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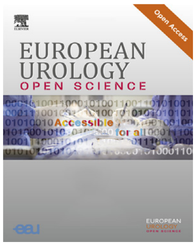

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Endo-urology

Flexible Ureteroscopic Lithotripsy with the Pulsed Thulium:Yttrium Aluminum Garnet Laser Thulio: Preliminary Results from a Prospective Study

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Abstract

Background and objective: Recently, the new pulsed thulium:yttrium aluminum garnet (p-Tm:YAG) laser technology has been introduced in endourology for lithotripsy. The aim of this study was to assess and validate the clinical laser performance and safety profile of p-Tm:YAG laser in a series of patients with renal and ureteral stones who underwent flexible ureteroscopy (fURS).

Methods: Prospective data were collected for patients who underwent fURS with the p-Tm:YAG laser Thulio (Dornier MedTech Systems GmbH, Wessling, Germany) at our institution by using two different laser fiber core diameters (270 and 200 μm). The primary endpoint of the study was stone-free rate (SFR), and the secondary endpoints were Clavien-Dindo complications grade ≥ 1 and the comparison between laser fibers of different diameters in all the parameters analyzed. Descriptive statistics relied on medians and interquartile ranges for continuous covariates, and on frequencies and percentages for categorical covariates. After stratification according to fiber types, differences between groups were tested with Wilcoxon and chi-square tests as appropriate. All the analyses and graphics were performed using R software (version 4.2.2).

Key findings and limitations: The SFR was 82% at 1-mo follow-up. In six out of 50 procedures (12%), Clavien-Dindo grade I–II complications were recorded. There were no differences regarding all the laser parameters considered between patients who were treated with 270 or 200 μm laser fibers ($p > 0.05$). Limitations of the study include small sample size in a single center and the lack of comparative groups.

Conclusions and clinical implications: In this prospective study of 50 patients who underwent fURS for ureteral and renal stones, the p-Tm:YAG laser Thulio was both effective and safe in a short-term follow-up. More prospective randomized studies

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in larger populations using different laser sources are required to confirm the clinical laser performance and safety of p-Tm:YAG laser for urinary stones treatment.

Patient summary: In this report, we looked at the outcomes for the pulsed thulium: yttrium aluminum garnet laser Dornier Thulio in patients who underwent flexible ureteroscopy for ureteral and renal stones. We found that this new laser technology is effective and safe, representing a good alternative to the other laser machines available for stone lithotripsy. We need more studies with larger populations to establish the superiority of this laser technology over the others.

1. Introduction

Laser technology is one of the most important technological innovations that have been introduced in endourology in the past three decades. Particularly, in endoscopic stone management, many cutting-edge novelties have been modifying our clinical practice in lithotripsy.

Holmium:yttrium aluminum garnet (Ho:YAG) laser has been considered the gold-standard laser for lithotripsy over the past 30 yr, thanks to its efficacy and safety profile [1,2]. Apart from the advancements of the well-known Ho:YAG laser, other lasers have been launched in endourology for lithotripsy, such as thulium fiber laser (TFL) [3] and the latest pulsed thulium:YAG (p-Tm:YAG) laser [4].

Several studies have been evaluating the laser performance of TFL, showing good outcomes in terms of dusting capabilities and low retropulsion rate [5,6], but due to its low peak power (500 W), in some scenarios, in particular in the case of hard stones, it may be not powerful enough to accomplish the best ablation rate.

Recently, the new p-Tm:YAG laser technology has been introduced in endourology for lithotripsy. Sparse clinical data have been published on this innovative technology for the treatment of upper urinary stones [7,8]. In particular, a recent study reported initial clinical experience of flexible ureteroscopy (fURS) with p-Tm:YAG laser, showing promising results in terms of efficacy and laser safety [8].

With the above limited clinical background, the aim of this study was to assess and eventually corroborate the clinical laser performance and safety profile of p-Tm:YAG laser in a series of patients with renal and ureteral stones who underwent fURS.

