

Influence of manual hand pump irrigation on intrapelvic temperature during retrograde intrarenal surgery: a thermography-based in vitro study

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Introduction Thermal injury to kidney tissue during holmium laser lithotripsy represents a significant complication. This issue is often unavoidable due to the variability of renal conditions and the absence of techniques for real-time intrarenal temperature monitoring. The objective of this research was to evaluate influence of manual hand pump irrigation on temperature of the fluid within a pelvicalyceal model during holmium laser lithotripsy.

Material and methods Laser lithotripsy of artificial stones was carried out in a 3D-printed model of the renal pelvicalyceal system. The irrigation system employed a continuous gravity approach ($P = 60 \text{ cmH}_2\text{O}$), augmented by manual pumping as required. A 9.2 Fr ureteroscope was inserted into the model via a ureteral access sheath (UAS), with sizes of either 10/12 Fr or 12/14 Fr. The power settings for the lithotripsy varied between 12 and 25 W. Temperature monitoring during the procedure was conducted using thermographic methods.

Results For all laser power settings, the temperatures recorded under gravity irrigation alone were significantly higher compared to those achieved when gravity was combined with a manual hand pump, regardless of the ureteral access sheath size. When using the hand pump system and a 12/14Fr UAS, the median temperatures in none of the laser settings exceeded 30°C . However, using a 10/12Fr UAS, the median temperatures did not exceed 35°C in any of the settings and were significantly lower compared to the use of the gravity flow system alone.

Conclusions The employment of gravity irrigation supplemented by a manually on-demand pump in retrograde intrarenal surgery is a critical component in mitigating the risk of significant temperature elevations, leading to thermal injury to the adjacent kidney tissues. Moreover, the interquartile ranges of temperatures indicating that gravity system enhanced by an on-demand pump irrigation not only reduce the median temperature but also promote a more consistent thermal environment.

Key Words: Retrograde Intrarenal Surgery ↔ intrapelvic temperature ↔ 3D printing
↔ ureteral access sheath ↔ kidney stone

INTRODUCTION

The retrograde intrarenal surgery (RIRS), which is a leading endoscopic method in kidney stones surgery worldwide, involves altering the physiological conditions in the upper urinary tract by changing

the pressure and temperature generated during the procedure. The intrapelvic temperature (ITP) produced throughout the RIRS is a multifactorial parameter, largely resulting from the irrigation conditions and the energy of the laser used for lithotripsy [1]. Since the 1990s, Holmium:YAG (Ho:YAG) laser

lithotripsy has been established as the gold standard for ureteroscopic stone treatment [2]. The primary mechanism of Ho:YAG lithotripsy involves the stones directly absorbing laser energy and undergoing chemical decomposition. Throughout this procedure, the generation of heat is not confined solely to the stone; concurrently, the fluid surrounding it within the pelvicalyceal system undergoes a considerable increase in temperature, leading to thermal injury to the adjacent tissues. The impact of heat on the surrounding tissue encompasses coagulation, carbonization, and denaturation [3]. The critical temperature for causing thermal harm to cells is established at 43°C, and it has been noted that this limit can be surpassed in pelvicalyceal and ureter models, even when utilizing standard low-power lasers settings [4].

The objective of the study was to examine the changes in real-time IPT during RIRS procedures with two different irrigation methods (gravity vs gravity supported by hand manual pump), using various energy settings from the holmium:YAG laser. The research was conducted using 3D printed models embedded with chemically synthesized stones.

MATERIAL AND METHODS

Development of the 3D printed pelvicalyceal model and artificial stones

The model of the pelvicalyceal system was created using an Ultimaker 2+ Connect 3D printer, which operates on Fused Filament Fabrication (FFF) technology. This printer used plasticized thermoplastic polyurethane (TPU), adhering to the specifications of patent application – WIPO ST 10/C PL442625. The phosphate stones were artificially created using phosphate salts (calcium phosphate), which were combined with distilled water and mixed with acrylic styrene resin. To form the stones, a hydraulic press applying a pressure of 3 MPa was used, and they were then sintered in a tube furnace at a temperature of 950 °C.

