ORIGINAL PAPER

UROLITHIASIS

Temperature effect of Moses™ 2.0 during flexible ureteroscopy: an *in vitro* assessment

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Introduction One of the main issues related to the use of high-power lasers is the associated rise in temperature. The aim of this study was to characterize temperature variations with activation of the Moses™ 2.0 laser.

Material and methods An in vitro experimental study was designed using a high-fidelity uretero-nephroscope simulation model to assess changes in temperature during intracorporeal laser lithotripsy. Renal and ureteral temperature records were obtained from the treatment of BegoStones positioned in the renal pelvis. Different laser settings over three time periods and two possible irrigation flow speeds were evaluated. We considered 43°C as the threshold since it is associated with denaturation of proteins. The Wilcoxon–Mann–Whitney test was used to assess quantitative variables and the Kruskal–Wallis test for categorical variables.

Results The highest increase in intrarenal temperature was reached with 30 seconds of laser activation at a laser setting of 0.5 J/100 Hz (50 W) and a flow of 10 mL/min. Only 15 seconds of activation was sufficient for most settings to exceed 43°C. The ureteral temperature did not increase significantly, regardless of the combination of laser setting, time, or irrigation flow, except when 30 W was used for a 30 second period. Multivariate analysis showed that an irrigation flow of 20 mL/min produced an intrarenal temperature decrease of 4.7–9.2°C ($p < 0.001$).

Conclusions Use of high-power lasers, both for the ureter and kidney, should involve consideration of temperature increases evidenced in this study, due to the potential biological risk entailed.

Key Words: urolitiasis ‹› retrograde intrarenal surgery ‹› kidney calculi ‹› laser

INTRODUCTION

High-power lasers have been gradually introduced for the endoscopic treatment of urinary stones. Several studies have evaluated the performance of this type of laser, mainly in the percutaneous approach [1, 2, 3], which is associated with promising results, especially in its application during mini-percutaneous nephrolithotomy [4, 5]. Recently, Moses™ Technology (MT, Lumenis®) with pulse modulation has emerged as a new way to improve the efficiency of laser lithotripsy. The Moses™ mode has been associated with a lower fragmentation/pulverization time and a reduction in retropulsion [6, 7]. The latest update of this technology has been called Moses™ 2.0 (Lumenis Pulse™ 120 H; Lumenis, San Jose, CA, USA), which was initially designed to improve prostate enucleation; however, its use in stone treatment has been poorly evaluated [8]. One of the main topics of interest that has arisen with the application of this technology is its effect on temperature and how temperature elevation, above certain margins, could affect the surrounding tissues, especially the renal parenchyma and ureteral wall [9, 10]. The aim of this study was to characterize temperature variations with different activation settings

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of the Moses™ 2.0 laser in a simulated model for Retrograde Intrarenal Surgery.

MATERIAL AND METHODS

An in vitro experimental study was designed to assess the increase in temperature during intracorporeal laser lithotripsy. For this purpose, a validated high-fidelity uretero-nephroscope simulation model (Uro-Scopic Trainer, Limbs & Things) [11] was prepared to work on a 4 mm stone phantom (BegoStone) localized in the renal pelvis of the left kidney. The stone phantoms were used to create a clinical scenario as close as possible to reality. BegoStone is a commercially available super-hard plaster originally developed for dental applications, subsequently examined as a potential stone phantom material for shock wave lithotripsy research [21]. For temperature measurement, a thermocouple (Leaton R Digital Thermometer) was positioned 5 mm proximal to the stone phantom (intra-renal temperature). A second thermocouple recorded temperature 5 mm distal to the stone (ureteral temperature) (Figure 1). Probes were fixed as shown in Figure 1, using the two openings of the high fidelity simulator (Proximal ureter and Renal pelvis). A flexible digital ureteroscope (Lithovue, Boston Scientific, Marlborough, MA, USA) was advanced through a 36 cm, 11/13F ureteral access sheath (Navigator, Boston Scientific), thereby placing the tip of the endoscope distal to the stone phantom. The tip of the ureteral access sheath was placed 2 mm distal to the ureteropelvic junction of the phantom. Gravity irrigation was performed using 3 L saline solution at room temperature (23°C) where inflow rates of 10 mL/min and 20 mL/min were employed (For 10 mL/min the 3 L saline solution bag was hanged at 70 cm over the tip of the ureteroscope, and for 20 mL/min at 130 cm over the tip of the ureteroscope). Both measurements were calculated at the beginning of the test. An unused, uncleaved, 230 μm ball-tip fiber (Moses™ 200 D/F/L) was used for the study. Laser settings included: 0.3 J/30 Hz, 0.5 J/50 Hz, 0.5 J/100 Hz, 0.3 J/120 Hz, 1 J/15 Hz, 1.5 J/20 Hz, and 2 J/15 Hz. Temperature readings from both thermocouples were obtained at 15, 20, and 30 s after laser activation, and only the maximum temperature reached in each test (in degrees Celsius) was recorded. These time periods were selected because they were similar to those used in our current clinical practice. The temperature for each power and irrigation combination was recorded three times. A rest period of 30 s was allowed to equilibrate the temperature for each new irrigation pressure before each run. For all trials, we considered 43°C as the threshold temperature because it is associated with denaturation of pro-