2. Patients and methods

Prospective data were collected for patients who underwent fURS with the p-Tm:YAG laser Thulio (Dornier MedTech Systems GmbH, Wessling, Germany) at our institution from August to October 2023. The study was approved by the local ethics committee, and the patients provided informed consent, following the ethical principles of Declaration of Helsinki.

The inclusion criteria were as follows: either sex and patients with single or multiple renal and proximal ureteral stones suitable for fURS treatment. The exclusion criteria were pregnancy, anatomic abnormalities of the upper urinary tract, and positive preoperative urine culture.

Routine preoperative and 1-mo postoperative workup included history, physical examination, urinalysis, urine culture, and blood tests.

An abdominal noncontrast computerized tomography (NCCT) scan was performed in all cases preoperatively and 1-mo postoperatively. Stone volume was reported as the volume of a single stone or the sum of the volumes of multiple stones on computerized tomography images by using the ellipsoid formula. Patients were reported to be stone free if there were no stones on postoperative NCCT.

Operative time was calculated from the first endoscope insertion to the completion of the final stent placement.

Peri/postoperative complications were reported according to the Clavien-Dindo classification system [9].

Laser fibers used had core diameters of 270 and 200 μm for the first and second set of patients, respectively. Laser fibers were used consecutively, first the 270 μm and then the 200 μm ones, regardless of the patient and stone characteristics.

Laser performance was evaluated by computing the following parameters: laser ablation efficiency (mm^3/J), laser ablation speed (mm^3/s), laser efficacy (mm^3/min), laser energy consumption (J/mm^3), laser time consumption (s/mm^3), and total operative consumption (min/mm^3).

The primary endpoint of the study was stone-free rate (SFR), and the secondary endpoints were Clavien-Dindo complications grade ≥ 1 and the comparison between laser fibers of different diameters (200 and 270 μm) in all parameters analyzed.

2.1. *Surgical technique*

Before the operation, according to the European Association of Urology guidelines, the patients were given a single shot of second-generation cephalosporin intravenously. After induction of general anesthesia, the patient was positioned in lithotomy position.

A single experienced surgeon (S.P.) carried out fURS, by using either a single-use (7.5 Fr) or a reusable (8.7 Fr) digital flexible ureteroscope. The patients were not prestented.

The irrigation system used was the T-flow Dual port (Rocamed, Monaco); passive irrigation was obtained by gravity keeping the saline bag at 40 cm above the operating bed at room temperature. When gravity irrigation was not enough, extra pressure was delivered by the assistant by gently squeezing the antireflux chamber of the abovementioned device.

A 10/12 Fr ureteral access sheath (Biflex Evo; Rocamed) was placed whenever possible; otherwise, fURS was performed sheathless. Once the stone was visualized, lithotripsy was started. Lithotripsy was performed by using the p-Tm:YAG laser Thulio (Dornier MedTech Systems GmbH) with Dornier Thulio performance laser fibers of 270 or 200 µm (single use). The following laser settings were used: energy between 0.4 and 1 J, frequency between 10 and 20 Hz, flex, long pulse modality.

The "painting technique" was used to obtain the smallest stone dust achievable. Before obtaining dust, a small fragment for a stone analysis was always caught by basketing. At the end of the procedure, a careful exploration of the ureter was done in order to check the ureteral integrity. A double-J stent was left for drainage at the end of each fURS. A Foley catheter was placed overnight. In cases where procedures were uneventful, the ureteral stent was removed after 5–7 d.

2.2. *Pulsed Tm:YAG technology*

Pulsed Tm:YAG laser was designed to combine known advantages of Tm:YAG laser, such as good coagulation and the proven pulsed properties of Ho:YAG laser [10]. Pulsed Tm:YAG laser uses a YAG crystal doped with thulium ions that is excited by diodes producing laser light that operates at a wavelength of 2013 nm. The cavity's performance requires only an internal water cooling system, minimizing laser unit size and the perceived noise; it also allows the operation on a common 240 V power supply. The p-Tm:YAG laser evaluated in this study provides 100 W maximum output power, pulse energies up to 2.5 J, pulse frequencies up to 300 Hz, and especially a peak power of up to 3.7 kW [4].

