

## Turning up the HEAT

### Surgical simulation of the Moses 2.0 laser in an anatomic model

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#### ABSTRACT

**INTRODUCTION:** With advancements in laser technology, urologists have been able to treat urinary calculi more efficiently by increasing the energy delivered to the stone. With increases in power used, there is an increase in temperatures generated during laser lithotripsy. The aim of this study was to evaluate the thermal dose and temperatures generated with four laser settings at a standardized power in a high-fidelity, anatomic model.

**METHODS:** Using high-fidelity, 3D-printed hydrogel models of a pelvicalyceal collecting system with a synthetic BegoStone implanted in the renal pelvis, surgical simulation of ureteroscopic laser lithotripsy was performed with the Moses 2.0 holmium laser. At a standard power (40 W) and irrigation pressure (100 cm H<sub>2</sub>O), we evaluated operator duty cycle (ODC) variations with different time-on intervals at four different laser settings. Temperature was measured at two separate locations: at the stone and ureteropelvic junction.

**RESULTS:** Greater cumulative thermal doses and maximal temperatures were achieved with greater ODCs and longer laser activation periods. There were statistically significant differences between the thermal doses and temperature profiles of the laser settings evaluated. Temperatures were greater closer to the tip of the laser fiber.

**CONCLUSIONS:** Laser energy and frequency play an important role in the thermal loads delivered during laser lithotripsy. Urologists must perform laser lithotripsy cautiously when aggressively treating large renal pelvis stones, as dangerous temperatures can be reached. To reduce the risk of causing thermal tissue injury, urologists should consider reducing their ODC and laser-on time.

#### INTRODUCTION

Advancements in laser technology have allowed urologists to safely treat urolithiasis endoscopically for years. The holmium:yttrium-aluminum-garnet (Ho:YAG) laser has been accepted as a standard lithotripsy laser due to its ability to pulverize stones of many compositions.<sup>1</sup> With the increasing prevalence of high-powered lasers ( $\geq 100$  W), more urologists have been utilizing this technology as they can deliver energy at higher frequencies ( $> 120$  Hz), leading to improved stone ablation efficiency and decreased operative time;<sup>2</sup> however, with increased power, there is increased heat generated. With this in mind, it is important to preserve patient safety while determining the most efficient method of stone ablation.

Lasers can be used for calculus ablation because the stone is able to absorb the emitted laser energy leading to stone fragmentation and melting; thus, temperature and thermal dose have been studied extensively. Thermal dose was first described by Sapareto and Dewey; it is the cumulative equivalent minutes, held at 43°C (TD<sub>43</sub>), and is a standard measure for tissue denaturation occurring when TD<sub>43</sub>  $\geq 120$  equivalent minutes.<sup>3-5</sup> Previously this lab, along with others, have attempted to study thermal loads during ureteroscopic (URS) laser lithotripsy.

The majority of these studies have been performed in low-fidelity in-vitro models consisting of test tubes or syringes or with ex-vivo porcine kidney models. The weakness of the

## KEY MESSAGES

- The time to TD<sub>43</sub> was generally faster at the stone.
- Temperatures and cumulative thermal doses were greater closer to the laser fiber tip.
- Longer laser-on times yielded greater cumulative thermal doses, while shorter laser-off intervals reached the TD<sub>43</sub> faster.
- ODCs of ≥75% reached the threshold of thermal injury.

in-vitro models is that they may not accurately simulate surgical conditions. Conversely, while ex-vivo models may be the closest simulation to surgery, animal models encompass financial and ethical dilemmas.

The goal of our study was to improve upon and confirm our prior studies, using a validated high-fidelity anatomic human kidney model.<sup>6</sup> Using image segmentation, 3D printing, and hydrogel casting, a model inclusive of a complete pelvicalyceal collecting system (PCS) with a ureteral access sheath (UAS) simulating the full-length ureter and incorporating a 2 cm BegoStone was fabricated. This model was then submerged in a water bath maintained at 37°C.

The aims of this study were to:

1. Evaluate the temperature profile of the Moses 2.0 Ho:YAG laser at the stone and ureteropelvic junction (UPJ) for four different 40 W laser settings (two fragmentation and two dusting) using three operator duty cycles (ODCs).
2. Evaluate and compare time to TD<sub>43</sub> for each laser setting.

