



# Initial clinical experience with the new thulium fiber laser: first 50 cases

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## Abstract

**Objective** To evaluate the efficacy, safety, and laser settings of thulium fiber laser (TFL) in laser lithotripsy during retrograde intrarenal surgery (RIRS) for ureteral and renal stones.

**Methods** A prospective study of the first 50 patients with ureteral and renal stones who underwent RIRS using TFL (SOL-TIVE Premium, Olympus, Japan) was performed. 200 and 150  $\mu\text{m}$  laser fibers were used for ureteral and renal stones, respectively. Stone size, stone density, laser-on time (LOT), and laser settings were recorded. We also assessed the ablation speed ( $\text{mm}^3/\text{s}$ ), laser power (W), and Joules/ $\text{mm}^3$  values for each lithotripsy.

**Results** A total of 50 patients were included in the study with a median (IQR) age of 66 (55.5–74) years old for patients with ureteral stones and 55 (44–61.5) years old for patients with renal stones. Most of the patients had a Charlson comorbidity index score of 0. Median (IQR) stone volume for ureteral stones was 486 (332–1250)  $\text{mm}^3$  and for renal stones was 1800 (682.8–2760)  $\text{mm}^3$ . Median (IQR) stone density for ureteral and renal stones was 998 (776–1300) HU and 1200 (750–1300) HU, respectively. Median (IQR) pulse energy for ureteral stones was 0.4 (0.2–0.4) J; and for renal stones, 0.3 (0.2–0.6) J. Median pulse frequency, laser power, and laser operative time were higher in the renal stones group. The overall complication rate was low in both groups.

**Conclusion** TFL is a safe and effective modality for lithotripsy during RIRS with minimal complication rates.

**Keywords** Thulium fiber laser · Urolithiasis · Urinary stones · Kidney · Ureter · RIRS

## Introduction

Laser evolution, in urology, started since the early 1960's and has gone non-stop until now [1]. A new laser technology represented by the thulium fiber laser (TFL) has been recently introduced in the market as an alternative to the current gold standard laser for urinary stone lithotripsy, the Holmium: YAG (Ho: YAG) laser [2]. One of the main advantages that this technology offers is its capacity to deliver a high power output from a small fiber core [1].

Over the past decade, divers research groups have been studying the TFL efficacy [2–4], demonstrating a superior in vitro performance, when compared to the Ho:YAG laser, in terms of a more efficient lithotripsy in both dusting and fragmentation modes, near to 1.5–4 times faster stone ablation, and a high prevention of stone retropulsion. However, in vivo studies are lacking, especially in Europe, where it became available in June 2020.

The aim of our study is to evaluate the efficacy, safety and laser settings of TFL in laser lithotripsy during retrograde intrarenal surgery (RIRS) for ureteral and renal stones. Also, we aim to compare the results obtained in this report with those previously obtained in the laboratory [5].

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## Materials and methods

### Study population

A prospective study of the first 50 patients with ureteral and renal stones who underwent RIRS using the TFL (SOLTIVE Premium, Olympus, Japan) in the period between June 2020 and November 2020 was performed, at Tenon Hospital Urology service. All patients underwent non-contrast-enhanced CT for stone volume and stone density. Stone volume was obtained with the formula of an ellipsoid ( $4/3 \times \pi \times \text{radius length} \times \text{radius width} \times \text{radius depth}$ ) and stone density was measured by Hounsfield units (HU). Exclusion criteria included patients with solitary kidney, anatomical abnormalities, and positive urine culture. All patients went through general anesthesia. Retrograde intrarenal surgery (RIRS) was performed using a flexible digital re-usable ureteroscope, the Flex—X<sup>c</sup> (Karl Storz, Germany), with a constant 0.9% saline irrigation pressure (40 cm H<sub>2</sub>O) at ambient temperature and a manual pump (Traxerflow Dual Port, Rocamed, Monaco). All the interventions were done by an experienced endourologist (OT). Lithotripsy was performed by the TFL, using laser fibers of 150  $\mu\text{m}$  for renal stones and of 200  $\mu\text{m}$  for ureteral stones. The tip of the laser fiber was cut off (not stripped), to eliminate the distal transparent part, at the beginning of every procedure. Data were collected during surgery, including laser-on time (LOT) and laser settings (pulse energy, frequency and pulse modality). We also assessed the ablation speed ( $\text{mm}^3/\text{s}$ ), the energy needed to ablate 1  $\text{mm}^3$  of stone volume ( $\text{Joules}/\text{mm}^3$ ) and the laser power ( $W = \text{Joule per second}$ ) for each lithotripsy. At the end of each surgery, we placed a ureteral stent (Double J) for 7–10 days and a Foley catheter (16–18F) was inserted for 1 day only. Postoperative complications were classified according to the Clavien–Dindo classification [6]

