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ORIGINAL ARTICLE

MOSES™ pulse modulation technology versus conventional pulse delivery technology: the effect on irrigation fluid temperature during flexible ureteroscopy

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Abstract
To compare the effect of MOSES™ modulation technology to conventional pulse delivery technology on the irrigation fluid temperature (IFT) under different irrigation conditions during flexible ureteroscopy (FURS) in a live-anesthetized porcine model. For this experiment was used one female pig. A percutaneous access was obtained and a 30Fr sheath was placed inside the upper calyceal system. A thermocouple was inserted through the sheath to the upper calyx to record the effect on IFT during FURS. A Lumenis 120H Ho:YAG laser was used and the IFT was recorded during laser activation for 30 s at a laser power of 20 W, 40 W and 60 W under gravity and manual pump irrigation using MOSES™ and conventional pulse delivery technology. In the highest power settings the maximum IFT was achieved in 18 s under gravity irrigation (66.4 °C). It seems that there is no significant difference on IFT between MOSES and conventional mode on the IFT under different irrigation conditions during FURS at 20 W, 40 W and 60 W power settings. Furthermore, our results indicate that under manual pumping even high-power settings (40 W, 60 W) can be performed with safety. In the in vivo model, the MOSES™ pulse delivery technology does not have a significant difference in the maximal IFT in comparison to conventional pulse delivery technology during FURS in the same power settings. Manual pumping should be used to keep the IFT within safe limits.

Keywords Temperature · Laser · Ureteroscopy · Irrigation · Pig

Abbreviations

FURS	Flexible ureteroscopy
IFT	Irrigation fluid temperature
Ho:YAG	Holmium: yttrium–aluminum-garnet
UAS	Ureteral access sheath

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Introduction

Endourologic techniques currently possess a starring role in the treatment of ureteral and renal calculi with laser lithotripsy being developed over the past few decades. According to the current guidelines, the gold standard method for treating ureteral stones and renal stones < 2 cm nowadays is the Holmium:yttrium–aluminum–garnet (Ho:YAG) which accommodates a wide range of pulse energy, pulse frequency and pulse width, providing the ability to perform "dusting", "popcorning" and "fragmentation" [1, 2]. The new high power (120 W) laser system developed by Lumenis (MOSES™ technology, Lumenis Ltd, Yokneam, Israel) optimizes the energy transfer from the laser fiber towards the target, leading to less stone retropulsion and more efficient ablation of the target [2]. The "Moses effect" creates a vapor bubble that separates the water, which then is delivered to the stone resulting to less energy loss [2, 3]. It is worth mentioning that there is a lack of studies and data concerning the intra-renal temperatures created from the use of lasers and the complications that may occur. Significant damage can be caused to the urinary system due to thermal injury from the laser activation [4]. The current study was planned to compare the effect of MOSES™ modulation technology and conventional pulse delivery technology on the irrigation fluid temperature (IFT) under gravity and manual pump irrigation, during flexible ureteroscopy (FURS) in a live-anesthetized porcine model. The main hypothesis of the experiment was that the application of higher power laser settings would produce higher intra-renal temperatures.

Materials and methods

Preparation of the pig for the experiment

The pig was kept unfed 12 h prior to the procedure. Ketamine, Atropine Sulfate and Xylazine were used for initiating the anesthesia. After the intubation, the pig was connected to the ventilator and with the use of Propofol 5% the anesthesia was maintained.

Operative setup and technique

The pig was placed in supine position. General anesthesia was initiated. A cystoscopy was performed and a 0.035 sensor guidewire (HiWire™ Nitinol Core Wire Guide, COOK Medical, Cook Ireland Ltd., Limerick, Ireland) was advanced to the right renal pelvis of the pig followed by a placement of a ureteral catheter. The pig was then put in prone position (Fig. 1a) and a percutaneous access with the use of an 18-gauge needle was performed using a fluoroscopic guided puncture (Bull's eye technique). A standard PCNL tract was established and a 30Fr sheath was placed inside the upper calyceal system. A K-type insulated flexible metal thermocouple was inserted through the sheath to the upper calyx to record the effect on IFT during FURS. Moreover, a 18Fr nephrostomy (COOK Medical, Cook Ireland Ltd., Limerick, Ireland) was used. The nephrostomy and the thermocouple were fixed within the access sheath by inflating the balloon of the nephrostomy with 5 ml (Fig. 1b). This provides a watertight sealing of the percutaneous tract. At that point, the pig was set again to supine position and a Super stiff guidewire (Amplatz Super Stiff™, Boston Scientific, Heredia, Costa Rica) was inducted in the kidney through the ureteral catheter. Finally, the Pusen PU3022a flexible ureteroscope (Zhuhai Pusen) was inserted and the experiment was initiated.

