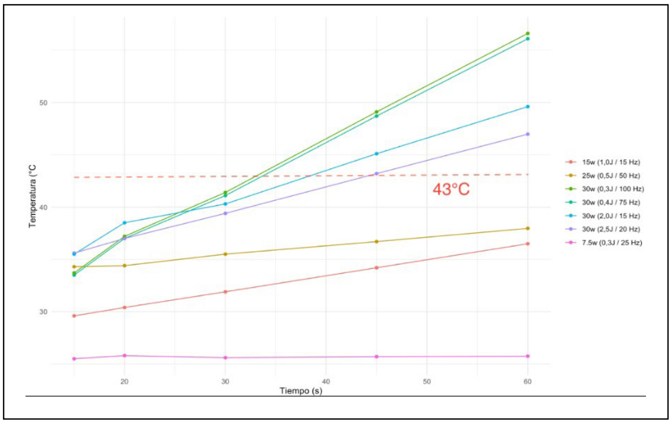

Figure 3. *Projected renal temperature with laser activation over 60 seconds at a flow rate of 20 ml/min.*

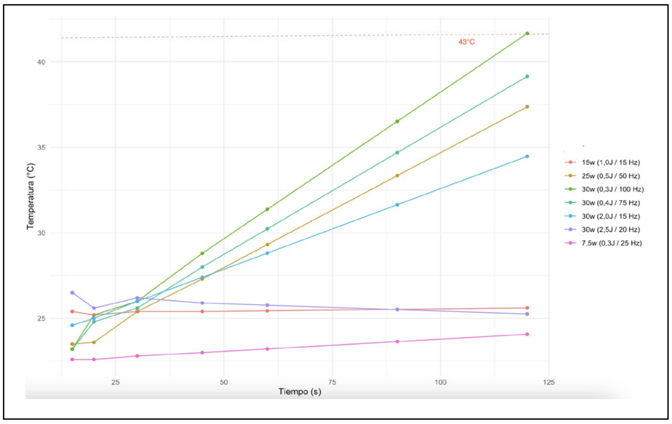

Figure 4. *Projected ureteral temperature with laser activation over 120 seconds at a flow rate of 10 ml/min.*

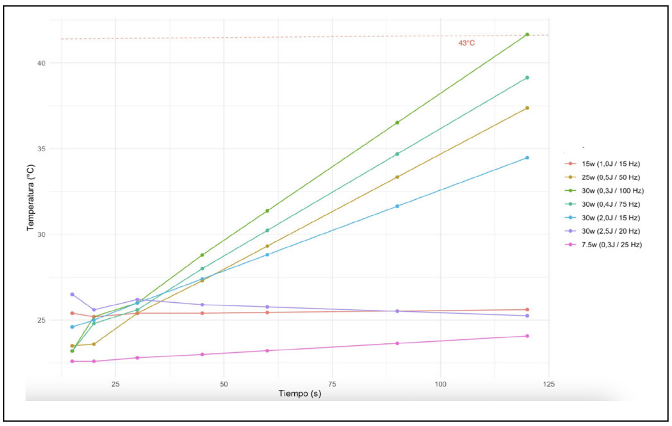

Figure 5. *Projected ureteral temperature with laser activation over 120 seconds at a flow rate of 20 ml/min.*

Table 2. *Logistic regression model for renal temperatures*

Laser setting	Coefficient	p-value
Renal temperature with flow rate of 10 ml/min		
7.5 W (0.3 J/25 Hz)	–0.054	0.09
30 W (2.0 J/15 Hz)	0.198	<0.01
30 W (2.5 J/20 Hz)	0.208	<0.01
30 W (0.3 J/100 Hz)	0.222	<0.01
25 W (0.5 J/50 Hz)	0.252	<0.01
30 W (0.4 J/75 Hz)	0.444	<0.01
Renal temperature with flow rate of 20 ml/min		
7.5 W (0.3 J/25 Hz)	–0.015	<0.01
25 W (0.5 J/50 Hz)	–0.006	<0.01
30 W (2.5 J/20 Hz)	0.098	<0.01
30 W (2.0 J/15 Hz)	0.147	<0.01
30 W (0.4 J/75 Hz)	0.34	<0.01
30 W (0.3 J/100 Hz)	0.347	<0.01
Temperature delta according to flow rate		
20 ml/min	–1.96	0.01