### TFL: operative settings and lasering technique

TFL is able to perform a variety of dusting settings [7]. We aimed at performing micro-dusting in all ureteral and renal stones cases. To date, there is no consensus on the exact definition of stone dust. Based on several experimental criteria, with a 200  $\mu\text{m}$  core diameter Ho:YAG laser fiber, our institution proposed that stone particles  $\leq 250 \mu\text{m}$  should be considered as stone dust [8]. TFL is capable of producing smaller dust particles than the Ho:YAG laser. Micro-dusting is a term associated with the previously size-related definition of stone dust; we used this term for stone particles that were smaller than the 150  $\mu\text{m}$  core diameter laser fiber.

**Table 1** Demographics of study population, stone characteristics and laser settings

	Ureteral stones	Renal stones	<i>p</i>
Total patients (n)	9	41	
Male adult, n (%)	5 (55.6%)	23 (56.1%)	0.9
Female adult, n (%)	4 (44.4%)	18 (43.9%)	
Age	66 (55.5–74)	55 (44–61.5)	0.06
Median (IQR)			
BMI	25.1 (24.2–30)	25.6 (22–28.7)	0.7
Median (IQR)			
CCI			
0, n (%)	8 (88.9%)	28 (68.3%)	0.2
1+, n (%)	1 (11.1%)	13 (31.7%)	
Mean stone volume ( $\text{mm}^3$ )	486 (332–1250)	1800 (682.8–2760)	0.06
Median (IQR)			
Number of stones			
1	8 (89%)	21 (51%)	0.03
1+	1 (11%)	20 (49%)	
Stone density (HU)	998 (776–1300)	1200 (750–1300)	0.5
Median (IQR)			
Pulse energy (J)	0.4 (0.2–0.4)	0.3 (0.2–0.6)	0.5
Median (IQR)			
Pulse frequency (Hz)	40 (20–55)	100 (50–180)	0.02
Median (IQR)			
Pulse modality			
Short pulse	8 (89%)	32 (78%)	0.7
Medium pulse	1 (11%)	7 (17%)	
Long pulse	0 (0%)	2 (5%)	

*BMI* Body mass index. *CCI* Charlson Comorbidity Index

For achieving micro-dusting, we used the dusting technique commonly described in previous reports as a “painting movement” [9, 10], this technique requires continuous movement of the tip of the laser fiber over the stone’s surface without touching the stone. We kept a laser fiber—stone distance of 1 mm, almost never lifting the foot from the laser pedal and respecting the “safety distance” between the laser fiber’s tip and the scope to avoid instrumental damage [11], which means that the laser tip was placed at one quarter of the distance to the monitor.

### Outcomes measurements and statistical analysis

For laser lithotripsy efficacy, we estimated  $\text{Joules}/\text{mm}^3$  by dividing the total amount of energy delivered by the TFL by the pre-operatively estimated stone volume. The ablation speed was calculated as the stone volume divided by the laser active time, and the laser power was represented

by the Joules per second. LOT was defined as the total lithotripsy time. Complications were classified according to the Clavien–Dindo classification.

For statistical analysis, we used SPSS 27.0 Windows (IBM Inc, New York, USA). Categorical variables were measured as percentages and numerical variables are expressed as medians (interquartile range (IQR)). Mood's median test was performed to compare median scores. Pearson's Chi-squared test was used to obtain the association between categorical variables. *P* values < 0.05 were considered significant.

