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Initial clinical experience with the pulsed solid-state thulium YAG laser from Dornier during RIRS: first 25 cases

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Abstract

Introduction Holmium:yttrium–aluminium–garnet (Ho:YAG) and thulium fiber (TFL) lasers are currently the two laser sources recommended for endocorporeal laser lithotripsy (ELL). Recently, the pulsed-thulium:YAG (Tm:YAG) laser was also proposed for ELL, as an answer to both Ho:YAG and TFL limitations. We aimed to evaluate the efficiency, safety, and laser settings of Tm:YAG laser in ELL during retrograde intrarenal surgery (RIRS).

Methods A prospective study of the first 25 patients with ureteral and renal stones who underwent RIRS using the Thulio (pulsed-Tm:YAG, Dornier©, Germany) was performed in a single center. 272 μm laser fibers were used. Stone size, stone density, laser-on time (LOT) and laser settings were recorded. We also assessed the ablation speed (mm^3/s), Joules/ mm^3 and laser power (W) values for each procedure. Postoperative results, such as stone-free rate (SFR) and zero fragments rate (ZFR) were also recorded.

Results A total of 25 patients were analyzed (Table 1). The median (IQR) age was 55 (44–72) years old. Median (IQR) stone volume was 2849 (916–9153) mm^3 . Median (IQR) stone density was 1000 (600–1174)HU. Median (IQR) pulse energy, pulse rate and total power were 0.6 (0.6–0.8)J, 15(15–20)Hz and 12(9–16)W, respectively. All procedures used “Captive Fragmenting” pulse modulation (Table 2). The median (IQR) J/ mm^3 was 14,8 (6–21). The median (IQR) ablation rate was 0,75 (0,46–2) mm^3/s . One postoperative complications occurred (streinstrasse). SFR and ZFR were 95% and 55%, respectively.

Conclusion The pulsed-Tm:YAG laser is a safe and effective laser source for lithotripsy during RIRS, using low pulse energy and low pulse frequency.

Keywords Thulium YAG · Ureteroscopy · Laser · Lithotripsy · Volume

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Introduction

Holmium:yttrium–aluminium-garnet (Ho:YAG) laser has been the main player for endocorporeal laser lithotripsy (ELL) since 1992; however, new laser technologies like the Thulium Fiber Laser (TFL) have recently emerged.

TFL is now recommended by the French Association of Urology as an alternative to the Ho:YAG laser in their urolithiasis guidelines, since studies have shown it to be effective in treating stones by ELL [1–4]. TFL emits a 1940 nm wavelength, resulting in a threefold higher water absorption coefficient and presents a low peak power (500W) with a uniform pulse profile (“superpulse”) [1]. As a result of these two aspects, the laser safety is improved (low levels of urothelial mucosae lesions) and also, the ELL efficiency is improved due to a lower level of retropulsion than with the Ho:YAG laser [5, 6]. Nonetheless, TFL’s peak power level could not be sufficient for treating hard stones, with a consequent loss of ablation rate. As the newest advance in endourology, the pulsed-Thulium:YAG (Tm:YAG, Dornier MedTech Laser GmbH, Wessling, Germany) suggested since 2021, has been released [7]. With a wavelength of 2013 nm, Tm:YAG could represent the perfect compromise between the Ho:YAG and TFL technologies, associating an intermediate water absorption coefficient, a relatively high peak power (500–2000 W) and a uniform pulse profile. According to promising *in vitro* studies, it has lower retropulsion forces (especially with longer pulse durations), similar temperature levels, and higher ablation rates than the Ho:YAG laser [7–9]. Although Tm:YAG and TFL dusting efficiency were similar, Tm:YAG and Ho:YAG fragmentation performance was better than the TFL’s [10, 11].

To date, Tm:YAG has not been clinically evaluated. Thus, we aimed to evaluate the efficacy, safety and laser settings of Tm:YAG laser in ELL during retrograde intrarenal surgery (RIRS) for ureteral and renal stones.