Table 1. *Renal and ureteral temperature*

Power		Renal temperature					
	Flow rates	10 mL/min			20 mL/min		
	Firing times	15 s	20 s	30 s	15 s	20 s	30 s
		Temperature (°C)					
9 W (0.3 J/30 Hz)		27	29.2	34.5	28.7	29.9	29.5
25 W (0.5 J/50 Hz)		42.2	46.2	53.2	39	37.8	39.9
50 W (0.5 J/100 Hz)		60	60	60.8	44.9	45	47.1
36 W (0.3 J/120 Hz)		49	57	57	40.9	43.6	45.4
15 W (1 J/15 Hz)		33	35	35	23.2	25.8	30.9
30 W (1.5 J/20 Hz)		44	46	47	37.1	43.5	45
30 W (2 J/15 Hz)		45	46	48	43	43.7	45
Power		Ureteral temperature					
	Flow rates	10 mL/min			20 mL/min		
	Firing times	15 s	20 s	30 s	15 s	20 s	30 s
		Temperature (°C)					
9 W (0.3 J/30 Hz)		23.7	23.8	23.8	26	25.4	25.6
25 W (0.5 J/50 Hz)		23.9	24.1	23.9	26	26.3	26
50 W (0.5 J/100 Hz)		24	24	25	26.8	27	27.3
36 W (0.3 J/120 Hz)		25.7	26	27.2	24.8	24.8	25.5
15 W (1 J/15 Hz)		32	33	33	22.6	22.7	23
30 W (1.5 J/20 Hz)		39	41	45	23.4	23.3	23.9
30 W (2 J/15 Hz)		39	42	46	24.8	25	25.3

Figure 1. *Experimental Setup: (1) Thermometer (2) Thermocouple at renal pelvis (3) Thermocouple at proximal ureter.*

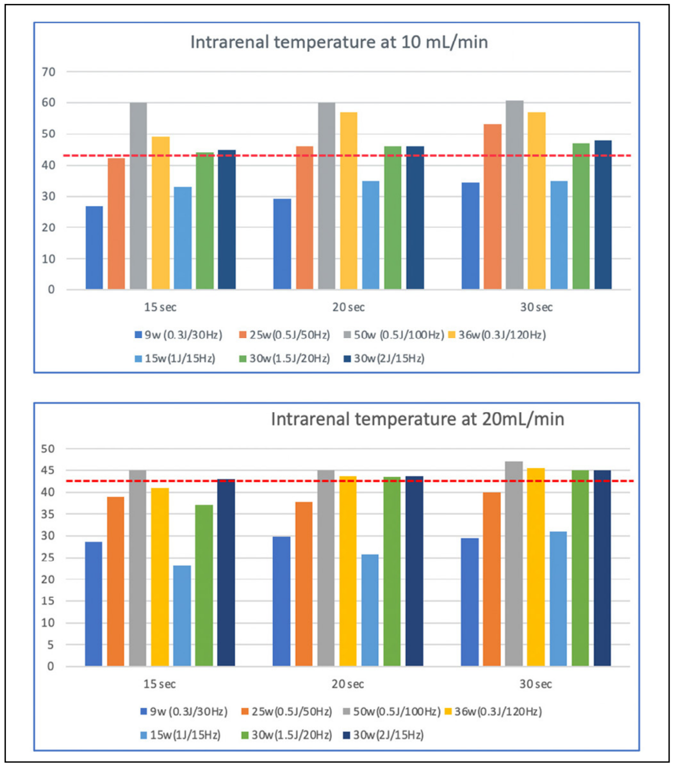

Figure 2. *Maximum intrarenal temperature measured by thermocouple at a flow rate of 10 and 20 mL/min.*