Pulsed Tm:YAG laser produces a uniform rectangular pulse profile similar to TFL, but with higher pulse peak powers of up to 3.7 kW, which generates vapor bubbles in water, similar to holmium laser but more oval-shaped than the spherical ones produced by Ho:YAG laser [11,12].

The clinical advantage of these different vapor bubble dynamics has not been evaluated yet.

2.3. *Statistical analysis*

Descriptive statistics relied on medians and interquartile ranges (IQRs) for continuous covariates, and on frequencies and percentages for categorical covariates. After stratification according to fiber types, differences between groups were tested with Wilcoxon and chi-square tests as appropriate. Laser performance parameters were evaluated as continuous covariates. Their distribution was depicted graphically, with boxplots showing the median, IQR, smallest value greater than the lower quartile minus 1.5 times the IQR, and largest value less than the upper quartile plus 1.5 times the IQR. Violin plots show the kernel probability density of the data. All the analyses and graphics were performed using R software (version 4.2.2; R Foundation for Statistical Computing, Vienna, Austria).

3. Results

A total of 50 consecutive patients met the inclusion criteria and were enrolled in the study. Demographic, stone characteristics, and peri/postoperative outcomes are reported in Table 1. Laser performance values are reported in Table 2 and Figure 1. Calcium oxalate monohydrate (COM) stones were reported in 15 cases and other stone composition types in 28 cases. In seven patients, a stone analysis was not feasible. The SFR was 82% at 1-mo follow-up. In six out of 50 procedures (12%), Clavien-Dindo grade I–II complications were recorded. No other intra- or postoperative complications were observed. For all the procedures, the target stone(s) were able to be treated, and no procedures were ended prior to completion. There were no differences regarding all the variables considered (laser ablation efficiency, speed, efficacy and laser energy consumption, laser

Table 1 – Descriptive variation

Fiber type	200 (*N* = 23)	270 (*N* = 27)	Total (*N* = 50)	*p* value
Age (yr)	58.0 (52.0, 69.0)	59.0 (51.5, 64.5)	58.5 (52.0, 67.0)	0.619
Male, *n* (%)	14 (60.9)	20 (74.1)	34 (68.0)	0.318
Body mass index	25.7 (22.6, 28.0)	26.1 (23.2, 28.4)	25.9 (22.9, 28.3)	0.340
ASA score, *n* (%)				0.131
1	0 (0.0)	4 (14.8)	4 (8.0)	
2	22 (95.7)	21 (77.8)	43 (86.0)	
3	1 (4.3)	2 (7.4)	3 (6.0)	
Renal stones, *n* (%)	19 (82.6)	18 (66.7)	37 (74.0)	0.200
Left side, *n* (%)	15 (65.2)	15 (55.6)	30 (60.0)	0.487
Number of stones	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	0.422
Stone volume	481.4 (305.2, 819.1)	643.9 (308.3, 964.3)	492.4 (300.5, 951.7)	0.690
Hounsfield unit	1190.0 (889.5, 1276.0)	1047.0 (751.0, 1339.5)	1052.5 (868.8, 1312.0)	0.559
Total energy (J)	8142.0 (2104.5, 13 150.0)	7500.0 (2292.5, 14 180.0)	7821.0 (2089.2, 13 660.0)	0.763
Lasing time (min)	7.2 (2.5, 15.8)	6.2 (3.1, 13.0)	6.7 (2.7, 13.9)	0.763
Operative time (min)	53.0 (41.0, 58.5)	44.0 (32.5, 53.5)	47.5 (38.0, 57.5)	0.083
Total pulse	8001.0 (3084.0, 16 610.0)	10 350.0 (3097.0, 16 380.0)	9625.0 (2927.0, 16 925.0)	0.869
Preoperative Hb (g/dl)	14.5 (13.2, 15.2)	14.4 (13.5, 15.1)	14.4 (13.5, 15.1)	0.808
Preoperative creatinine (mg/dl)	1.1 (0.8, 1.1)	1.1 (0.9, 1.3)	1.1 (0.9, 1.2)	0.251
Postoperative Hb (g/dl)	13.7 (12.4, 14.6)	13.7 (12.6, 14.5)	13.7 (12.4, 14.5)	0.891
Postoperative creatinine (mg/dl)	1.1 (0.9, 1.2)	1.1 (1.0, 1.4)	1.1 (0.9, 1.4)	0.392
Stone free, *n* (%)	20 (87.0)	21 (77.8)	41 (82.0)	0.400
Complications, *n* (%)	3 (13.0)	3 (11.1)	6 (12.0)	0.834