## METHODS

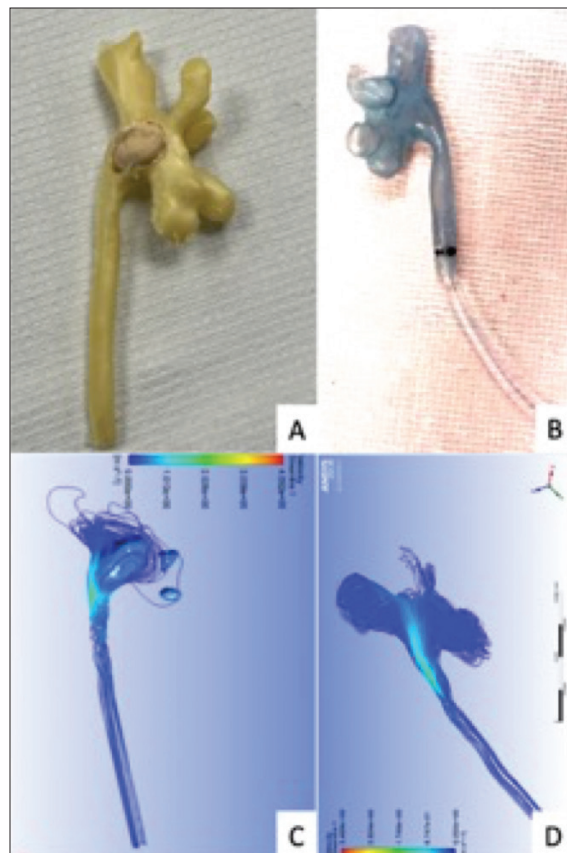
## Simulation model fabrication

Digital Imaging and Communications in Medicine (DICOM) data from a patient's CT scan was segmented into a 3D computer-aided design (CAD) model using Mimics software (Materialize, Leuven, Belgium). The 3D CAD model (including the PCS/ureter) was 3D-printed using hydrogel filament (Fusion3 Design, Greensboro, NC) with a synthetic BegoStone (prepared with 10:1 powder to water ratio by weight) positioned in the renal pelvis and coated with a second polyvinyl alco-