Intrapelvic temperature measurement

During laser lithotripsy, temperature monitoring within the pelvicalyceal model was achieved using the FLIR C5 thermal imaging camera, model C51.1, manufactured by FLIR Systems AB in Taby, Sweden. The analysis focused on the highest temperature levels recorded throughout the RIRS process. Situated 60 cm above the 3D model, the camera's calibration took into account the ambient temperature and the relative humidity present in the

operating room. Temperature readings were taken continuously every 30 seconds for the purpose of analysis. Recording of temperature measurements began with the start of every laser lithotripsy session, following the infusion of irrigation fluid into the model.

Study design

All retrograde intrarenal surgery procedures were conducted under nearly identical conditions, utilizing a 3D model and phosphate artificial stones of comparable size deposited in the renal pelvis of the model. The stones had an average volume of 550 mm³, calculated using the formula by Sorokin et al., $A \times B \times C \times 0.524$ [5], with their dimensions averaging 15 mm in length, 10 mm in width, and 7 mm in height. The mean density of the stones, measured by non-contrast computed tomography (NCCT), was 1078 HU (range 660–1383, SD ± 150). Each procedure, under specified laser parameters, was repeated three times. Average temperature values were used for the statistical analysis. A flexible ureteroscope (Pusen; PU3022A, 9.2Fr diameter with a maximum insertion width of 3.2 mm) was used, inserted through either a 10/12Fr (Flexor; Cook Medical; Bloomington, IN, USA) or 12/14Fr (ReTrace; Coloplast, France) ureteral access sheath, and placed around 1 cm beneath the ureteropelvic junction of the model. Stone disintegration was achieved with a holmium:YAG laser (Quanta System Cyber Ho 60W; Samarate, Italy) using a 272 mm laser fiber (Quanta System; Samarate, Italy). A constant gravity irrigation system was kept at a height of 60 cm above the model. The procedure was done by an operator with 15 years of endourology experience, including 8 years specializing in RIRS, adjusting the laser settings within a range of 12 to 25 watts for power, 10 to 15 Hz for pulse frequency, and 0.8 to 2.5 joules for energy. The manual pumping system was used on the operator's demand due to the loss of safe visibility during lithotripsy. The system was operated by an assistant with five years of experience in performing RIRS procedures. The virtual basket technique was utilized for all procedures. Endourological equipment such as the flexible ureteroscope, holmium laser fiber, and ureteral access sheath were reused and sterilized for the study. Temperature measurements within the model were taken shortly before starting lithotripsy, after the model was filled with fluid. The initial temperature inside the pelvis varied slightly between 23.2°C to 23.4°C, aligning with the ambient temperature of the irrigation fluid.

Statistical analysis

The primary objective of this analysis was to assess the influences of gravity irrigation system supplemented by on-demand manual pumping during RIRS using different holmium laser settings and two ureteral access sheath (UAS) sizes. The threshold for statistical significance in this analysis was set at $\alpha = 0.05$. An application of the Shapiro-Wilk test served to assess the normality of the distribution of variables. Analyses were carried out utilizing the R Statistical language (version 4.1.1; R Core Team, 2021) on Windows 10 pro 64 bit (build 19045), using the packages rio (version 0.5.29), ARTool (version 0.11.1), sjPlot (version 2.8.14), report (version 0.5.7), psych (version 2.1.6), ggplot2 (version 3.4.0), readxl (version 1.3.1), dplyr (version 1.1.2) and tidyr (version 1.2.0).

The study focused on analyzing temperature measurements, examining them in relation to irrigation method (gravity vs gravity + on-demand manual pump) and various laser power settings (12W, 15W, 18W, 20W, 25W) over a specified time period using two different ureteral access sheath (UAS) sizes. Data collection occurred at intervals of 0.5 minutes.

The overall duration of measurements for each set of conditions varied, ranging from 12.5 minutes to 30.5 minutes.

RESULTS

The studied sample consisted of 919 measurements, with the duration of recorded time intervals extending from 17.5 to 30.5 minutes. Table 1 has been provided which delineated the raw temperature distributions corresponding to irrigation method for 10/12Fr ureteral access sheath (UAS), segmented by the power parameter.

Analysis of the temperature distributions across different irrigation methods and power settings for the 10/12Fr ureteral access sheath (UAS) reveals statistically significant differences in median temperatures (for graphical representation see Figure 1).