ASA = American Society of Anesthesiologists; Hb = hemoglobin.

Table 2 – Descriptive derived quality

	Fiber size (µm)		Total (N = 50)	p value
	200 (N = 23)	270 (N = 27)		
Stone free	20 (87.0%)	21 (77.8%)	41 (82.0%)	0.400
Laser ablation efficiency (mm^3/J)	0.1 (0.1, 0.2)	0.1 (0.1, 0.2)	0.1 (0.1, 0.2)	0.946
Laser ablation speed (mm^3/s)	1.3 (0.7, 2.9)	1.4 (0.8, 2.7)	1.3 (0.7, 3.0)	0.566
Laser efficacy (mm^3/min)	9.8 (5.2, 16.7)	17.0 (9.5, 23.2)	12.0 (6.2, 19.1)	0.089
Laser energy consumption (J/mm^3)	13.9 (5.2, 19.1)	13.8 (6.8, 19.0)	13.8 (5.1, 19.2)	0.946
Lasing time consumption (s/mm^3)	0.8 (0.3, 1.5)	0.7 (0.4, 1.3)	0.8 (0.3, 1.4)	0.566
Total operative time laser consumption (min/mm^3)	0.1 (0.1, 0.2)	0.1 (0.0, 0.1)	0.1 (0.1, 0.2)	0.089

time consumption, and total operative consumption) between patients who were treated with 270 or 200 µm laser fibers ($p > 0.05$; Table 2 and Fig. 1). Even considering the limited cohort, we did not find any statistically significant difference in terms of SFR between patients with COM and other stone composition types (Table 3).

4. Discussion

The ideal laser for lithotripsy should be effective, safe, capable to treat all stone sizes and compositions, and cost effective, and should integrate seamlessly into the operating room (OR).

The evaluated p-Tm:YAG laser seems to offer all these characteristics thanks to its physical features of 3.7 kW peak power and rectangular uniform pulse profile that may guarantee efficient stone ablation of all kinds of urinary calculi with low retropulsion, providing great versatility in different endourological procedures. In addition, the ease of use of this laser machine through a small footprint, easy movability, quietness, and the standard 240 V power supply offers undoubted advantages in the OR.

Pulsed Tm:YAG laser seems to be positioned favorably in the middle ground between Ho:YAG laser and TFL, having the virtues of both technologies.

With the present study, we aimed to assess the clinical laser performance and safety profile of p-Tm:YAG laser on 50 patients with renal and ureteral stones who underwent fURS.

The SFR was 82% at 1-mo follow-up with a low complication rate.

The SFR is higher than that reported by Panthier et al [8] (82% vs 55%), but in their study, the stone volume was greater than that in ours (median 492.4 mm^3, IQR 300.5, 951.7; vs 2849 mm^3, IQR 916–9153).

Although, the authors stated that the stone size in their cohort was big for fURS according to the international guidelines, they supposed that the lower SFR reported in the study than that demonstrated by Ulvik et al [13] for TFL (80%) was owing to the use of larger laser fibers of 270 µm.

In our study, in which both 270 and 200 µm laser fibers were utilized, no statistical differences were found between the two different laser fibers' calibers in terms of SFR, laser performance, and complication rate ($p > 0.05$).

Nevertheless, a limitation of p-Tm:YAG laser is the currently available fiber core sizes of >200 µm, facing the same coupling difficulties as Ho:YAG laser [14].