Table 3. *Logistic regression model for ureteral temperatures*

Laser setting	Coefficient	p-value
Ureteral temperature with flow rate of 10 ml/min		
30 w (2.5 J/20 Hz)	–0.011	<0.01
7.5 w (0.3 J/25 Hz)	0.011	<0.01
30 w (2.0 J/15 Hz)	0.091	<0.01
25 w (0.5 J/50 Hz)	0.131	<0.01
30 w (0.4 J/75 Hz)	0.145	<0.01
30 w (0.3 J/100 Hz)	0.168	<0.01
Ureteral temperature with flow rate of 20 ml/min		
7.5 w (0.3 J/25 Hz)	0.037	<0.01
30 w (0.3 J/100 Hz)	0.037	<0.01
25 w (0.5 J/50 Hz)	0.09	<0.01
30 w (0.4 J/75 Hz)	0.15	<0.01
30 w (2.0 J/15 Hz)	0.172	<0.01
30 w (2.5 J/20 Hz)	0.472	<0.01
Temperature delta according to flow rate		
20 ml/min	2.5	<0.01

at 30 seconds. Regardless of the laser settings, physiological saline flow rate, and laser activation time, temperatures above 43°C were never recorded. Table 1 summarizes the results obtained. Using a linear logistic regression model, the temperature behavior was projected up to 120 seconds. It was observed that only the 30 W configuration (0.3 J/100 Hz) would reach 43°C at a flow rate of 10 ml/min (Figure 4).

At a flow rate of 20 ml/min, only the 30W configuration (2.5 J/20 Hz) would exceed 43°C (Figure 5). When comparing with the 15 W configuration, it was observed that at a flow rate of 10 ml/min, the 30 W configuration (0.3 J/100 Hz) showed the highest temperature increase per second ($p < 0.01$). At a flow rate of 20 ml/min, the 30 W configuration (2.5 J/20 Hz) exhibited the highest temperature increase per second ($p < 0.01$). However, it is noted that the 20 ml/min flow rate resulted in an increase in ureteral temperature of 2.5°C ($p < 0.01$) (Table 3).