For the 12W power setting, temperatures under gravity irrigation (Mdn = 39.20°C) were significantly higher compared to those achieved using gravity combined with a manual hand pump (Mdn = 30.72°C), with a $p < 0.001$. The trend of lower temperatures with the use of a manual hand pump persists consistently across tested

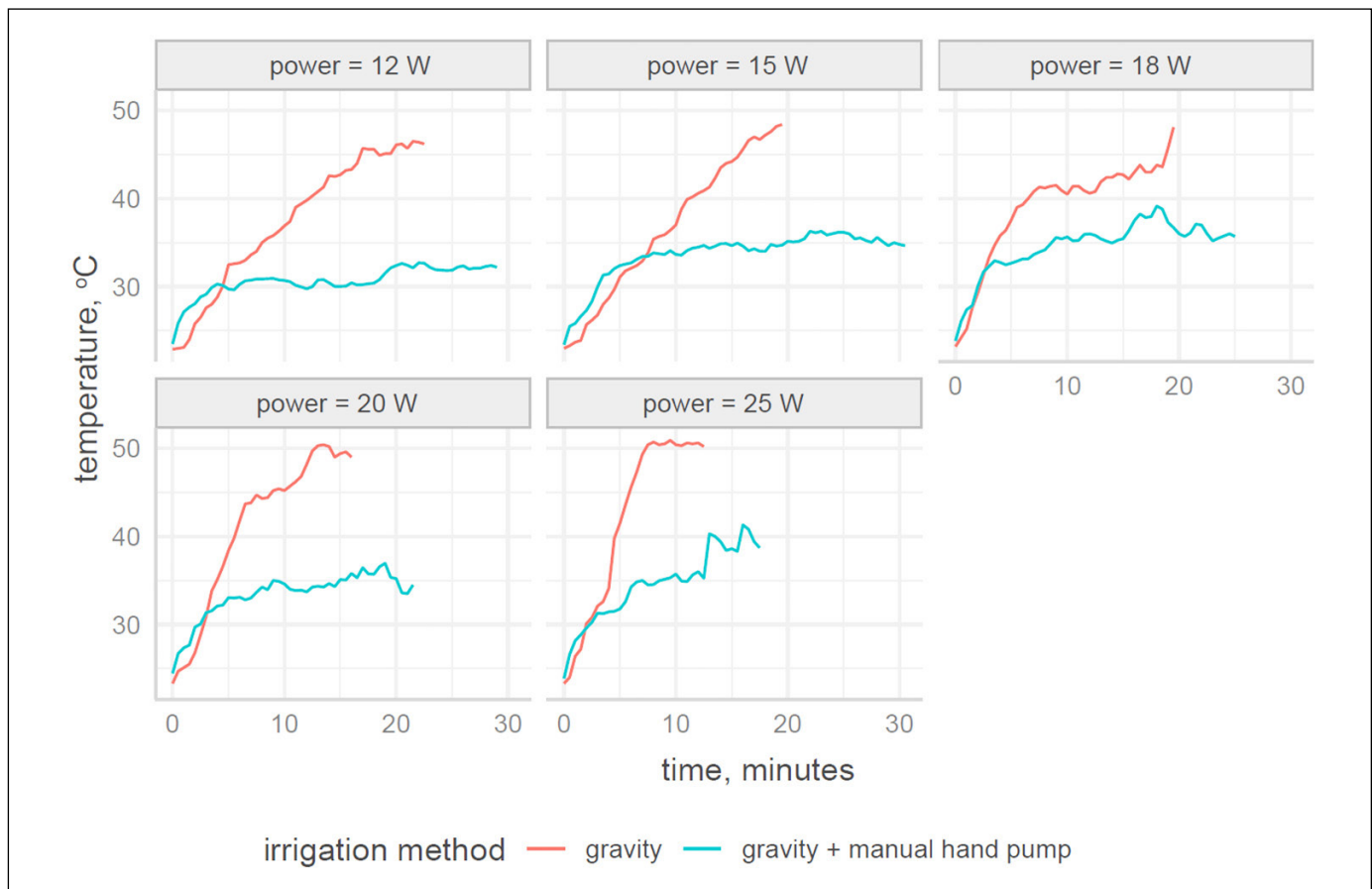


Figure 1. Temperature distribution (°C) across different power settings for 10/12Fr UAS by irrigation method.

higher power settings, with p-values indicating statistical significance (<0.001 at both 18W and 20W, and 0.007 at 25W).