## Results

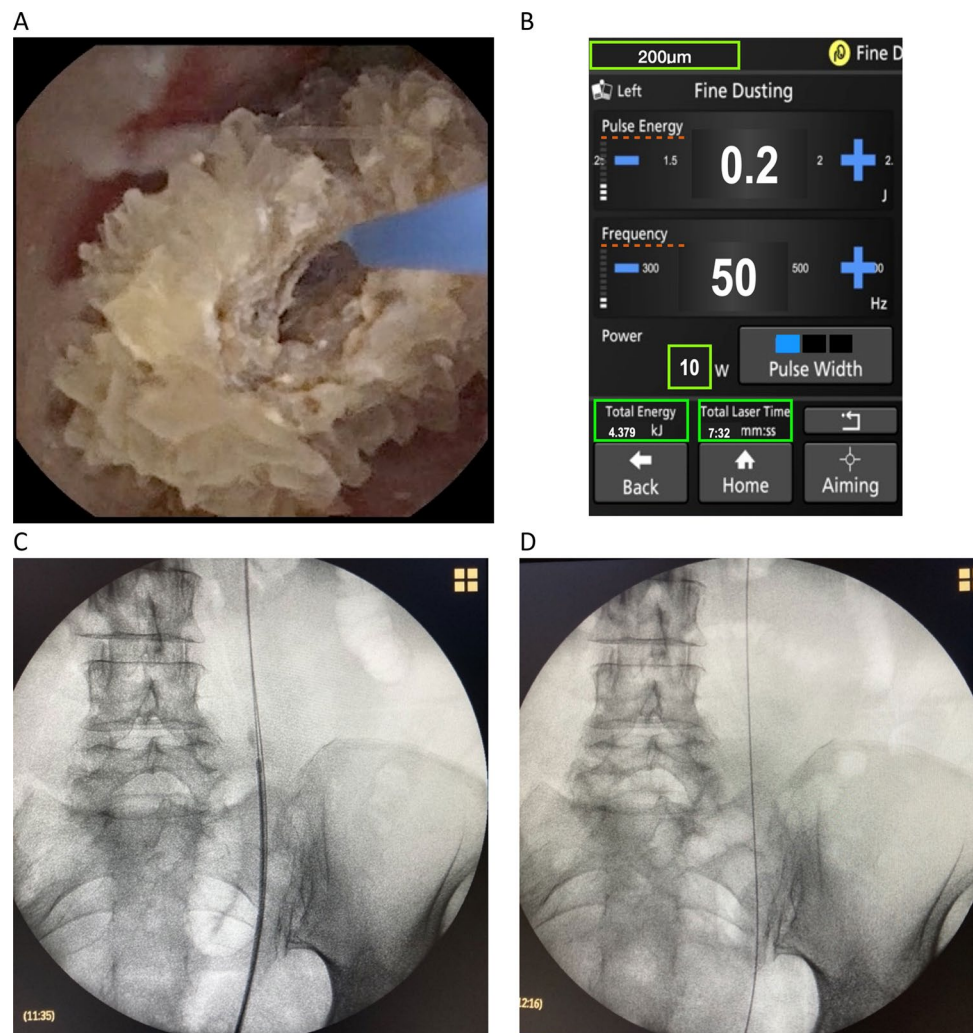
Demographics of the study population included in this report are shown in Table 1. Median (IQR) age for patients with ureteral stones was 66 (55.5–74) years old and for patients with renal stones was 55 (44–61.5) years old, without statistically significant difference between groups.

Most of the patients had a Charlson comorbidity index (CCI) score of 0.