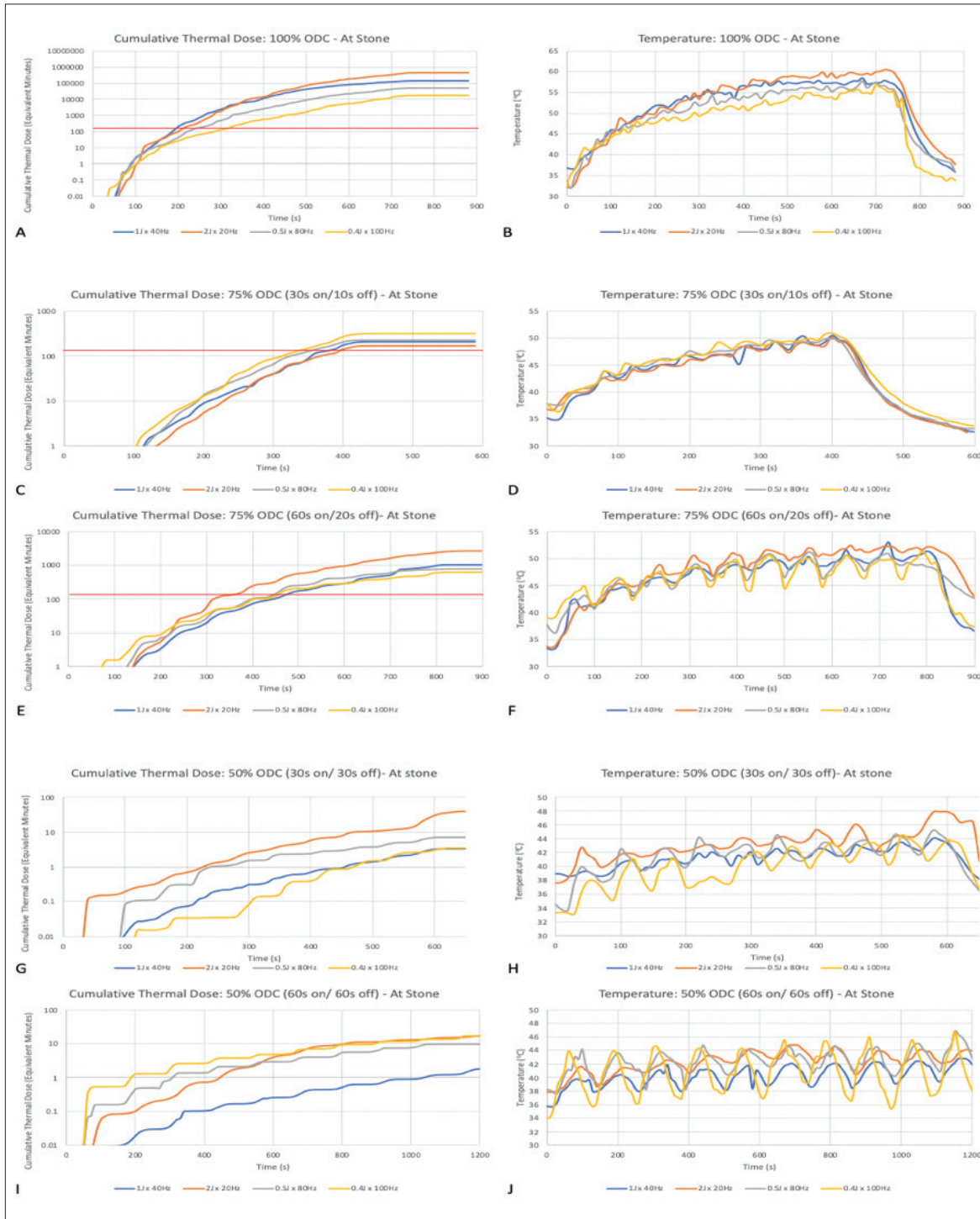
hol (PVA) mixture (Figures 1A & B). This was then implanted into a hydrogel kidney block. The model was submerged in a warm water bath at anatomic temperature (starting temperature 37.0°C +/- 2.0°C); the water was circulated using a sous vide precision cooker (Anova Applied Electronics, San Francisco, CA). The final product underwent extensive mechanical and computational fluid dynamic (CFD) testing to replicate PCS properties, stone lithotripsy, and fluid flow (Figures 1C & D).

## Laser lithotripsy

URS laser lithotripsy was performed at a standardized power (40 W, short pulse width, Moses Technology activated) with continuous normal saline irrigation (17.5 ml/min) via retrograde access with a flexible ureteroscope (LithoVue, Boston Scientific, Marlborough, MA, U.S.) and a 200 µm Ho:YAG laser fiber (Moses 2.0, Boston Scientific, Marlborough, MA, U.S.) (Figure 2).



**Figure 1.** (A) 3D printed PVA PCS model with embedded BegoStone before coating with hydrogel. (B) Final hydrogel PCS model with drainage tubing secured acting as UPJ (stone inside model, unable to be visualized). (C&D) CFD testing of the model at 100 cm H<sub>2</sub>O. CFD: computational fluid dynamic; PCS: pelvicalyceal collecting system; PVA: polyvinyl alcohol; UPJ: ureteropelvic junction.



**Figure 2.** Temperature and thermal dose graphs of each laser setting at the stone. TD43 (solid red line) is on the thermal dose graphs. 100% operator duty cycle (ODC). (A) thermal dose; (B) temperature. 75% ODC: 30 seconds on/10 seconds off; (C) thermal dose and (D) temperature 60 seconds on/20 seconds off; (E) thermal dose and (F) temperature 50% ODC: 30 seconds on/30 seconds off; (G) thermal dose and (H) temperature 60 seconds on/60 seconds off; (I) thermal dose; and (J) temperature.