At 18W, 20W, and 25W, not only temperatures were consistently lower with the combined irrigation method, but the interquartile range (IQR) also tends to be narrower, suggesting a more consistent temperature control compared to gravity alone. For instance, at 25W, the temperature under gravity alone shows

a wide range from 32.23°C to 50.40°C, whereas the combination method results in a range from 31.48°C to 38.33°C. These findings emphasize the effectiveness of integrating a manual hand pump with gravity irrigation in maintaining lower and more stable temperature distributions when using 10/12Fr ureteral access sheath (UAS) at varying power settings. The analysis of the temperature data for the 12/14Fr ureteral access sheath (UAS) size across different

Table 1. Distribution of temperatures (°C) by irrigation method for 10/12Fr ureteral access sheath (UAS)

Power	gravity		gravity + manual hand pump		p ^a
	n ₁	Mdn (Q1, Q3)	n ₂	Mdn (Q1, Q3)	
12 W	46	39.20 (32.63, 44.68)	58	30.72 (30.04, 32.08)	<0.001
15 W	40	36.70 (30.75, 44.05)	61	34.59 (33.44, 35.08)	0.028
18 W	40	41.05 (37.30, 42.48)	50	35.43 (33.15, 36.00)	<0.001
20 W	33	44.40 (35.10, 48.20)	61	33.98 (32.95, 35.01)	<0.001
25 W	26	46.45 (32.23, 50.40)	36	34.95 (31.48, 38.33)	0.007

^aWilcoxon rank sum test

n – number of measurements, Mdn – median; Q1 – the first quartile (25%); Q3 – the third quartile (75%); p – p-value of statistical test

Table 2. Distribution of temperatures (°C) by irrigation method for 12/14Fr ureteral access sheath (UAS)

Power	gravity		gravity + manual hand pump		p ^a
	n ₁	Mdn (Q1, Q3)	n ₂	Mdn (Q1, Q3)	
12 W	58	30.72 (30.04, 32.08)	56	26.96 (26.68, 27.28)	<0.001
15 W	61	34.59 (33.44, 35.08)	47	28.55 (27.98, 28.92)	<0.001
18 W	50	35.43 (33.15, 36.00)	56	27.32 (26.98, 27.73)	<0.001
20 W	44	33.98 (32.95, 35.01)	54	28.70 (28.44, 28.96)	<0.001
25 W	36	34.95 (31.48, 38.33)	42	29.11 (28.50, 29.61)	<0.001

^aWilcoxon rank sum test

n – number of measurements, Mdn – median; Q1 – the first quartile (25%); Q3 – the third quartile (75%); p – p-value of statistical test