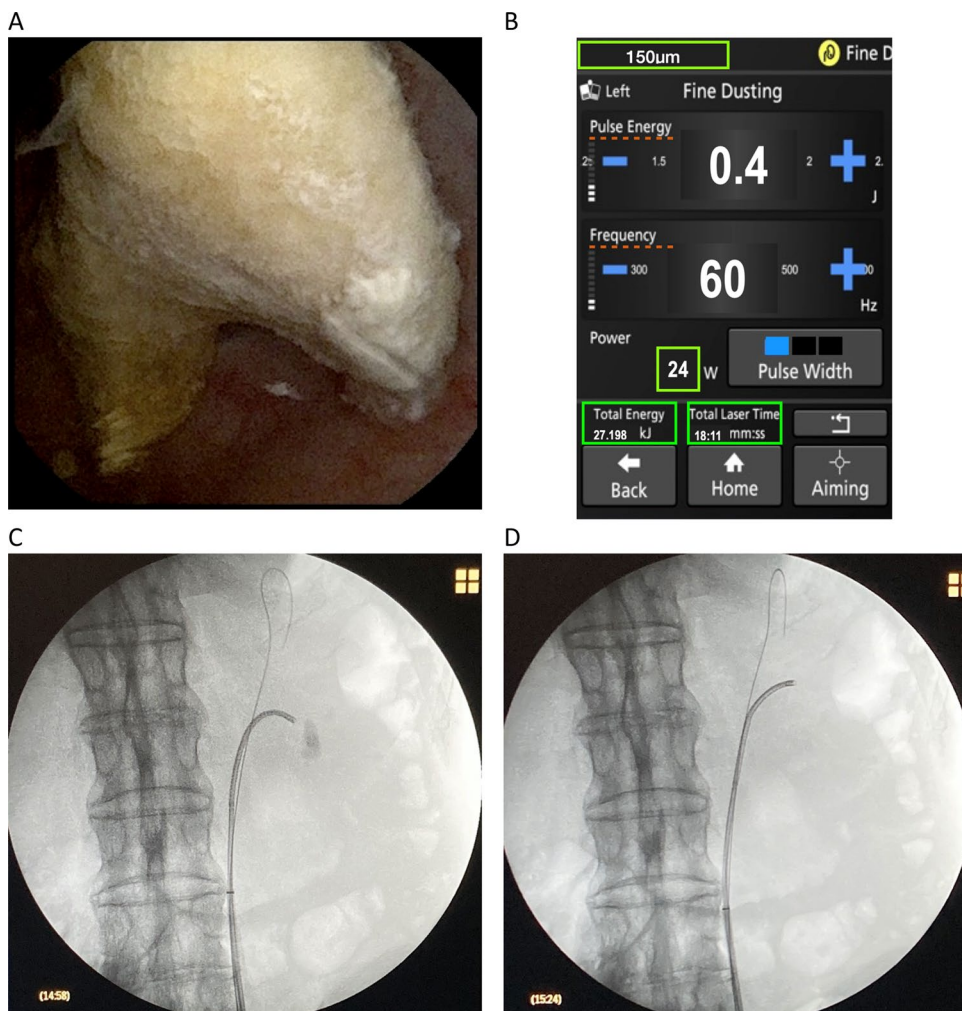
Summary of stone characteristics and laser setting are also shown in Table 1. Median (IQR) stone volume for ureteral stones was 486 (332–1250) mm<sup>3</sup> and for renal stones was 1800 (682.8–2760) mm<sup>3</sup>. Median (IQR) stone density for ureteral and renal stones was 998 (776–1300) HU and 1200 (750–1300) HU, respectively. Those results were similar and not statistically significant. Most patients had a solitary stone. According to laser settings, median (IQR) pulse energy and frequency for ureteral stones were 0.4 (0.2–0.4) J and 40 (20–55) Hz, respectively; and for renal stones, 0.3 (0.2–0.6) J and 100 (50–180) Hz, respectively. Statistically significant difference was observed between groups when compared in terms of pulse frequency. Short pulse was chosen as the most common pulse modality. A case example for laser settings in ureteral and kidney stones are shown in Figs. 1 and 2, respectively.