Methods

Study population

A prospective study of the first 25 patients with ureteral and renal stones who underwent RIRS using the Tm:YAG laser (Dornier MedTech Laser GmbH, Wessling, Germany) between December 2022 and February 2023 was performed, in a single center. Written Informed consent was obtained before surgery for each patient (IRB approval: CERU-AFU2020/003). Patients presenting with unique or multiple renal or ureteral stone, confirmed on

non-contrast computed tomography (NCCT) and planned for retrograde intrarenal surgery (RIRS) were eligible for inclusion. Low dose and standard NCCT protocols were managed for non-obese and obese patients, pre- and post-operatively [12]. Based on preoperative NCCT, stone volume and stone density (Hounsfield units (HU)) were estimated, using three-dimensional segmentation with 3DSlicer [13, 14]. Exclusion criteria included patients with untreated preoperative positive urine culture or combined or percutaneous procedures. Stones were classified according to their number and morphology: a unique stone was defined as solitary stone, based on NCCT segmentation (“split into islands” module of 3DSlicer < 50Voxels) and a complex stone as complete or incomplete staghorn stones. Urolithiasis pathology were defined as a medical condition directly associated with urinary stones (cystinuria, tubular renal acidosis for example). All patients underwent general anesthesia. Retrograde intrarenal surgery (RIRS) was performed by a single surgeon (FP) using non-disposable digital or fiber optic flexible ureteroscopes (Flex—Xc or Flex-X2, Karl Storz®, Germany) with a gravity-based 0.9% saline irrigation pressure (40 cm H₂O) at ambient temperature and a manual pump (Traxerflow Dual Port, Rocamed®, Monaco).

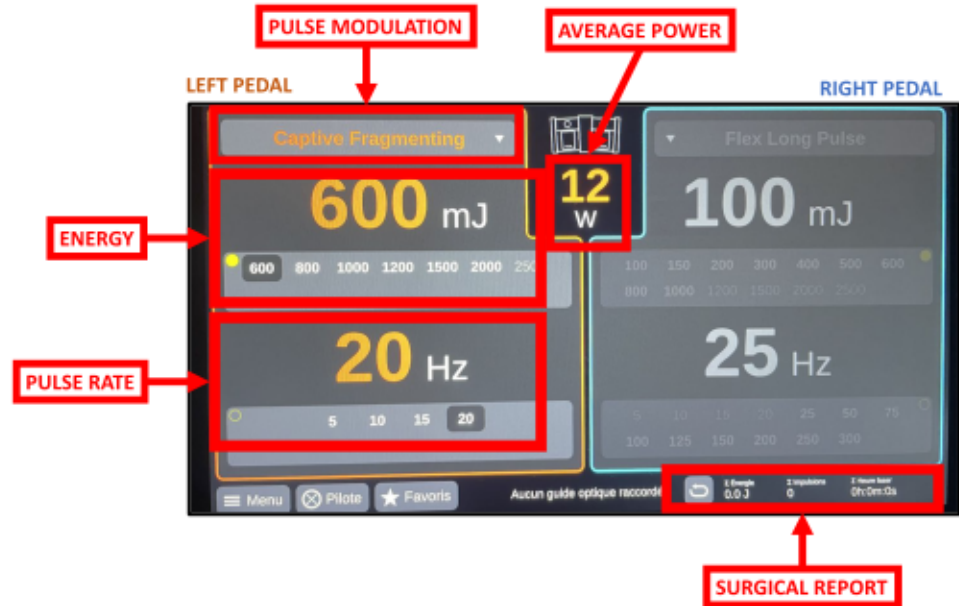
Lithotripsy was performed by the pulsed-Tm:YAG laser, using single-use laser fibers of 270 μm. The tip of the laser fiber was cut off (not stripped) by standard scissors, to eliminate the distal transparent part, at the beginning of every procedure. Intraoperative data were collected during surgery, including laser-on time (LOT) and laser settings (pulse energy, frequency and pulse modality). Each lithotripsy’s ablation efficiency was calculated based on its ablation speed (mm³/s) and energy needed to ablate 1 mm of stone volume (Joules/mm³). 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, in case of over 60 min operative time, solitary kidney and suspicion of infected stones. Postoperative complications were classified according to the Clavien–Dindo classification [15].