Thermocouple and data logger

The SE001 from (Pico Technologies, Cambridgeshire, UK) was the thermocouple we chose for the experiment. It has an exposed junction, 0.3 mm twisted pair conductor and its 1.5 mm tip can record temperatures from − 6 to + 350℃. For real time temperature measurements, a data logger (TC08, Pico Technologies, Cambridgeshire, UK) was connected to the thermocouple. During the whole process it was connected to a computer via USB cable and the acquisition rate of the data was set at 1 count/s (Fig. 1b). The distance of the laser from the tip was set to be approximately 1 mm.

Laser activation

Placing the bag at 1 m over the table and while using gravity irrigation settings, one 200 µm laser fiber (Lumenis Ltd, Yokneam, Israel) was activated in the center of the calyx for 30 s at a laser power of 20 W(1 J, 20 Hz), 40 W(1 J, 40 Hz) and 60 W(2 J, 30 Hz), using a Lumenis 120H Ho:YAG laser system (MOSES™ technology, Lumenis Ltd, Yokneam, Israel). The limit of 30 s laser activation was set, since in real surgery, a high-power laser is never used for over 30 s. This is because of high amount of dust production which limits the surgeon's visibility. During the process, FURS was performed with the use of a single use Pusen Flexible Ureteroscope. The laser was activated under gravity and manual pump irrigation using MOSES™ pulse delivery and conventional pulse delivery technology. The irrigation fluid inside the bag was at room temperature (~ 25 ℃) and

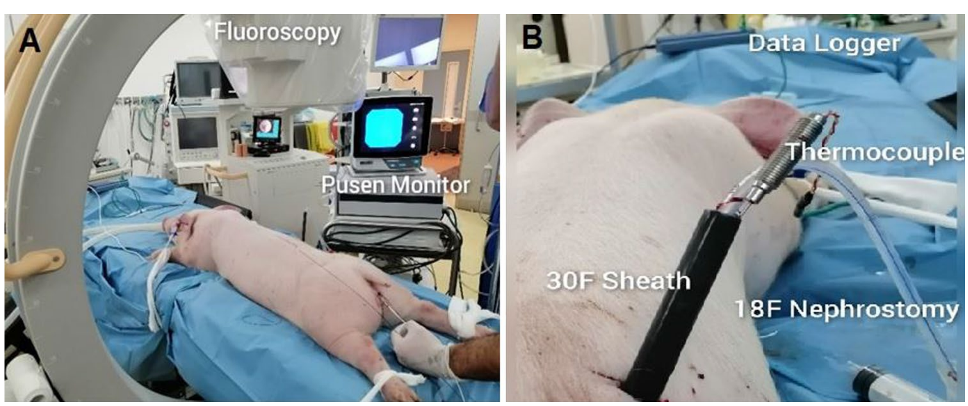

Fig. 1 **A** Photo of the setup, after dilation of the upper calyx (30F sheath), **B** The thermocouple fixed inside the upper calyx

the rate of manual irrigation was set at 1 pump every 3 s. Based on already existing data, the threshold for a dangerous IFT was considered 54℃ [5]. In addition, concerning the MOSES™ pulse delivery technology, the longest pulse mode and distance were selected to have the highest effect for pulse modulation. We believe, in this way the MOSES effect can be depicted at its maximum.

