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RESEARCH

Prospective evaluation of efficacy, safety, cumulative laser energy, and stone-free rates in the post-market SOLTIVE™ SuperPulsed laser system registry: insights from team of worldwide endourological researchers' (T.O.W.E.R.) research consortium

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Abstract
The Thulium fiber laser (TFL) is a relatively new tool for endoscopic laser lithotripsy. The Endourological Society's T.O.W.E.R. registry sought to evaluate the stone-free rate (SFR) at 3 months following URS. A subset of the study sought to determine the association between cumulative TFL energy and SFRs. 423 patients with planned ureteroscopic lithotripsy using TFL (SOLTIVE™, Gyrus ACMI, Inc. d/b/a Olympus Surgical Technologies America) were prospectively enrolled between December 2020 and May 2023 at nine international sites. Baseline clinical characteristics and SFR data for kidney and ureteral stones were separately analyzed according to quartile cumulative TFL energy ranges. Median patient age was 58.0 (IQR: 44–67) years and maximal stone diameters were 9.9 (IQR: 7–12.9) mm and 7.4 (IQR 6.1–9.4) mm for kidney and ureteral stones, respectively. Overall SFR (no fragments) for renal and ureteral stones were 73.0% and 85.7% at 3-months. Cumulative energy levels were divided into quartiles and lower SFRs were observed with the highest quartile for kidney stones ($p = 0.001$), but not in ureteral stones. This correlated with kidney stone size as larger stones required more energy. The rate of adverse events related to the procedure was 1.9% (8/423). Higher stone burdens had lower stone free rates and required more cumulative laser energy. The TFL is effective in endoscopic lithotripsy. This post-marketing survey demonstrates that TFL is a safe and effective tool for endoscopic laser lithotripsy.

Keywords Kidney stones · Urolithiasis · Ureteroscopy · Laser lithotripsy · Thulium fiber laser · Holmium:YAG

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Abbreviations

Ho:YAG	Holmium:yttrium–aluminium-garnet
TFL	Thulium fiber laser
SFR	Stone-free rate
URS	Ureteroscopy
KUB	Ultrasound, kidney-ureter-bladder
SD	Standard deviation
IQR	Interquartile range
SAEs	Serious adverse events
RF	Residual fragment

Introduction

The Holmium:yttrium–aluminium-garnet (Ho:YAG) laser, first introduced in 1993, has been the gold standard for laser lithotripsy [1]. The Thulium Fiber Laser (TFL) was introduced in 2019 and has garnered attention due to its lower and prolonged peak power with a longer pulse duration resulting in lower retropulsion, and the ability to deliver higher frequencies than Ho:YAG [2–5]. Furthermore, the TFL's wavelength of 1940 nm is closer to water absorption resulting in greater ablation efficiency when applied to all stone types in pre-clinical testing [6]. Given the uniformity and focused shape of the laser beam of TFL, smaller fibers (as small as 50 µm) can be utilized, leading to improved irrigation flow, better scope flexibility and deflection, and less fiber burn back [7–9]. Recently published clinical data showed the superiority of TFL in stone ablation efficacy, shorter operative times, and higher stone-free rates (SFR) compared to Ho:YAG [10, 11]. This prospective study conducted by the investigators of the Team of Worldwide Endourological Researchers' (T.O.W.E.R.) research consortium on behalf of the Endourological Society aimed to evaluate the stone-free rates (SFRs), ablative performance, and patient outcomes following ureteroscopy (URS), percutaneous nephrolithotomy (PCNL), or mini-PCNL with the first commercially available TFL system, SOLTIVE™ SuperPulsed Laser System (Gyrus ACMI, Inc. doing business as Olympus Surgical Technologies America).

Methods

This prospective, single-arm, global clinical registry was conducted at nine centers internationally: University of British Columbia (Canada), Sorbonne University Tenon Hospital (France), Mayo Clinic Arizona (USA), Loma Linda University Medical Center (USA), Kansas University Medical Center (USA), Ohio State University Wexner Medical Center (USA), Mount Sinai West (USA), University of Southern Denmark (Denmark), and Hospital CUF Descobertas (Portugal). Ethics approval was obtained at each institution. Adult patients (Age > 18) booked for URS with laser lithotripsy who met the eligibility criteria were enrolled in the study following informed consent. Laser systems used in this study were purchased by the respective institutions for standard clinical care. All study procedures and data collected were conducted according to routine standard-of-care practices at each institution (12/2020-5/2023).