DISCUSSION

The potential thermal damage generated by laser during endoscopic urinary stone lithotripsy had been intensely evaluated in the last time [14–17]. There is increasing awareness about this issue and there is consensus that exceeding 43°C implies a risk [13, 14]. Theoretically a few seconds of activation of the Ho:YAG laser of lithotripsy can produce ureteral injury even without direct contact due to its photothermal mechanism. In a laboratory study using a simulated model, it was observed that in the absence of irrigation flow, temperatures can reach between 44 to 100 degrees Celsius even with laser powers starting from 5 watts. However, most of the heat effect dissipates when irrigation flow exceeds 15 ml/min [18]. In our study, a similar observation was made, where an increase of 10 mL/min (from 10 to 20 ml/min) in irrigation flow prevents any combination of laser settings from exceeding 43°C, even when reaching a total power of 30 watts. The effect of irrigation on temperature reduction becomes even more evident when using a semi-rigid ureteroscope, which has a larger working channel diameter than traditionally flexible ureteroscopes and a shorter distance for irrigation outflow. In a study published in 2019 using a simulation model to evaluate the temperature effect when using Ho:YAG laser, measurements were taken every second during activation for a total of 15 seconds. Temperature increases of more than 6°C above baseline were chosen as the threshold for potential ureteral damage risk, given the average body temperature of 37°C, which would reach 43°C with such an increase. When using a semirigid ureteroscope with irrigation pressures of 200 mmHg with saline solution, the temperature increases never exceeded the 6°C threshold. In contrast, with flexible ureteroscopes, the threshold was surpassed within 15 seconds of activation, even with power settings as low as 10 W [19]. Regarding the thermal effect of TFL, it has also been *in vivo* predominantly evaluated *in vitro* studies comparing it simultaneously with Ho:YAG laser. In an setting, Okhunob et al. [20] conducted temperature measurements in a porcine model, continuously recording temperatures in the upper, middle, and lower calyxes, as well as using an additional probe to measure temperatures near the tip of the ureteroscope. One of the most striking findings of this study was that temperatures recorded at the tip of the ureteroscope were between 4°C to 22°C lower than those recorded in the renal calyces [20]. In our study, temperature increases at the level of the proximal ureter consistently remained lower than those recorded in the renal pelvis, regardless of the laser settings employed and irrigation flow used. This phenomenon could theoretically be explained by a rapid decrease in temperature once the peak is reached and as the irrigating fluid flows back towards the bladder. In the same vein, a factor rarely evaluated relates to the total volume of fluid present at the laser activation site. In the only study published so far, conducted in real patients, it was demonstrated that a renal pelvis anteroposterior diameter greater than 20 mm is an independent protective factor against temperature increases exceeding 43°C [21]. Regarding our study, the p-Tm:YAG laser appears to exhibit quite stable and safe behavior, at least in this simulated scenario and with preset laser parameters not exceeding 30 W of total energy. The temperature only exceeded the 43°C threshold when a relatively slow irrigation flow was used, coupled with total energies above 25 W. One of the most striking findings of our study is the effect of pulse modulation on temperature. When comparing various combinations to achieve 30 W, the "Flex Long Pulse" modulation consistently resulted in higher temperatures compared to "dusting" modulation, across each measured time interval and regardless of the combination of Hertz and Joules used. In a previous study published by Petzold et al. [22], the effect of temperature generated by p-Tm:YAG laser was evaluated and compared with that generated by Ho:YAG laser. In this study, laser activation was continuous for 120 seconds, with energies ranging from 2 to 30 W and an irrigation flow of 50 ml/min. The temperature increases were found to be very similar and comparable between both lasers, posing a higher risk when reaching 30 W in either case. In 2023, our group published the results of a study similar to the one presented this time, where the experimental setup was the same, but we evaluated the Ho:YAG laser with the Moses 2.0 effect [12]. In that study, the 43°C limit was exceeded on several occasions, even during activation periods as short as 15 seconds and with energies starting from 25 W, although the effect of increased irrigation led to a decrease in temperature, it was not as pronounced as that achieved with the p-Tm:YAG laser. A potential explanation for this phenomenon could be attributed to the shape of the bubble generated by each laser, which could impact the distribution and dissipation of the heat generated during lithotripsy. The Ho:YAG laser tends to produce more spherical bubbles, whereas the p-Tm:YAG laser generates more elongated bubbles [23]. The p-Tm:YAG laser has recently shown clinical effectiveness. In a publication detailing the first 25 patients treated with this technology, stone-free rates of 95% and zero-fragment rates of 55% were achieved, which is comparable to traditionally reported outcomes with TFL or Ho:YAG lasers [10]. In any case, it should be noted that in that initial experience, "Captive Fragmenting" pulse modulation was used in all cases, mode that was not evaluated in our study. The efficacy in terms of ablation has also been evaluated, demonstrating that this laser achieves good results regardless of the chemical composition of the stone. Thus, the total energy consumption (J/mg) per treated stone did not show a statistically significant difference when comparing calcium oxalate monohydrate stones with uric acid stones [8]. To our knowledge, this is the first study evaluating the effect of p-Tm:YAG laser with different pulse modulation alternatives on temperature. However, there are several limitations to consider. Firstly, the study was conducted using a high-fidelity simulation model, which may not necessarily reflect clinical reality. Additionally, we only selected two pulse modulation alternatives from those available, based arbitrarily on our experience with this laser in real patients. A third limitation relates to its application in daily practice, as we defined activation times and irrigation flows based on our practice, which may not be standard elsewhere in the world.

CONCLUSIONS

The p-Tm:YAG laser is one of the tools available in the attempt to achieve better stone free rates, and like its competitors in this pursuit, there is a real risk of generating thermal damage. We believe that this study can contribute to the ongoing search for safer treatments for patients, always mindful of the potential harmful thermal effects, especially in this new era of so-called "high-power lasers".

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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ETHICS APPROVAL STATEMENT

The ethical approval was not required.

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