Results

Gravity irrigation

For the lowest laser power used (20 W), the IFT during FURS did not reach hazardous values for 30 s when either the MOSES™ technology or the conventional pulse delivery technology were used (Fig. 2a). The 54 ℃ threshold was exceeded in both 40 W and 60 W settings under gravity irrigation. In detail, for the 40 W setting the IFT reached 58℃ in ~ 17 s when the conventional pulse delivery technology was used and 57 ℃ in ~ 28 s when the MOSES technology was used (Fig. 3a). Finally, for the highest power settings (60 W) both the MOSES and the conventional laser technology exceeded the safety threshold of 54 ℃ in approximately 10 s reaching the hazardous temperature of 66.4 ℃ in 18 s (Fig. 4a). It is worth mentioning that the IFT was increasing at a faster rate as the laser power increased.

Manual pump irrigation

With the application of manual pump irrigation, the IFT during FURS was kept in safe values (< 54 ℃) during the whole process. The IFT when the 20 W was tested did not exceed 33 ℃ when either MOSES or conventional technology was activated (Fig. 2b). For the 40 W power setting, the temperature did not surpass 35.3 ℃ regardless the used laser technology (Fig. 3b). Concerning the highest power setting of 60 W, the MOSES laser was close to a highest temperature of 42 ℃ and the standard laser close to 44 ℃ throughout the 30 s recording of the IFT (Fig. 4b).

Discussion

As kidney stone prevalence continuously rises, the advancement of minimally invasive techniques in the last 50 years is remarkable. The application of high-power lasers in urology has revolutionized the way urolithiasis is treated. Flexible ureteroscopy is constantly evolving, enabling the surgeon to use a wide range of modalities and settings and achieve better therapeutic outcomes. The absence of adequate data regarding the optimum settings for the use of these new technologies is a fact, and further research is a necessity. This study is an effort to contribute to this research. It provides information on the effect of irrigation fluid temperatures during flexible ureteroscopy using high-power lasers in an

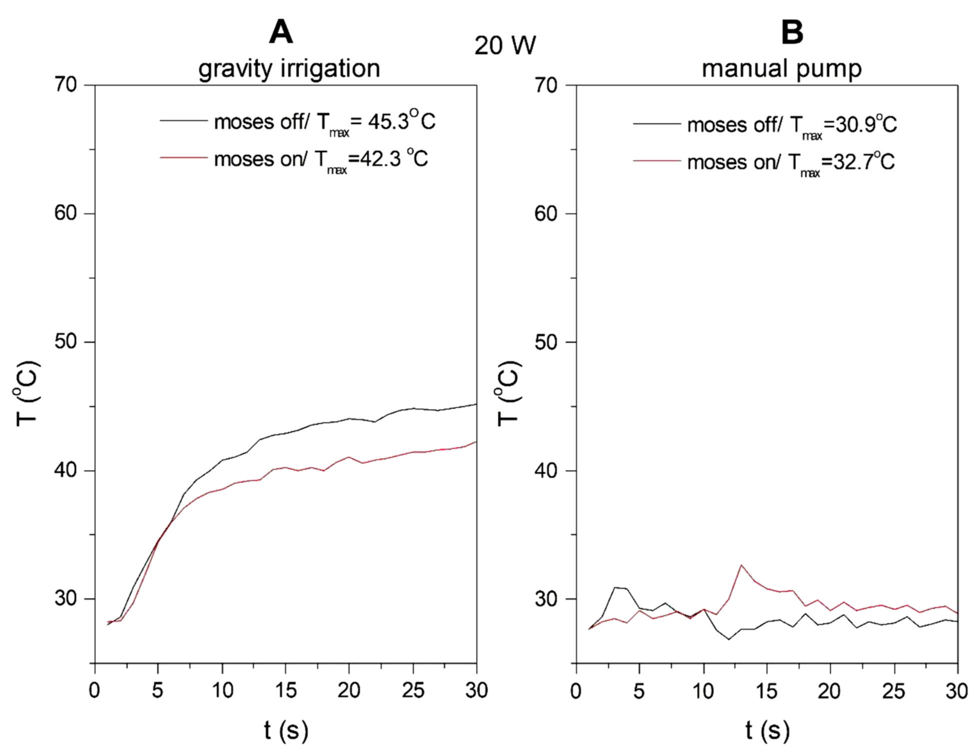

Fig. 2 **A** Activation of 200-µm laser fiber at 20 W for 30 s under gravity irrigation, **B** Activation of 200-µm laser fiber at 20 W for 30 s under manual pump irrigation