In contrast, current TFL offers smaller laser fibers (>150 µm) due to its uniform and focused laser beam and therefore its easy coupling [15], which certainly represents an advantage in favor of TFL.

Panthier et al [16] have demonstrated in vitro that the smaller fiber diameter of TFL allows for a smaller fragment size, but these outcomes have still to be proved in a clinical scenario. On the contrary, Taratkin et al [17] were not able to demonstrate in vitro that smaller laser fibers led to increased stone ablation or decreased dust particles size. In addition, in the latter study, the authors showed no differences in stone retropulsion, temperature increase, fiber burnback, or energy transmission between 150 and 200 µm laser fibers with straight or bended ureteroscopes. Moreover, only a minimal improvement in the deflection angle was detected for 150 µm laser fibers; both laser fibers showed a deflection angled of approximately 270°, which was akin to the flexibility without fiber.

Probably, a decreased 150 µm laser diameter may improve irrigation flow leading to better visibility during the procedure, but this hypothesis needs to be confirmed in further research.

Undoubtedly, comparative studies are needed between 200 µm p-Tm:YAG laser fibers and 150 µm TFL laser fibers.

As suggested by Kwok et al [18], in order to standardize terminology, laser performance in our study was assessed by evaluating different parameters: laser ablation efficiency was 0.1 mm^3/J (IQR 0.1–0.2), laser ablation speed 1.3 mm^3/s (IQR 0.7–3), laser efficacy 12 mm^3/min (6.2–19.2), laser energy consumption 13.8 J/mm^3 (IQR 5.1–19.2), laser time consumption 0.8 s/mm^3 (IQR 0.3–1.4), and total operative time laser consumption 0.1 min/mm^3 (IQR 0.1–0.2).

Our findings highlighted that the laser energy consumption and the laser ablation speed parallel the outcomes of Panthier et al [8], which were 14.8 J/mm^3 (IQR 6–21) and 0.75 mm^3/s (IQR 0.46–2), respectively, witnessing low and reasonable total laser energy consumption for ablation of a given stone volume.

As reported in a recent systematic review of the literature, a wide range of laser lithotripsy performance results are available for Ho:YAG laser and TFL but with high heterogeneity of data due to several laser technologies and laser settings being used; last but not least, surgical technique might also play an important role [18]. As such, it is arduous to compare these data with ours.

Moreover, a recent publication has shown that p-Tm:YAG laser in vitro is able to produce stone dust from lithotripsy of all human stone composition types analyzed, producing dust particles of ≤250 µm [19]. In addition, the same group has proved that in vitro p-Tm:YAG laser shows no