Baseline data collected prior to procedure included patient demographics, medical and stone history, target stone(s) characteristics, prior radiological imaging, and concomitant medications. Procedures with TFL lithotripsy was conducted in routine fashion as per each institution's respective standard-of-care. Total stone volume measurements were conducted from pre-operative CT (if available) via manual measurement using the standard formumla $\pi \times l \times w \times d \times 0.169$) for all stones visualized. During the procedure, total procedural time, total laser time, laser settings, cumulative laser energy, accessory devices used, device malfunction, and adverse events were recorded. All stones were treated with standardized initial laser settings (that differed from the manufacturer's starting settings (Table 1). After one minute of laser time, settings were changed at the discretion of the surgeon with guidelines to stay below approximately 10W in the ureter and 20W in the kidney for total power.

Follow-up visits occurred at one- and three-months post-procedure and chart reviews up to 90 days post-procedure. Standard-of-care imaging (ultrasound, kidney-ureter-bladder (KUB) x-ray, or CT) to determine stone-free status or residual fragment characteristics, re-interventions, and adverse events were recorded post-operatively.

The primary objective of this study was stone-free status at one- and three-month post-procedure confirmed via standard-of-care radiological imaging (US, X-ray KUB, CT). Secondary objectives included laser ablation metrics based on active lasing time (ablation speed and efficacy, energy per minute, and total laser energy), total procedure time (time of initial ureteroscope insertion to time of ureteroscope withdrawal), device deficiencies, adverse events, and reinterventions.

Statistical analysis was conducted on Statistical Analysis Software (SAS) 9.4M8 (SAS Institute, Cary, NC, USA).

Table 1 Initial laser setting

Setting	Left pedal		Right pedal	
Kidney 1	0.2 J	100 Hz SP	0.6 J	30 Hz SP
Kidney 2	0.4 J	40 Hz SP	1.0 J	20 Hz SP
Kidney 3	0.05 J	400 Hz MP	0.1 J	20W SP
Ureter 1	0.05 J	50 Hz MP	0.1 J	50W MP
Ureter 2	0.15 J	14 Hz SP	0.1 J	20W SP

SP short pulse, *MP* medium pulse

Mean, standard deviation (SD), median and interquartile range (IQR) values, and quartile distributions were calculated. Study data was not normally distributed according to the Shapiro–Wilk test. Bivariate and quartile analyses of study variables were conducted using the logistic regression model and the Kruskal–Wallis Chi-Squared test, respectively. Spearman's rank-order correlation was used to measure the strength and direction of association between stone densities and ablation metrics. A sub-analysis was performed depending on location of treated stone burdens (renal, ureteral, or combination of stones in both locations).

Results

Patient demographics and stone characteristics

The registry accrued 423 patients with a median age of 58.0 (IQR 44–67) and a mean BMI of 28.1 ± 6.7 kg/m^2. 47.5% (201) of patients enrolled were female while 52.5% (222) were male (Table 2). Median total stone burden was 198 (89–500) mm^3 (Table 2). Distribution of stone locations treated within the urinary collecting system is shown in Table 2. Stone-free status was reported via institutional standard-of-care imaging at either 1-month and/or 3-months post-procedure: 36.4% CT, 50.3% Ultrasound, 34.3% KUB x-ray. Within this imaging distribution, 68 (21.0%) patients had both ultrasound and KUB x-ray performed. Four (1.24%) patients had CT scan and ultrasound/KUB x-ray performed.

Stone-free rates and residual fragments

SFR was defined as the absence of any residual fragments in radiological imaging. Overall SFR was 68.1% at one month and 76.5% at three months post-procedure. Patients with ureteral stones had a higher SFR compared to those with only renal stones or patients with stones in both the kidney and ureter (1 Month: 74.0% vs. 66.7% vs. 65.0%, 3-Months 85.7% vs. 73.0% vs. 76.0%, respectively). 3-month SFR based on stone location is shown in Fig. 1. SFR data was further stratified and defined using the definition of residual fragments (RFs) with a cut-off of ≤ 4 mm or ≤ 2 mm. Under the RF definitions, 86.2% of patients were stone-free or had RFs ≤ 4 mm, and 80.3% were stone-free or had RF ≤ 2 mm at 3 months post-procedure (Table 3). Similar trends were observed when comparing RFs based on initial stone location.

An inverse relationship between total stone burden quartiles mm^3 and 3 month SFR was found to be statistically significant in renal stones treated ($p < 0.0054$) (Table 4). Although not significant, a trend was seen in which stone volume increase resulted in decreasing SFR ($p = 0.1312$). A similar trend was observed in ureteral stones but was not statistically significant ($p = 0.39$, Table 4). Quartile analysis of stone densities revealed similar SFRs across all densities for renal stones; however, SFR trended lower (although not significantly) for ureteral stones with densities in Q1 and Q2 when compared with Q3 and Q4 ($p = 0.083$).