**Table 1. Comparison of cumulative thermal dose, time to TD43, and statistical comparison at the stone vs. UPJ**

Laser setting	ODC	Time on (s)/ time off (s)	Cumulative thermal dose (CEM)		Time to thermal injury threshold (s)		p at vs. away from stone
			At stone	Away from stone	At stone	Away from stone	
1 J x 40 Hz	100%		<b>93909.8907</b>	<b>134501.2717</b>	<b>200</b>	<b>195</b>	<0.0001
	75%	30/10	<b>221.6387713</b>	<b>206.1101383</b>	<b>380</b>	<b>370</b>	<0.0001
		60/20	<b>1125.62778</b>	<b>1025.910058</b>	<b>440</b>	<b>465</b>	<0.0001
	50%	30/30	3.569467179	3.071237613	NR	NR	<0.0001
		60/60	3.233970832	1.882688132	NR	NR	<0.0001
2 J x 20 Hz	100%		<b>318276.667</b>	<b>449089.338</b>	<b>195</b>	<b>205</b>	<0.0001
	75%	30/10	<b>187.32621</b>	<b>169.9063665</b>	<b>395</b>	<b>395</b>	0.0004
		60/20	<b>3398.569694</b>	<b>2690.290273</b>	<b>325</b>	<b>330</b>	<0.0001
	50%	30/30	51.75861439	39.50125173	NR	NR	<0.0001
		60/60	24.86021107	18.09596256	NR	NR	<0.0001
0.5 J x 80 Hz	100%		<b>62134.7335</b>	<b>51936.32456</b>	<b>230</b>	<b>230</b>	<0.0001
	75%	30/10	<b>344.6057609</b>	<b>228.1060048</b>	<b>320</b>	<b>350</b>	<0.0001
		60/20	<b>1253.588927</b>	<b>788.0238063</b>	<b>395</b>	<b>435</b>	<0.0001
	50%	30/30	11.20336357	7.050187058	NR	NR	<0.0001
		60/60	23.62071365	9.677738417	NR	NR	<0.0001
0.4 J x 100 Hz	100%		<b>18045.01532</b>	<b>8502.241086</b>	<b>295</b>	<b>315</b>	<0.0001
	75%	30/10	<b>316.2694821</b>	<b>242.2321829</b>	<b>330</b>	<b>380</b>	<0.0001
		60/20	<b>739.8320632</b>	<b>627.1075826</b>	<b>410</b>	<b>450</b>	<0.0001
	50%	30/30	3.071237613	3.569467179	NR	NR	<0.0001
		60/60	18.93383935	17.0028632	NR	NR	<0.0001

Bolded cells indicate tests that exceeded threshold of thermal injury. NR indicates that the threshold of thermal injury was not reached. Statistics comparing cumulative thermal dose and calculated with Kruskal-Wallis. UPJ: ureteropelvic junction.

A 12/14 Fr, 40 cm UAS was inserted just distal to the UPJ to simulate a complete ureteral length. Four laser settings – two fragmentation (1 J x 40 Hz and 2 J x 20 Hz) and two dusting (0.5 J x 80 Hz, 0.4 J x 100 Hz) were tested. We evaluated 3 ODCs (50, 75, and 100%) with different laser-on (30, 60, and 120 s) times. Each experiment consisted of 10 cycles (1 cycle = 1 laser-on/laser-off sequence = 1 ODC); the 100% ODC consisted of pedal-on time of 12 minutes straight with no laser-off time. Five permutations of each laser setting were tested. A total of 20 experiments were performed. Temperature was measured continuously with data analysis performed in 10-second intervals.

### Data collection and analysis

Temperature was recorded with K-type needle thermocouple probes and data logger (Omega, Norwalk,

CT) at two standard positions (registered in the model) in the PCS – at the stone (renal pelvis) and UPJ. Additionally, a third temperature probe was inserted into the hydrogel block. Thermal dose was calculated with the Sapareto and Dewey formula. Statistical analysis for thermal dose was analyzed via area under the curve (AUC) and Kruskal-Wallis comparison and temperature data was analyzed via non-linear regression in a third-order polynomial (Prism 9). P<0.05 was considered statistically significant.

### RESULTS

When evaluating the cumulative thermal dose, it was found to be higher *at the stone* than at the UPJ for each laser setting tested. There was a statistically significant difference between cumulative thermal dose at the stone and UPJ for each laser setting tested (Table 1).