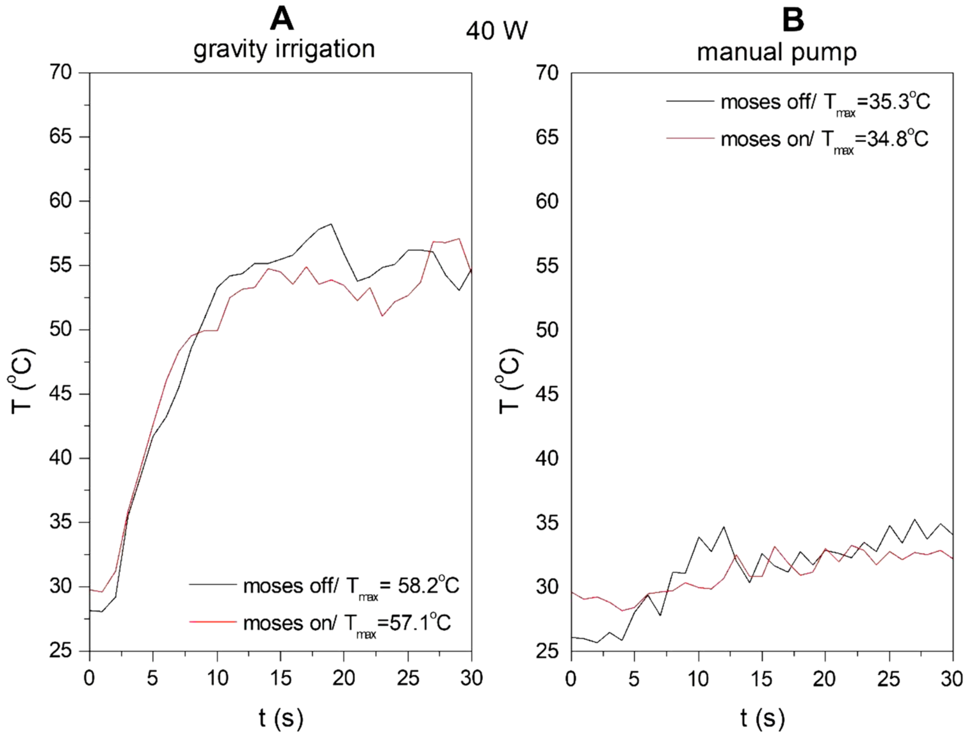

Fig. 3 **A** Activation of 200-μm laser fiber at 40 W for 30 s under gravity irrigation, **B** Activation of 200-μm laser fiber at 40 W for 30 s under manual pump irrigation