teins [12]. Statistical analyses were performed using the STATA 2.0 software. The Wilcoxon–Mann–Whitney test was used to assess quantitative variables and the Kruskal–Wallis test for categorical variables. The level of statistical significance was set at $p < 0.05$.

RESULTS

The maximum temperatures reached were directly related to the total power used. Additionally, a greater drop in temperature was observed as the flow rate increased. Intra-renal temperature data are summarized in Table 1. The highest increase in intrarenal temperature was reached after 30 s of laser activation with a laser power of 0.5 J/100 Hz (50 W) and a flow of 10 mL/min. However, 15 s of activation was sufficient to exceed the threshold of 43°C in the vast majority of settings combinations, except for 9 W (0.3 J/30 Hz) and 1 W (1 J/15 Hz), when using a 10 mL/min flow (Figure 2). When the flow is increased to 20 mL/min, the situation changes significantly, with temperature remaining lower than the risk threshold at most laser settings, with the exception of the 0.5 J/100 Hz and 0.3 J/120 Hz settings (Figure 2). On the other hand, the ureteral temperature did not increase significantly, only slightly exceeding the risk threshold when combinations of high energy and low frequency (30 W) were used (Table 1). Finally, multivariate analysis showed that, for intrarenal temperature, all parameter combinations above 25 W were related to significant temperature changes. The same situation was observed for ureteral temperatures in settings above 30 W. In contrast, an irrigation flow of 20 mL/min produced an intrarenal temperature decrease of 4.7–9.2°C ($p < 0.001$) and a ureteral temperature decrease of 2.6–8.8°C ($p = 0.01$) (Table 2).

Table 2. *Multiple linear regression for renal and ureteral temperatures*

		Renal temperature		
		Coefficient	CI 95%	p value
Power	25 W (0.5 J/50 Hz)	12.6	(8.3; 16.8)	<0.001
	30 W (1.5 J/20 Hz)	13.3	(9; 15.5)	<0.001
	30 W (2 J/15 Hz)	14.6	(10.4; 18.9)	<0.001
	36 W (0.3 J/120 Hz)	18.3	(14.1; 22.6)	<0.001
	50 W (0.5 J/100 Hz)	22.5	(18.2; 26.7)	<0.001
Flow rate	20 mL/min	-7.0	(-9.2;-4.7)	<0.001
		Ureteral temperature		
Power	30 W (2 J/15 Hz)	6.0	(0.2; 11.7)	0.043
Flow rate	20 mL/min	-5.7	(-8.8;-2.6)	0.001