Thulium:YAG: operative settings and lithotripsy technique

The graphical user interface (GUI) of the Thulium:YAG laser generator is summarized in Fig. 1. Several pulse modulations (flex long pulse, short pulse, dusting, manual, captive and standard fragmenting) with suggested pre-settings are available [16]. Similar to Ho:YAG and TFL, there are no consensus or individual pre-setting recommendations for Tm:YAG laser [17, 18]. Based on our ELL technique maintaining a continuous laser activation, we aimed to perform stone dusting, respecting low frequency (< 30 Hz)/low power settings (< 30W). Using the

Fig. 1 Thulium:YAG “Thulio” Generator’s graphical user interface

THULIO’S GRAPHICAL USER INTERFACE



painting technique, we tried to obtain the smallest fragments sizes until stone dust was achieved. Floating particles believed to be $< 250 \mu\text{m}$ in diameter were described as stone dust [19, 20]. The pulse energy was increased if needed, to achieve the desired stone fracture. The frequency was then adapted to the possible ablation speed, and laser fiber displacement velocity. In case of ureteral stone, pulse energy, frequency and total power were limited to 0.8 J, 10 Hz and 8W, respectively, whereas for renal stones, 15W maximal power was respected with 1 J maximal pulse energy. Laser fiber to stone distance was adapted to intraoperative observations.

Outcome measurement and statistical analysis

As previously described, J/mm^3 and mm^3/s were used as efficacy and efficiency coefficients [21]. Postoperative NCCT measurements of residual stone volume were subtracted from preoperative measurements for complex stone cases. Thus, we were able to calculate mm^3/s and J/mm^3 for these patients. The success depended on the postoperatively stone-free rate (SFR) and zero-fragment rate (ZFR). SFR was defined as the absence of residual fragments $> 3 \text{ mm}$ on a NCCT in bone window and the ZFR was defined as the total absence of fragments. Both, the SFR and ZFR are reported for all patients (intention to treat) and for those who did not have complex cases (multiple sessions). Complications were classified according to the Clavien–Dindo classification [15].

Statistical analysis

For statistical analysis, we used GraphPad Prism and Rstudio. Categorical variables were measured as percentages and numerical variables are expressed as medians (interquartile range (IQR)).

Results

Table 1 summarizes the demographics of the included population. Median (IQR) age was 55 (44–72) years old, with a sex ratio (M/F) of 4. Mean ASA score was 2. Median (IQR) BMI was 25 (22,9–28). Three patients presented known infectious urolithiasis disease and four of them an anatomic abnormality: pyelo-ureteral junction obstruction [2], solitary kidney with ureteral stenosis [1] and incomplete ureteral duplication [1]. Regarding the pyelo-ureteral junction obstruction cases, a 7.5 Fr ureteroscope was admitted without difficulty in both cases. Stone surgery was managed first before renal scintigraphy assessment of the obstruction degree. Considering the stone characteristics, 68% of patients presented non-complex renal stones, 20% a complex renal stone, 8% a ureteral stone. One patient was planned for RIRS but a spontaneous migration of the stone into the bladder was observed. Therefore, after confirming the absence of stone in the renal cavities, ELL was done with f-URS in the bladder. A unique multiple and complex stones were reported in 8, 12 and 5 patients, respectively. Median (IQR)

Table 1 Demographic and stone characteristics

Variables		Values	
Patients (n)		25	
Age (IQR)		55 (44–72)	
Gender	Female (%)	20%	
	Male (%)	80%	
ASA score		2	
BMI (IQR)		25 (22,9–28)	
Comorbidities	High blood pressure (%)	13 (52%)	
	Obesity (%)	6 (24%)	
	Diabetes (%)	4 (16%)	
	Urolithiasis pathology (%)	3 (12%)	
Anatomic abnormalities (%)		4 (16%)	
Current stone	Localization	Superior Calyx	8 (32%)
		Inferior Calyx	2 (8%)
		Pelvis	7 (28%)
		Complex	5 (20%)
		Ureteral	2 (8%)
		Bladder	1 (4%)
	Side	Left (%)	7 (28%)
		Right (%)	16 (64%)
		Bilatéral (%)	2 (8%)
	Number of stones	1 (%)	8 (32%)
		> 1 (%)	12 (48%)
		Complex	5 (20%)
	Stone density (IQR)		1000(600–1174) UH
Maximum diameter (mm)		20 (12–30)	
Median (IQR)			
Volume (mm ³)		2849 (916–9153)	
Median (IQR)			