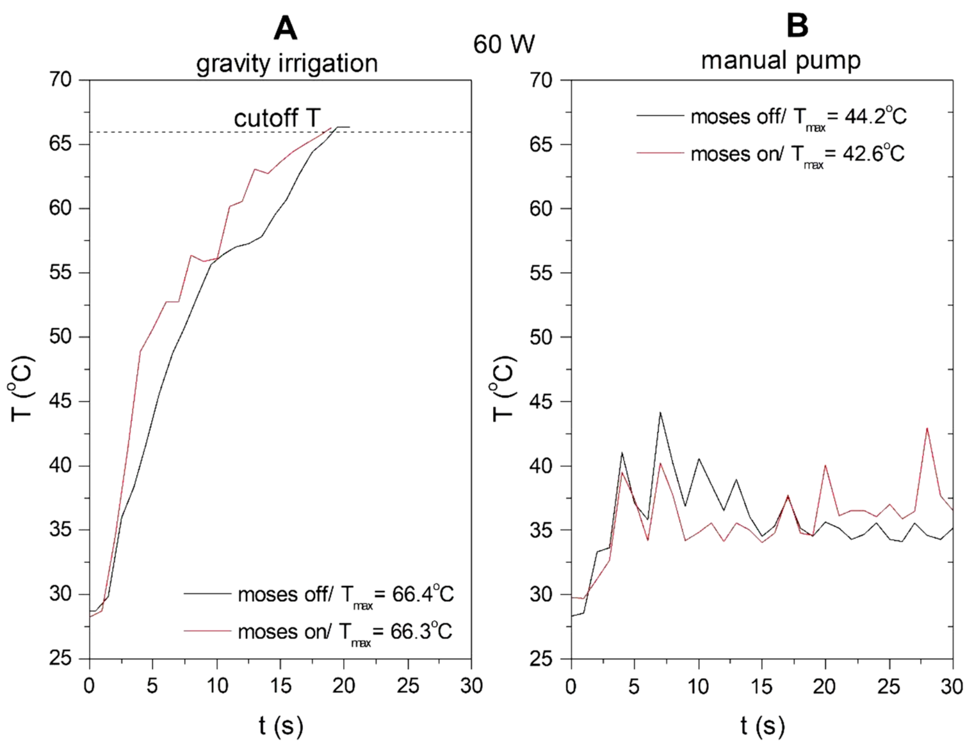

Fig. 4 **A** Activation of 200-μm laser fiber at 60 W for (approximately) 18 s under gravity irrigation, **B** Activation of 200-μm laser fiber at 60 W for 30 s under manual pump irrigation

in vivo porcine model. The experiment compares the IFTs that MOSES™ pulse delivery technology and conventional technology develop and examines the use of different irrigation conditions with three different laser power settings being activated.

It has been proved by previous studies that 43 ℃ is the limit for the urinary tract proteins to become denaturized [4]. In this study the temperature threshold that was taken into consideration for thermal damage of the urinary tract tissues was 54 ℃, since further research has shown that coagulative tissue necrosis occurs at temperatures over 54 ℃, in experiments with porcine kidney [5]. Considering the results of our study and the specific threshold, it is easily understood that the combination of ureteroscopic lithotripsy and gravity irrigation leads to hazardous temperatures for the urinary tract (Figs. 3a, 4a). The configurations in which manual pump irrigation was used, never exceeded 54℃ in any of the power settings tested (Figs. 2b, 3b, 4b). In conclusion, manual pump irrigation should be a necessary configuration, when power settings above 20 W are used for both MOSES™ technology and the conventional pulse delivery technology to avoid tissue damage (Figs. 3, 4).

In vitro studies have been performed that prove the connection between different irrigation conditions and the variation of temperature during FURS. In a study conducted by Hui Liang et al. an in vitro model mimicking FURS laser lithotripsy was created to investigate the temperature changes during Ho:YAG laser application. Laser power ranging from 10 to 30 W and irrigation flow rates between 10 and 30 ml/min were tested, in various laser firing times (3 s, 5 s, 10 s). The variance of the temperatures generated was from 25 to 78 ℃. The 20 W laser setting reached a temperature close to 73 ℃ when the irrigation was insufficient but on the contrary, while using the 30 ml/min irrigation flow rate it is noted that the recorded temperature never exceeded 43 ℃. They concluded that the temperature was rising when they were increasing the laser power, prolonging firing time, reducing the irrigation flow and the opposite [6].

In another study by Winship et al. an effort was made to mimic in vitro a normal caliber ureter and renal pelvis using a 250 ml saline bag. They used a flexible and a semirigid ureteroscope, placed within a 11/13F UAS, different irrigation flows (0, 100, 200 mmHg) and a thermocouple to record the temperatures created during the experiment. Five power settings were tested, which varied between 3.6 and 20 W. The results showed that under the lowest irrigation flow (0 mmHg) the temperature surpassed the 43 ℃ threshold during all power settings. Contrariwise, under the highest irrigation flow tested (200 mmHg) the temperature exceeded the threshold in only three power settings (10 W, 16 W, 20 W) when using the flexible ureteroscope (in total, ten measurements were recorded for both flexible and a semirigid ureteroscope). The results demonstrated that as the laser power rose the IFT also rose and the higher the irrigation pressure the lower the IFT [7]. A similar study was conducted by Hein et al. The authors performed FURS with the use of the Ho:YAG laser, to measure the thermal changes at a postmortem porcine kidney which was placed in a 37 ℃ water bath. The irrigation rates were between 0–100 ml/min and the laser power varied from 5 to 100 W. They concluded that during Ho:YAG laser lithotripsy, harmful temperatures for the urinary tract can occur even at low power settings if irrigation flow is insufficient [8].