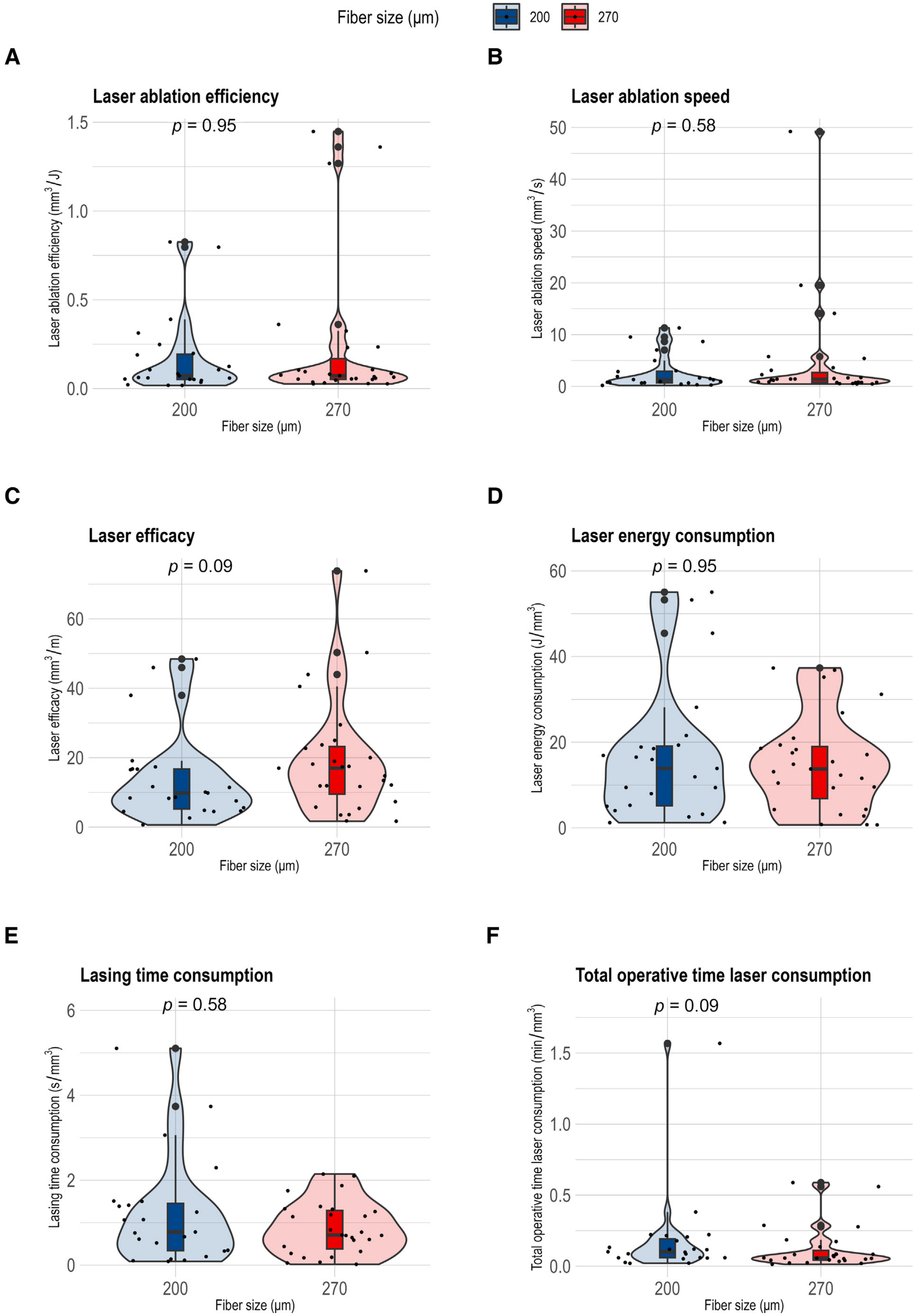

Fig. 1 – Laser performance metrics depicted with boxplots showing the median, IQR, smallest value greater than the lower quartile minus 1.5 times the IQR, and largest value less than the upper quartile plus 1.5 times the IQR. Violin plots show the kernel probability density of the data. The *p* values were derived from Wilcoxon test. IQR = interquartile range.

Table 3 – Descriptive statistics of quality derived parameters based on stone composition

	Stone composition		Total (*N* = 43)	*p* value
	COM (*N* = 15)	Other (*N* = 28)		
Stone free	13 (86.7%)	23 (82.1%)	36 (83.7%)	0.702
Laser ablation efficiency	0.1 (0.1, 0.1)	0.1 (0.1, 0.2)	0.1 (0.1, 0.2)	0.415
Laser ablation speed	1.3 (0.7, 4.3)	1.2 (0.7, 2.9)	1.3 (0.7, 3.1)	0.683
Laser efficiency	7.3 (4.1, 17.2)	11.8 (8.4, 20.7)	11.7 (5.7, 18.6)	0.114
Laser energy consumption	16.5 (8.7, 19.0)	13.8 (4.2, 19.9)	14.9 (4.7, 19.4)	0.415
Lasing time consumption	0.8 (0.2, 1.5)	0.8 (0.3, 1.3)	0.8 (0.3, 1.4)	0.683
Total operative time laser consumption	0.1 (0.1, 0.2)	0.1 (0.0, 0.1)	0.1 (0.1, 0.2)	0.114

COM = calcium oxalate monohydrate.

significant differences in ablation efficiency between the lithotripsy of COM and uric acid stones [19]. Even though we understand that it is arduous to parallel these laboratory results with a clinical scenario, in our study, we found no difference in SFR between the patients with COM and those with other stone composition types. Therefore, we may argue that the evaluated p-Tm:YAG laser is a laser with the greatest versatility, being able to dust all kinds of stones, including hard ones.