**Table 2. Comparison of maximal temperature, and statistical comparison at the stone vs. UPJ**

Laser setting	ODC	Time on (s)/ time off (s)	Maximum temperature (°C)		p at vs. away from stone
			At stone	Away from stone	
1 J x 40 Hz	100%		<b>58.5</b>	<b>58.2</b>	<0.0001
	75%	30/10	<b>50.4</b>	<b>50.2</b>	<0.0001
		60/20	<b>52.9</b>	<b>51.6</b>	0.1618
	50%	30/30	44.1	43.1	0.0018
		60/60	42.8	43.3	0.1187
2 J x 20 Hz	100%		<b>60.5</b>	<b>59.9</b>	<0.0001
	75%	30/10	<b>50.1</b>	<b>50.1</b>	<0.0001
		60/20	<b>52.4</b>	<b>52.7</b>	0.0224
	50%	30/30	47.9	48.8	0.1638
		60/60	44.8	45.3	0.0301
0.5 J x 80 Hz	100%		<b>57.8</b>	<b>57.6</b>	<0.0001
	75%	30/10	<b>49.9</b>	<b>50.8</b>	<0.0001
		60/20	<b>51.2</b>	<b>52.1</b>	0.0014
	50%	30/30	45.2	44.4	<0.0001
		60/60	46.9	45.1	<0.0001
0.4 J x 100 Hz	100%		<b>56.7</b>	<b>55.3</b>	<0.0001
	75%	30/10	<b>50.8</b>	<b>49.9</b>	<0.0001
		60/20	<b>51.4</b>	<b>51.0</b>	<0.0001
	50%	30/30	44.4	43.8	<0.0001
		60/60	46.7	45.2	<0.0001

Bolded cells indicate tests that exceeded threshold of thermal injury. Statistics comparing temperature curves and calculated with non-linear regression in a third-order polynomial. UPJ: ureteropelvic junction.

The threshold of thermal injury was reached for the 100 and 75% ODCs both at the stone and UPJ but was not reached in any 50% ODC. The threshold of thermal injury was reached faster for 100% ODC than either of the 75% ODC time intervals. For the 75% ODCs, the 30 seconds on/10 seconds off time interval reached the threshold faster for all laser settings tested, except for 2 J x 20 Hz, where the 60 seconds on/20 seconds off interval was faster. The time to reach the threshold of thermal injury was typically faster at the stone compared to the UPJ except for 1 J x 40 Hz (100% ODC, 30 seconds on/10 seconds off), where the UPJ reached the threshold faster; while for 2 J x 20 Hz (30 seconds on/10 seconds off) and 0.5 J x 80 Hz (100% ODC) the threshold was reached at approximately the same time (Table 1).

The cumulative thermal dose was greater for each laser setting with greater ODCs both at the stone and UPJ. 2 J x 20 Hz delivered the greatest cumulative thermal dose for each time interval tested except for 30 seconds on/10 seconds off, where it delivered the lowest cumulative thermal dose. There was no other generalizable pattern appreciated between the laser settings otherwise when compared against one another (Tables 1 and 2).

Considering maximal temperatures at the stone vs. UPJ, the temperatures were higher at the stone in 13/20 tests, higher at the UPJ in 6/20 tests, and in one test, the maximal temperature was the same (2 J x 20 Hz, 30 seconds on/10 seconds off). There was a statistically significant difference in the temperature curves for all but three tests (1 J x 40 Hz – 60 seconds on/20 seconds off and 60 seconds on/60 seconds off, 2 J x 20 Hz – 30 seconds on/30 seconds off). Temperatures were hotter with greater ODCs for each laser setting both at the stone and at the UPJ. Considering the 75% ODCs, hotter maximal temperatures were recorded with a longer laser-on time (60 seconds on/20 seconds off) for each laser setting both at the stone and at the UPJ. Considering the 50% ODCs, there were mixed results as to which laser time-on cycle generated hotter maximal temperatures; for the fragmentation settings, the 30 seconds on/30 seconds off cycle yielded hotter temperatures, while for the dusting settings, the 60 seconds on/60 seconds off cycle was hotter. This held true both at the stone and at the UPJ (Table 2).