TFL study outcomes and peri-operative complications are summarized in Table 2. Median (IQR) LOT for ureteral

**Fig. 1** Ureteral stone laser settings example. **a** Left ureteral stone. Stone density: 1300 HU, stone volume: 500 mm<sup>3</sup>. **b** TFL settings. Energy: 0.2 J, frequency: 50 Hz and laser power: 10 W. Total energy: 4.379 kJ. Total laser time: 07:32 mm:ss. **c** Fluoroscopy before the intervention. **d** Fluoroscopy after the intervention



**Fig. 2** Kidney stone laser settings example. **a** Left kidney stone. Stone density: 1600 HU, stone volume: 1800 mm<sup>3</sup>. **b** TFL settings. Energy: 0.4 J, frequency: 60 Hz and laser power: 24 W. Total energy: 27.198 kJ. Total laser time: 18:11 mm:ss. **c** Fluoroscopy before the intervention. **d** Fluoroscopy after the intervention



**Table 2** TFL study outcomes and peri-operative complications

	Ureteral stones	Renal stones	<i>p</i>
Laser-on time (minutes)	9.3 (7.3–17)	23 (14.2–38.7)	0.01
Median (IQR)			
J/mm <sup>3</sup>	16.3 (8.6–35.5)	18.6 (9.5–26.1)	0.7
Median (IQR)			
Ablation speed (mm <sup>3</sup> /s)	0.7 (0.3–1.6)	1.16 (0.8–2.1)	0.3
Median (IQR)			
Laser power (W)	8 (6.5–16)	24 (20–32)	0.01
Median (IQR)			
Complications (Clavien–Dindo)			
No complication	8 (89%)	38 (93%)	0.8
Grade 1–2	1 (11%)	2 (7%)	
Grade > 2	0 (0%)	0 (0%)	

stones was 9.3 (7.3–17) minutes and for renal stones was 23 (14.2–38.7) minutes with statistically significant difference between groups. The median (IQR) amount of energy needed to ablate 1 mm<sup>3</sup> of stone volume in the

ureter and in the kidney was 16.3 (8.6–35.5) J/mm<sup>3</sup> and 18.6 (9.5–26.1) J/mm<sup>3</sup>, respectively, without statistically significant difference between groups. Median (IQR) ablation speed was 0.7 (0.3–1.6) mm<sup>3</sup>/s for ureteral stones and 11.16 (0.8–2.1) for renal stones, also, without statistically significant difference between groups. Focusing on the median (IQR) laser power, it was higher for kidney stones than for ureteral stones, 24 (20–32) vs 8 (6.5–16), *p* = 0.01. Micro-dusting was achieved in all cases. Complications analyzed by the Clavien–Dindo classification system were similar and relatively low in both groups, with Clavien grade I and II only.

**Discussion**

TFL technology was introduced into the medical world recently [12] as an alternative to the well-known gold standard laser for urinary stones lithotripsy, the Ho:YAG laser. One of the limitations of the Ho:YAG laser architecture is the multimodal output beam with hotspots that

prevents to tightly focus down into a small spot; therefore, the need to work with optical fibers of 200  $\mu\text{m}$  core diameter or larger [2]. On the contrary, TFL consists of a very thin silica fiber of 10–20  $\mu\text{m}$  core diameter and a length of 10–30 m. The light originates within the core of that small optical fiber and for laser pumping, thulium ions are excited by multiple diode lasers [1]. The resulting laser beam has a wavelength of 1.94  $\mu\text{m}$  that can work in a continuous or pulsed mode, reaching an average laser power of 50–55 W [2]. We decided to use a 200- $\mu\text{m}$  fiber for ureteral stones and a 150- $\mu\text{m}$  fiber for renal stones principally because the latter offers a better flexibility and minimizes scope deflection loss when compared to  $\geq 200$   $\mu\text{m}$  laser fibers [1, 13]. In terms of pulse duration, the urologist can choose between short, intermediate and long pulse duration. TFL offers the most wide and flexible range of parameters when compared to other lithotripters. For instance, it can deliver a pulse energy of 0.025–6 J (0.005 J for some prototypes), a pulse frequency of 5–200 Hz, a pulse duration of 200–12 000  $\mu\text{s}$  and a maximum average laser power of 50–55 W [5]. Suggested settings for the dusting/fragmentation of ureteral stones are 0.2–0.5 J/10–15 W, for dusting of kidney stones 0.1–0.2 J/15–30 W and for fragmentation of bladder stones, 2–5 J/30–50 W. [14]. In the current report, we performed endoscopic lithotripsies for ureteral and kidney stones using, mostly, a short pulse mode and reaching a median laser power of 8 and 24 W, respectively. The lower laser power used in the ureter, by keeping a low frequency, helped us to respect the integrity of the ureter. The energy delivered in the ureter and in the kidney were similar to the previously recommended settings [14], using a higher frequency in the kidney vs the one delivered in the ureter ( $p=0.02$ ). This combination makes it possible to obtain a fine micro-dusting [15, 16], not seen with the Ho:YAG laser [2]. Our results are similar to those previously reported by Enikeev et al. [17] that mentioned a more efficient renal stone dusting after performing RIRS with a higher frequency regimen (0.5 J  $\times$  30 Hz = 15 W vs 0.15 J  $\times$  200 Hz = 30 W vs). The retropulsion seen with the high frequency Ho:YAG laser was not observed in our study, agreeing with TFL in vitro results from another authors [3, 18, 19].