Our previous in vivo experimental study with a porcine kidney demonstrated that the IFT did not rise to unsafe temperatures during activation of a Ho:YAG laser at powers of 10 W and 20 W. However higher power settings for the Ho:YAG laser were not tested [9]. In another study we investigated the correlation of the irrigation modes and access sheath sizes during FURS with a high-power laser, and their effects on the intra-renal temperatures. It became clear that while using gravity irrigation, the 54 ℃ threshold was surpassed in a short period of laser activation in all power settings at 40 W and above, with or without an access sheath. On the other hand, under forced irrigation, the intra-renal temperature never exceeded the threshold, even after 60 s of continuous laser activation, regardless the power or the ureteral access sheath that were used [10].

The current in vivo study, underlines the significance of the irrigation parameters and their effects on the intra-renal temperatures during FURS when MOSES™ or conventional pulse delivery technology is activated. Under gravity irrigation, the safety threshold was not surpassed only at 20 W power setting (Fig. 2a). At 40 W both technologies reached 54 ℃ in approximately 13 s (Fig. 3a), and at 60 W the lasers were deactivated at 18 s because the IFT reached the hazardous temperature of 66 ℃ (the 54 ℃ threshold was reached in about 10 s) (Fig. 4a). Contrariwise, with the use of manual pump irrigation, the IFT was never recorded above 44.2 ℃ (throughout the 30 s recording), regardless the power setting or the technology that was used (Figs. 2b, 3b, 4b). It is worth mentioning that forced irrigation leads to increased intra-renal pressures which may result to complications after surgery, with the most common of these being post-operative fever and SIRS (systemic inflammatory response syndrome) because of increased pyelovenous and pyelolymphatic absorption [11, 12].

Taking into consideration all the previous mentioned data, we can conclude that in the in vivo model, *there is no significant difference between MOSES and non MOSES technology on the IFT* under different irrigation conditions during FURS at 20 W, 40 W and 60 W power settings (Figs. 2, 3, 4). In addition, it is strongly recommended that endoscopic surgeons should *use manual pump irrigation* when using either technologies at a power setting beyond 20 W for maximal safety.

Despite the fact that this study is designed in vivo, limitations and weaknesses still exist. Firstly, the lack of stone in the experiment should be addressed. The laser was not activated in stone which means that no fragmentation took place. Fragmentation of urinary stones leads to energy absorption by the stone and so, less energy is transferred to the irrigation fluid. In that case the IFTs would be lower than our results. Therefore, our study and the IFTs we have recorded, represent the highest temperatures that a holmium laser can possibly achieve. Secondly, the continuous activation of a high-power laser for approximately 30 s is not applied in real surgery. The prolonged laser activation could result in high amount of dust, obstructing the visibility of the surgeon and compromising the safety of the procedure. Thirdly, the in vivo design of the study means that dynamic elements are present. The alive intubated pig was breathing during the whole procedure which does not allow to keep the laser fiber completely stable. We attempted to overcome this issue by repeating our measurements multiple times, and our results showed consistency. Thus, our measurements should be considered reliable. During the execution of the experiment we have performed 3 measurements for each of the three conditions to verify our results and be considered reliable. We have chosen the highest measurement to be included to the study, to indicate the "worst case scenario".

Despite the limitations, this experiment has many strengths that are worth mentioning. Its in vivo design gave as the benefit of including the heatsink effect of renal blood flow of a live porcine model in our study. The surgical instruments, the procedure and the environment are identical with the normal clinical practice. In addition, the K-type thermocouple was fixed during the whole experiment through the 30Fr sheath, ensuring that our measurements are reliable. All the above contribute so our study can be characterized trustworthy and help the medical community use the new technologies in the best way possible.

Conclusion

In conclusion, our data indicate that in the in vivo model, MOSES™ pulse delivery technology does not seem to have a significant difference in the maximal IFT in comparison to conventional pulse delivery technology during FURS in the same power settings. In addition, high-power settings (> 20 W) can be applied in clinical practice, provided that high irrigation flow is used, to keep the IFT in safe values. This can be achieved with the use of manual pump irrigation in both laser technologies.

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Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose.

Research involving animals Ethics approval was obtained from the related state services and one female pig approximately 30 kg was used.

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