While there was not an apparent trend as to which laser setting produced the hottest temperatures, we did appreciate statistically significant differences between laser settings which demonstrates that frequency and energy can strongly influence temperature and thermal dose, even at a standardized power. For 100% ODC, 2 J x 20 Hz was hottest at the stone and UPJ, while 0.4 J x 100 Hz was the lowest for both. For the other 4 ODC/time-on intervals evaluated, there was no overall trend (Tables 1 and 2).

Temperatures of the hydrogel block started at 37.0°C +/- 2.1°C and increased 1.0°C +/- 2.0°C. There were no statistically significant changes in temperature measured at this location. It was observed that the temperatures increased slightly more when the starting temperature was lower (<37°C) opposed to a minimal temperature fluctuation at higher starting temperatures (≥37°C).

## DISCUSSION

In this study, we were able to establish that temperatures and cumulative thermal doses were greater closer to the tip of the last fiber, which has also been recognized in previous studies.<sup>7</sup> Additionally, we demonstrated that energy and frequency play a significant role in the thermal load delivered, and the previously accepted concept that power is the sole determinant of temperature may not be entirely accurate.<sup>5, 8-10</sup> In general, greater thermal doses and maximal temperatures were achieved with greater ODCs and longer laser-on times for 100% and 75% ODCs, which is in agreement with previously published literature.<sup>11,12</sup> When comparing laser-on times for 75% ODC, 60 seconds on/20 seconds off delivered greater cumulative thermal doses and maximal temperatures for each laser setting both at the stone and UPJ.

Interestingly, when evaluating 50% ODCs, the fragmentation settings delivered greater cumulative thermal doses for shorter laser-on time (30 seconds on/30 seconds off) while the dusting settings delivered greater cumulative thermal doses for the longer laser-on time (60 seconds on/60 seconds off). When considering maximal temperatures, the same results held true, except for 1 J × 40 Hz at the UPJ (43.1°C for 30 seconds on/30 seconds off vs. 43.3°C for 60 seconds on/60 seconds off). This shows that the laser-off time may play a crucial role in fluid cool-down, as the longer the laser is off, the greater the opportunity that the fresh irrigation inflow can cool more of the PCS.

There have been numerous studies manipulating variables involved during URS laser lithotripsy. Dr. William Robert's laboratory at the University of Michigan has led many studies via in-vitro bench models and computational modelling. They have evaluated the Ho:YAG laser power (2.5–50 W), frequency (5–80 Hz), irrigation rate (0–40 ml/min), irrigation temperature (~0°C and 19°C), and ODC (≥50%).<sup>4,5,11-14</sup> Their work sought to adapt their previous findings to an in-vivo porcine model and found that temperatures capable of tissue damage were easily achieved but can be negated by increasing irrigation flow rate.<sup>15</sup> Other labs have also evaluated irrigation rates and have determined that increased irrigation rates can mitigate temperature increases during active lasing, as too can the use of a UAS.<sup>16-18</sup>

A recent study evaluated intraoperative irrigation fluid temperatures during URS treatment of urolithiasis. They compared laser settings of 1 J × 20 Hz and 0.5 J × 20 Hz with irrigation rates of 0 ml/min, 15 ml/min, and 30 ml/min. They found that with irrigation rates of

15 ml/min and 30 ml/min, a temperature of 43°C was not reached after 60 seconds straight of laser activation.<sup>19</sup> Our study used a UAS with a constant irrigation flow (100 cm H<sub>2</sub>O=17.5 ml/min). We found that at a constant power, the threshold of thermal injury could be reached in as little as 195 seconds (2 J × 20 Hz at the stone and 1 J × 40 Hz at the UPJ). While there was a significant difference in power tested between Teng, et. al's study and ours, it is obvious that when treating larger stone burdens, urologists must be diligent when continuously lasing as temperatures can reach dangerous levels, even with UAS use.