These outcomes are surely preliminary, but these pave the way for the larger future application of p-Tm:YAG laser in clinical routine.

Another in vitro study on TFL has demonstrated that this laser is also able to disintegrate all prevailing urinary stone composition types, but at the same time, it has been proved that most stone dust samples revealed changes in crystalline organization, except for COM and carbapatite, which conserved their initial characteristics [20]. This could suggest that TFL with its low peak power (500W vs 3.700 W) has more difficulties in disrupting the crystalline structure of harder stones.

Regarding the safety profile of p-Tm:YAG laser, we encountered only a low-grade complications rate in six out 50 patients (12%) and specifically not related to the use of the laser.

To date, there is no standardization of the laser settings for lithotripsy in fURS, especially regarding the p-Tm:YAG laser technology. Since this technology is clearly in its infancy, we are still figuring out the ideal setting: for sure, what we already have clear in mind is that we have to use low power settings, in particular in the ureter where its preservation from thermal damage is of utmost importance.

Petzold et al [21] demonstrated that p-Tm:YAG laser is similar to Ho:YAG laser in terms of temperature development in in vitro experiments. By using low power settings, no temperature higher than 43 °C was noted after 120 s of free laser firing. No comparative studies on intrarenal temperature between p-Tm:YAG and TFL technologies are present in the literature.

Concerning the ergonomics, a p-Tm:YAG laser machine is smaller and lighter than the high-power Ho:YAG laser and similar to or slightly heavier than some TFL machines.

Thereby, as for TFL, a p-Tm:YAG machine saves precious space in the endourological OR, which is always overcrowded with medical and radiological equipment.

In addition, similarly to TFL, another point in favor of p-Tm:YAG laser is the electrical installation in the OR. While p-Tm:YAG laser and TFL work with a 240 V standard power supply available in every OR, high-power Ho:YAG laser machines need a dedicated power supply (32 or even 64 Amp). This may require an overhaul of the electrical installation of the OR along with its related costs as well as creating mobility restrictions inside the OR [22].

Probably, similar to TFL, p-Tm:YAG laser guarantees a really quiet working environment, allowing better concentration, communication, and task completion by OR staff (maximum noise 65 dB). It has been demonstrated that TFL produces 3.1–4.3 dB less noise than holmium laser [23]; further studies are needed to evaluate the real impact of noise hazard in the OR of p-Tm:YAG laser compared with other laser technologies.

Limitations of the present study include the small sample size in a single center and the lack of comparative groups, which limits generalizability of the data.

However, this is the second study that explores the use of p-Tm:YAG laser in clinical settings in 50 patients with ureteral and renal stones, with the novel addition of a comparison of different laser fiber diameters that was never shown previously.

Prospective randomized studies in larger populations using different laser sources are required to confirm the clinical laser performance and safety profile of the new p-Tm:YAG laser in treating urinary calculi.

5. Conclusions

In this prospective study of 50 patients who underwent fURS for ureteral and renal stones, the p-Tm:YAG laser Dornier Thulio was both effective and safe in a short-term follow-up. More prospective randomized studies in larger populations with longer-term follow-up using different laser sources are required to confirm both the clinical laser performance and the safety of p-Tm:YAG laser for the treatment of urinary stones, and also potentially the superiority of this technology over the already established urology laser machines.

Author contributions: Silvia Proietti had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Proietti, Giusti.
Acquisition of data: Proietti, Oo, Scalia, Gisone, Escobar Monroy.
Analysis and interpretation of data: Proietti, Marchioni, Giusti.
Drafting of the manuscript: Proietti, Marchioni, Giusti.
Critical revision of the manuscript for important intellectual content: Proietti, Marchioni.
Statistical analysis: Marchioni.

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Other: None.

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