Table 2 Perioperative results

Variables		Values
Laser on time (min)		35 (21,3–52,11)
Laser settings	Energy (J)	0,6 (0,6–0,8)
	Pulse rate (Hz)	15 (15–20)
	Power (W)	12 (9–16)
	Pulse modulation	Captive fragmenting (100%)
Total energy (kJ)		26 (11,94–32,8)
J/mm ³		14,8 (6–21)
Ablation speed (mm ³ /s)		0,75 (0,46–2)
Post-operative stenting		24 (96%)
Stone-free rate (< 3 mm)		19/20 (95%)
Zero fragment rate (< 1 mm)		11/20 (55%)
Intention to treat	Stone free rate (< 3 mm)	19/25 (76%)
	Zero fragment rate (< 1 mm)	11/25 (44%)
Complications	Clavien–Dindo 1–2	1/25 (4%)
	Clavien–Dindo 3–4	0
Median (IQR)		

stone volume was 2849 (916–9153)mm³. Median (IQR) stone density was 1000 (600–1174)HU.

Table 2 presents the peri-operative outcomes. Regarding the laser settings, median (IQR) pulse energy, pulse rate and total power were 0.6 (0.6–0.8)J, 15 (15–20)Hz and 12 (9–16)W, respectively. As described earlier, we respected a low frequency–low power setup (< 30 Hz, < 30W). All procedures used “Captive Fragmenting” pulse modulation mode. An example of the Tm:YAG’s GUI is represented in Fig. 1 and a ELL videoclip is available in supplementary material 1. The median (IQR) J/mm³ was 14,8 (6–21). The median (IQR) ablation rate was 0,75 (0,46–2)mm³/s. No per-operative complication occurred, especially no vision impairment due to micro-bleeding. Only one patient (with solitary kidney) had Clavien–Dindo 2 complication postoperatively. This patient, who had a 90 min LOT and double J placement for a complex stone, presented with anuria at postoperatively day 3. Postoperative day 3 NCCT revealed Steinstrasse of small particles which was treated by double J replacement. Steinstrasse was then spontaneously evacuated aside the double J. The SRF was 95% and the ZFR was 55%, and 76% and 44%, respectively, when including complex cases (intention to treat).

Post-operative renal fragments < 3 mm were monitored by ultrasound at 6 month follow-up.

Discussion

Thulium:YAG’s technology

We report a clinical evaluation of ELL during RIRS with the new pulsed Tm:YAG laser, which has been suggested as being a compromise between Ho:YAG and TFL, with the advantages of both technologies. Tm:YAG is a conventional cavity laser (likely to Ho:YAG laser) but the light is produced by diode lasers (as the TFL). The YAG crystal is doped with Thulium ions, producing a 2013 nm wavelength and 100 W power in a single cavity. The cavity’s performance only requires an internal closed-loop water cooling system, minimizing the precepted noise. The pulse profile is supposed to be uniform with a peak power ranging from 500 to 200 W, depending on the pulse modulation mode. These characteristics may confer to this new technology a higher peak power compared to TFL, but with the same uniform “superpulse” [1]. To our knowledge, no data have been published to confirm these results but are mandatory for further evaluations. Induced vapor bubble (IVB) dynamics with Tm:YAG have been compared to Ho:YAG, in vitro [22]. Tm:YAG presents longer IVB and longer pulse durations when compared to the Ho:YAG laser. Moreover, oval shaped IVB are found with Tm:YAG whereas Ho:YAG’s IVB are more spherical. These findings are also found

when comparing TFL and Ho:YAG [23, 24]. Additionally, the retropulsion forces, measured in vitro with a piezoelectric sensor, were lower than Ho:YAG’s [8]. We can suggest Tm:YAG’s lower peak power can explain the in vitro equivalence between TFL and Tm:YAG laser and their superiority to Ho:YAG in terms of stone dusting [10]. Further studies are needed to validate Tm:YAG’s effectiveness and position between TFL and Ho:YAG given the limited number of publications on it, which are mainly in vitro experiments.