It is important to consider that in this study, we were lasing a large calculus in the renal pelvis where there is more volume/area for fluid and irrigation flow. Previous studies have demonstrated that when lasing in smaller spaces, temperatures increased faster, and the threshold of thermal injury could be reached faster when compared to larger spaces.<sup>20,21</sup> In agreement with our prior evaluations and previous studies, the threshold of thermal injury was reached during ODCs greater than 70%.<sup>11</sup> This held true regardless of the laser settings tested and for laser-on time. Aldoukhi, et. al. performed a chart review of 63 URS cases and determined that during the 60 seconds of greatest power delivered, the ODC was 63%.<sup>12</sup>

Although studies have demonstrated that ODCs <70% are less likely to cross the threshold of thermal injury, it is important to consider that more powerful laser settings can deliver greater thermal loads in shorter amounts of time and with shorter ODCs. Additionally, when lasing in tighter spaces, such as a calyx opposed to the renal pelvis, it is reasonable to believe that the threshold of thermal injury could be reached even with lower ODCs or less powerful laser settings, particularly after a stone is broken; as the laser tip may be closer to the urothelium with no interruption from a stone, and it is not absorbing energy once pulverized. In an in-vitro model, it was found that the presence of a phantom BegoStone was related to lower rises in fluid temperatures when compared with no stone present at an array of powers tested (10, 20, 40, 60 W).<sup>20</sup>

It is recognized that BegoStones may possess distinctive photothermal properties compared with real urolithiasis during laser lithotripsy;<sup>22</sup> however, BegoStones are often accepted as a synthetic analogue for real urolithiasis during in-vitro urologic laser studies since they are able to be composed without significant difficulty in an efficacious manner and are able to be fabricated and reproduced with the same composition.

To date, this appears to be the first study evaluating thermal loads performed in a high-fidelity anatomic in-vitro model at anatomic temperature with a UAS used while actively lasing a phantom stone. Other studies have been performed using ex-vivo and in-vivo models with or without UAS that can simulate the complete ureteral length. It is well recognized that using a UAS can facilitate higher irrigation flow rates and modulate temperature increases more easily, in addition to reducing intrarenal pressures during irrigation.<sup>17,23</sup>

With regards to the power setting evaluated utilizing the Moses 2.0 Ho:YAG laser in this study, 40 W was chosen as the standard because this power allowed for the variation of both frequency and energy settings for four different laser settings — two dusting and two fragmentation — while maintaining constant power. It is recognized that urologists may commonly utilize lower power settings in clinical practice, however, the goal of this study was to evaluate variables besides power, since many previous studies have already compared different power settings.<sup>4,5,13</sup>

This study addressed some of the limitations of our previous studies which had been performed at room temperature. With this experimental model, we evaluated thermal dose and temperatures in the high-fidelity anatomic model performed at anatomic temperature with a UAS. This experimental design appears to be a quality, realistic in-vitro model for URS laser lithotripsy. The majority of previous studies have been performed with in-vitro test tube models or with ex-vivo porcine kidney models.

While we have addressed some limitations of our prior studies, we recognize that some limitations are present in this study. First, although this project was performed in a high-fidelity anatomic PCS model, some caution should be maintained when attempting to correlate this data to a surgical scenario. Second, only one PCS model was used in our evaluations in efforts to further reduce confounding variables influencing our results. Finally, although BegoStone models may simulate actual kidney stones, they may not act as an exact analogue. Our laboratory hopes to continue pursuing urologic laser research in the future, building on this study, and addressing some of these limitations.

This study had several strengths. First, this study evaluated four variables: laser frequency, laser energy, ODC, and laser time-on, in an anatomically correct, high-fidelity model that has been validated with mechanical and CFD testing; but this time, at anatomic temperature with the use of a UAS. Second, we were able to evaluate thermal load in two locations in the

PCS. Finally, we were able to measure the temperatures while actively lasing a synthetic 2 cm calculus. The combination of these components into one model while analyzing four separate variables strengthens the results of this study. While prior studies have compared some of these factors affecting irrigation fluid temperature, the majority of these studies focus on fewer variables.

## CONCLUSIONS

We were able to validate our previous studies and address several limitations with this experimental model. We confirmed that dangerous thermal loads can be delivered with greater ODCs and longer laser-on times. We demonstrated again that at a standardized power, energy and frequency manipulations can strongly influence thermal dose and temperatures. Based on the results of this study, it is important that urologists perform URS laser lithotripsy diligently, as irrigation fluid temperatures and cumulative thermal doses in the PCS can reach critical levels and potentially cause urothelial injury, regardless of laser setting.

**COMPETING INTERESTS:** The authors do not report any competing personal or financial interests related to this work.

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