To assess the efficacy of Ho:YAG laser lithotripsy for the treatment of upper tract urinary stones, Ventimiglia et al. [20] introduced the concept of  $\text{J}/\text{mm}^3$ , which is the total energy needed to ablate 1  $\text{mm}^3$  of stone volume. The current gold standard laser had a median of 19  $\text{J}/\text{mm}^3$  for stones with median HU of 1040. The principal energy influencer was stone density, meaning that for urinary stones above 1000 HU, the energy delivered for stone ablation would be higher; followed in much less importance by stone volume [20]. In this report, we noticed that less energy is needed to ablate 1  $\text{mm}^3$  of stone volume in both ureteral and renal stones, regardless stone density, translating a more efficient

energy delivery with the TFL. This reaffirms its capacity to produce stone dust from all prevailing stone types [16]. Furthermore, the ablation speed was higher for renal stones, two times faster stone ablation than the average one documented by the Ho: YAG laser [2, 19]. It has been published before that TFL even reduces operative time by 20–40%, when associated with dusting settings with higher frequencies [17, 21]. Additionally, the small retropulsion generated by this technology can also contribute to the more precise lasering and the reduced operative time [19].

Complication rate was low and similar in both groups, mostly Clavien grade I and II. None of the complications was related to the TFL, which infers its safety and reproducibility in human beings.

This promising technology correlates with the expectations already made before its release onto the market, for urological purposes. Moreover, it could become the new gold standard for urinary stones lithotripsy.

This report has some limitations. The first and main one is the absence of a comparison group, using the Ho:YAG laser. Nonetheless, the aim of this pilot study was to show our initial experience with this new technology, without a more specific patient selection. Second, the small sample size, due to its recently arrival in Europe and the lack of a longer follow-up. Third, the lack of consensus of the most appropriate laser settings. Since this is a new technology, recommendations for TFL lithotripsy are mainly based on in vitro and a few in vivo experiences. Further randomized control trials are needed to arrive to more precise conclusions.

## Conclusions

TFL is a safe and effective modality for lithotripsy during RIRS with minimal complication rates. Its particular properties have made for this laser to be a promising alternative for the current gold standard laser. Further clinical trials with this new technology are needed to reaffirm the preliminary results obtained in this initial experience.

**Author contribution** MC: Data collection, data analysis, and manuscript writing. OT: protocol/project development, and manuscript editing.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest. Prof. Olivier Traxer is a consultant for Coloplast, Rocamed, Olympus, EMS, Boston Scientific and IPG.

**Research involving human participants, their data or biological material** Approval was obtained from the ethics committee of Tenon Hospital. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

**Consent to participate** Verbal informed consent was obtained prior to the surgery, when interviewed with the patient in the Urology service.

**Consent to publish** The authors affirm that human research participants provided informed consent for publication of the images in Figs. 1 and 2.

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