Preclinical and clinical results

The present study reports 76% SFR and 44% ZFR during RIRS for stone treatment. In a previous clinical trial, Ulvik et al. reported a SFR of 92% and 67%, and a ZFR of 80% and 57% for TFL and Ho:YAG laser, respectively [25]. Our results seem non-inferior to the Ho:YAG laser, but the SFR is lower than the one reported by Ulvik et al. for the TFL. We could explain this difference by the laser fiber size that was used for the Tm:YAG, which is limited to 272 µm. As smaller fibers are supposed to produce thinner fragments and dust, we could have reported better ZFR results with a 200 µm or 150 µm laser fiber [26]. This could partially explain our findings, in association with the technology and the operative technique.

Regarding the efficiency ratios, we found 14,8 (6–21)J/mm³ and 0,75 (0,46–2)mm³/s coefficients, which are similar with the TFL clinical experiences, using a similar dusting technique. Thus, 18,6 and 14,3 J/mm³ and 1,2 and 0,7mm³/s were reported with two distinct TFL generators [27, 28]. Tm:YAG could present the same effectiveness in ELL, compared to TFL but this was not the purpose of our study. However, this hypothesis is supported by the in vitro results, described earlier [10]. We acknowledge that a comparative evaluation of Ho:YAG, Tm:YAG and TFL is required to confirm our preliminary results.

Regarding our cohort, we emphasize the stone size was big for RIRS, according to international guidelines [29]. Our dusting technique associates low frequency and low power settings, in order to produce the smallest achievable dust, avoiding basketing. With this setup, along with a proper irrigation, we intended to limit the temperature increase in the urinary system, but we emphasize only low level data is available on temperature profiles during Tm:YAG laser [9]. Other laser techniques are described, such as Operator Duty Cycle (Burst Laser Lithotripsy) but no evidence is provided about Tm:YAG temperature levels in clinical use. Temperature concerns are still under evaluation for the Tm:YAG laser; however, it appeared safe to use low frequency–low power settings [30]. Our experience shows that the dusting technique with Tm:YAG is similar to the one with Ho:YAG laser, but a greater fiber-to-stone distance is needed if we compare

it with the TFL. In case of ureteral stones, we did not encounter any difficulty but larger cohorts are needed. The higher peak power and pulse modulation (“captive fragmenting”) could explain our clinical constatation. “Captive Fragmenting” was used, because the GUI only allows a low pulse energy (0,6 J) and a low frequency (down to 5 Hz) in this mode (except for “Standard Fragmenting”). For example, the “Dusting” setting has a minimum frequency level of 25 Hz, which does not fit with our laser setup.

This study has some limitations. First and foremost, there is no comparative group using the Ho:YAG laser. Nonetheless, the aim of this pilot study was to show our initial experience with the new pulsed-Tm:YAG, including consecutive patients without a more specific selection. Then, we acknowledge our cohort contains a small number of participants, due to its recent authorization. Considering laser durations, the lithotripsy duration was not evaluated and compared to LOT, but further evaluation should compare this information to TFL and Ho:YAG. The absence of clinical or preclinical laser settings recommendations is another consequence of its novelty. Further randomized control trials are needed to confirm our preliminary results.

Conclusion

The new pulsed-Tm:YAG laser is a safe and effective laser source for endocorporeal laser lithotripsy during RIRS. We reported a low level of complications, and similar outcomes to those reported with TFL. The laser technique may differ from that of TFL, with a slightly longer fiber-to-stone distance. Further clinical trials, especially comparative ones, are needed to define the place of the pulsed-Tm:YAG among all the other laser options for ELL.

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Author contributions FP: protocol development, data collection and management, data analysis, manuscript writing and editing. CS: data collection and management. SD: protocol development, manuscript writing and editing. SK: data collection and management. MC: manuscript writing and editing. LC: manuscript writing and editing. MC: manuscript writing and editing. OT: protocol development, data analysis, manuscript writing and editing.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest but: Olivier Traxer has declared as consultant for Karl Storz, Coloplast, IPG photonics, Ambu, Quanta System and Rocamed. Steeve Doizi has declared as consultant for Boston Scientific Corporation and Coloplast.

Research involving human participants or animals Approval was obtained from the ethics committee of the French Association of Urology. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Consent to participate Verbal and written informed consent were obtained prior to the surgery.

Consent to publish The authors affirm that human research participants provided informed consent for publication of the supplementary videoclip.

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