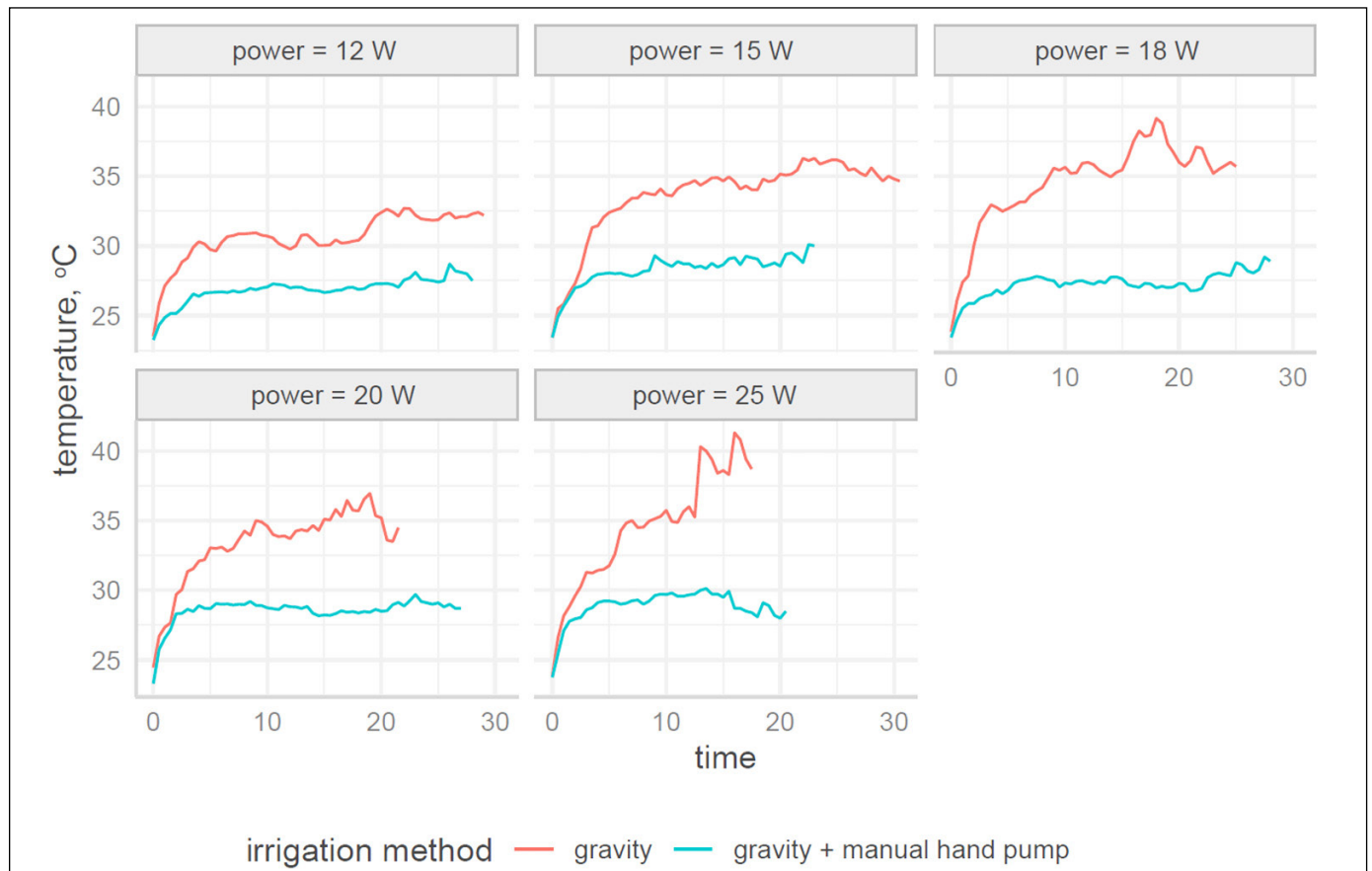


Figure 2. Temperature distribution (°C) across different power settings for 12/14Fr UAS by irrigation method.

power settings and irrigation methods also demonstrates a consistent pattern of statistically significant differences in median temperatures. Table 2 has been provided which delineated the raw temperature distributions corresponding to irrigation method, segmented by the power parameter (for graphical representation see Figure 2).

At the 12W power setting, the median temperature for the gravity irrigation method was recorded at 30.72°C. In contrast, the gravity combined with manual hand pump method showed a significantly lower median temperature of 26.96°C, yielding a $p < 0.001$. This significant reduction in temperature with the addition of the manual hand pump suggests a more efficient cooling and temperature control effect by this method. Temperature values were naturally higher when using a narrower ureteral access sheath (UAS) due to reduced flow; however, the trend of lower temperatures with the combined irrigation method persists across all power settings tested, all showing statistically significant differences with $p < 0.001$. Moreover, the interquartile ranges consistently remain narrower for the combined method across all power settings, indicating that this method not only reduces the median temperature but also provides a more stable temperature environment compared to gravity irrigation alone. The consistency of these findings across different power settings strongly indicates that integrating a manual hand pump with gravity irrigation significantly enhances temperature control.