DISCUSSION

An important factor in the increase in flexible ureteroscopy is the greater availability of high-power lasers, which have allowed effective pulverization of kidney stones. With the idea of further improving the efficiency of the laser, the option to modulate the pulse arose. In 2017, the first laser was launched in the market that allowed the delivery of two pulses with different peak powers (Moses™ Technology, Lumenis®) that can reach up to 80 Hz. The latest update of this technology is Moses™ 2.0, which reaches up to 120 Hz. However, evidence on the usefulness of this technology for urinary lithiasis is scarce. One study showed that the extended frequency rate of Moses™ 2.0 had a superior ablation volume to that of the Moses™ Distance of Moses™ 1.0 across all pulse energies at a stone distance of 0 mm, resulting in greater efficiency because of its lower retropulsion with low pulse energies and higher pulse frequencies [13]. The main holmium laser mechanism of action is related to the photoacoustic and photothermal effects generated during intracorporeal lithotripsy [14, 15]. A large proportion of the energy delivered will have a thermal effect, boiling the fluid around the laser tip. One of the most important issues related to laser usage is the potential harm caused by temperature increases. However, the question remains: How hot is too hot? Several studies have attempted to answer this question. Recently, in vitro and in vivo studies have focused on the optimal laser settings and operational parameters for laser firing in the renal collecting system [9, 10, 17]. The thermal effect is the main factor because its biological effects determine cell death and tissue injury. This requires consideration of temperature as well as duration at a given temperature [12]. A clinical observation study showed that even when using 10 W, the lavage solution achieved a threshold of 43°C in 100% of cases [16]. In our study, the threshold was exceeded by over 25 W in the renal pelvis. Furthermore, ureteral temperatures exceeded 43°C when 30 W was used, regardless of the parameter combination. Therefore, it is important to note that backflow from the renal pelvis to the ureter retains heat, having less capacity to dissipate heat because of the lack of space in the ureter in comparison to the renal cavities. The thermal effect is also affected by the pattern of laser activation, specifically by the lasing time (the duration for which the laser is activated by pedal depression). In a recent publication, Aldoukhi, et al. showed that 9 s of activation at 40 W was sufficient to cross the threshold with laser activation patterns of 30 s on/off and 15 s on/off [17]. The settings selected for this study were based on activation patterns that are similar to those used in our clinical practice when using a high-power laser. Although it seems logical to think that the time the laser remains active should have an independent influence on temperature, multivariate analysis did not reveal any such influence, maintaining the power used and the irrigation flow rate as the main factors influencing temperature increase. Most studies on temperature and laser use have identified the flow volume infused through the working channel of the endoscope as a fundamental factor. In an ex vivo model evaluating the temperature of the ureter during laser lithotripsy for three seconds, a maximum temperature of 49.5°C was reached when no irrigation was used. In the same scenario, but with an irrigation of 8 mL/s, the peak temperature was 37.4°C [18]. Another in vitro assessment showed that fluid outflow rates of 20 and 30 mL/min were sufficient to maintain the temperature below the threshold (43°C) when using 40 W and 60 W in an intermittent activation fashion [19].

In our study, all the possible parameter combinations were directly affected by the increase in flow rate, with a flow rate of 20 mL/min decreasing temperature by a maximum of 9°C for both the kidney and the ureter. The presence of an access sheath could facilitate more stable temperature control because the continuous outflow would help eliminate the excessive heat caused during intracorporeal lithotripsy. A study performed in a porcine model showed that, under gravity irrigation, flexible ureteroscopy was associated with hazardous intrarenal temperatures at laser powers as low as 20 W. When a ureteral access sheath was used, the temperature remained safe; however, the protective effect disappeared when the laser power was increased to 40 and 60 W [20]. Most of the studies conducted to date have been performed in a simulated environment. The only study that evaluated temperature change in a real clinical setting showed that the majority of laser parameter combinations were associated with potentially harmful temperatures, especially when incarcerated ureteral calculi were treated [16].

Our study had some limitations. First, although the study was carried out in a high-fidelity simulator, it was difficult to determine the real clinical impact of the temperature increase observed in our evaluation. In the same vein, as this is an in vitro study, effort was made to perform the tests in the most standardized condition. Operating room temperature was fixed as it is usually fixed in real conditions. Although this study was executed in a high-fidelity simulator, body temperature could determine different results in real life. Likewise, temperature increased less in the ureter than in the kidney in our model. This could be explained by the theory that the irrigation flow at the ureteral level is greater than the flow at the renal pelvis when using the ureteral access sheath, although this should be confirmed in further studies. Second, the selection of times during which the laser was active was predetermined based on our usual clinical practice, which is not necessarily the same worldwide. Third, the most appropriate combination of parameters for Moses™ 2.0 technology in urinary stone lithotripsy is still a matter of debate because of the lack of validating publications. Finally, the objective of this study was to asses changes in temperature during intracorporeal lithotripsy. Although it would have been interesting to monitor renal pelvis pressure during this experiment, it was not measured in this opportunity. We believe that this study will encourage investigators to conduct studies that ascertain our findings and assess these other queries.

CONCLUSIONS

To our knowledge, this is the first in vitro evaluation of temperature modifications using Moses™ 2.0. The use of high-power lasers, for both the ureter and kidney, should involve consideration of the temperature increases evidenced in this study, due to the potential biological risk that the use of high-power lasers entails. The results of this study constitute a starting point for future clinical trials and for understanding the implications of temperature variations generated by the Moses™ 2.0 laser in real patients.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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