DISCUSSION

Extensive research has been undertaken to investigate the thermal effect associated with laser lithotripsy, employing a variety of experimental frameworks and laser technologies. The temperature elevation during laser lithotripsy is influenced by a multitude of variables, among which the laser type, laser settings (notably high power and frequency), the flow rate of the irrigation fluid, duration of laser engagement, volume of the pelvicalyceal system, and the heat absorption by stone fragments during lithotripsy are significant [6–8]. The Ho:YAG and Thulium lasers stand out as the primary technologies utilized in endoscopic lithotripsy, with both systems experiencing numerous advancements over time [9]. These advancements highlight a progressive evolution in lithotripsy technology aimed at optimizing procedural efficiency and safety. One of the elements of good practice during laser lithotripsy should be maintaining a safe balance between intrapelvic pressure (IPP) and IPT – the two most

significant intraoperative physical parameters. Given the present level of technological advancement, it's not possible to monitor both parameters at the same time, making experimental research critically important. Utilizing a ureteral access sheath (UAS) can enhance the outflow of irrigation fluid, potentially reducing both intrapelvic pressure and the temperature of fluids within the kidney [10]. In their *ex vivo* research, Gallegos et al. [11] found that using a ureteral access sheath (UAS) results in reduced temperatures within the kidney, irrespective of the laser setup and the height of the irrigation solution. Employing an 12/14 Fr ureteral access sheath (UAS) led to a more gradual rise in intrarenal temperatures following one minute of laser use. This resulted in a lower temperature increase, with a difference (ΔT) of 8.8°C, when compared to scenarios where no sheath was used. Noureldin et al. [10] conducted an animal study on the impact of irrigation flow rates and the size of ureteral access sheath (UAS) on intrarenal temperature during flexible ureteroscopy using a live-anesthetized porcine model. Their research revealed that conducting surgery with gravity-based irrigation ($P = 100 \text{ cmH}_2\text{O}$) without the use of a ureteral access sheath (UAS) led to the attainment of perilously high intrarenal temperature, reaching 54°C, even when the laser power was set to a relatively low level of 20 W for a brief duration of 20 seconds of laser activation. Conversely, when utilizing pump-assisted irrigation, activating the laser at its maximum power of 60 W for a duration of 60 seconds resulted in the maintenance of intrarenal temperatures within safe thresholds. The effectiveness of integrating a manual hand pump with gravity irrigation in maintaining lower and more stable temperature distributions at varying power settings was also confirmed in our study. Regardless of the parameters used for the holmium laser, assisting the gravity flow with a manual pump as needed resulted in a significant reduction in the temperature generated by the laser, particularly noticeable during lithotripsy with a narrower ureteral access sheath (UAS) (10/12Fr). When using a 25W laser, the difference in median temperature between using the gravity system alone and the gravity system supplemented by a manual pump irrigation exceeded 11 degrees for 10/12Fr ureteral access sheath (UAS). The larger sized sheath facilitates easier backward flow of fluid around the ureteroscope compared to its smaller counterpart. This enhancement simplifies the system's filling due to an improved flow rate and accelerates drainage [12]. When using the hand pump system and a 12/14Fr ureteral access sheath (UAS), the median temperatures in none of the laser

settings exceeded 30°C. Employing a pumping system during flexible ureteroscopy is crucial for maintaining constant irrigation. It's essential to remember that poor outflow can significantly reduce the irrigation flow. Ensuring the correct placement of the sheath at the ureteropelvic junction is vital for achieving smooth fluid outflow. Moreover, the diameter of the ureteroscope's operating channel plays a significant role in affecting the flow of irrigation [6].

Our study has a few notable limitations that warrant mention. First and foremost, while our in vitro approach reflects real-life dynamics to some extent, the 3D printed model we employed does not possess the physiological attributes of an actual kidney. Key differences such as the natural vascularity of the kidney, varying blood flow rates, continuous urine production, and tissue elasticity – which allows for expansion – are significantly distinct from those in an artificial model. These differences are likely to influence temperature variations observed during the experiment. Additionally, in the context of RIRS, the generation of high intrapelvic pressure may cause a continuous backflow of irrigation solution into the venosinusoidal system, further affecting temperature dynamics within the kidney.

CONCLUSIONS

Fundamentally, the use of gravity irrigation assisted by an on-demand manual pump during RIRS is a crucial factor in reducing the risk of critical temperature increases, which could induce thermal damage to kidney structures. The observed trend of reduced temperatures using the combined irrigation method continues across all power settings tested using different ureteral access sheath (UAS) sizes. Furthermore, the interquartile ranges are consistently narrower for the combined method across all power settings, suggesting that this method not only lowers the median temperature but also ensures a more stable thermal environment compared to sole gravity irrigation.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

All the data are available within the study.

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