Laser ablation metrics—speed, efficacy, energy per minute, total energy

Dusting was the primary TFL lithotripsy technique in renal, ureteral and combined stone locations (67.5%, 48.3%, 52.9%, respectively). Surgeons used combined fragmentation and dusting modes in renal, ureteral and combined stone locations (28.8%, 33.9%, and 38.2%, respectively). 61.0% of all procedures performed utilized the dusting technique only. In the study cohort, the median total energy used during lithotripsy was 4.5 kJ (1.6–11.1). Higher total laser energy was used for renal stones compared to ureteral stones or stones in both locations (6.0 kJ (IQR 2.9–13.8) vs. 1.3 kJ (IQR 0.6–3.9) vs. 4.9 kJ (IQR 1.7–10.1).

The overall median ablation speed and efficacy were 0.60 mm^3/s (IQR 0.3–1.2) and 18.5 J/mm^3 (IQR 8.8–37.9), respectively. Faster ablation speeds were observed for renal stones (0.68 mm^3/s, IQR 0.3–1.5) compared to ureteral stones (0.5 mm^3/s, IQR 0.3–0.9) or for patients with stones found in both locations (0.5 mm^3/s, IQR 0.2–0.7). Laser energy consumption was higher in renal stones (21.8 J/mm^3, IQR 11.6–43.7) compared to ureteral stones (11.5 J/mm^3, IQR 5.3–28.5) or in patients with stones in both locations (19.0 J/mm^3, IQR 8.4–34.4).

Total laser energy and laser time correlated with stone density across quartiles for renal stones (Fig. 2), but none of the other laser parameters varied significantly or correlated with stone density (Table 5). TFL laser energy consumption was equally effective across all stone densities as laser energy (J) per mm^3 of stone treated remained similar across all four density quartiles for kidney and ureter (Fig. 2a. $p = 0.33$, 0.80). Ablation speeds were comparable across all stone densities within the kidney and ureter (Fig. 2b. $p = 0.12$, 0.88). Laser energy per minute delivered to renal or ureteral stones remained comparable throughout density quartiles (Fig. 2c. $p = 0.652$, 0.478).

Laser energy per minute (kJ/min) was significantly different overall across renal stone volume quartiles ($p = 0.01$); however, although statistically significant ($p < 0.001$), the correlation was weak ($r = 0.16$) (Table 5). Pairwise multiple comparisons revealed significant differences between Q1 and Q4 ($p = 0.02$) stone volume. A similar relationship was not found when comparing ureteral stones volumes, as laser energy per minute used was comparable, with an insignificant correlation ($r = 0.13$, $p = 0.12$). Upon investigation of correlation between laser

Table 2 Patient demographics, stone characteristics, reinterventions, and adverse events

		Overall	Kidney	Ureter	Kidney & ureter
	n	423	271	118	34
Patient demographics	Median age (IQR)	58 (44–67)	58 (44–67)	59 (44–67)	61 (46–67)
	Sex (Female)	201 (47.5%)	132 (48.7%)	55 (46.6%)	14 (41.2%)
	Sex (Male)	222 (52.5%)	139 (51.3%)	63 (52.4%)	20 (58.8%)
	Mean BMI (kg/m^2)	28.1 (6.7)	28.2 (6.9)	28.2 (6.2)	27.1 (6.4)
Stone Characteristics	Maximal Stone Diameter (mm) (IQR)	8.7 (6.9–12.0)	9.9 (7–12.9)	7.4 (6.1–9.35)	8.3 (7–11)
	Median Total Stone Burden (mm^3) (IQR)	198 (89–500)	282 (124–674)	112 (68–230)	224 (100–393)
	Median Stone Density (HU)	855 (559–1187)	886 (554–1207)	780 (562–1034)	880 (558–1132)
	Number of stones	1 (1–3)	2 (1–3)	1 (1–1)	3 (2–6)
Stone location	Upper Calyces	90 (21.3%)	74 (27.3%)	0 (0.0%)	16 (47.1%)
	Middle Calyces	98 (23.2%)	80 (29.5%)	0 (0.0%)	18 (52.9%)
	Lower Calyces	170 (40.2%)	147 (54.2%)	0 (0.0%)	23 (67.7%)
	Renal Pelvis	64 (15.1%)	62 (22.9%)	0 (0.0%)	2 (5.9%)
	Ureteropelvic Junction	14 (3.3%)	12 (4.4%)	0 (0.0%)	2 (5.9%)
	Upper Third of Ureter	44 (10.4%)	0 (0.0%)	36 (30.5%)	8 (23.5%)
	Middle Third of Ureter	39 (9.2%)	0 (0.0%)	27 (22.9%)	12 (35.3%)
	Lower Third of Ureter	69 (16.3%)	0 (0.0%)	56 (47.5%)	13 (38.2%)
	Ureterovesical Junction	7 (1.7%)	0 (0.0%)	6 (5.1%)	1 (2.9%)
Laser efficacy	Total Laser Energy (kJ)	4.47 (1.5–10.3)	6 (2.9–13.8)	1.34 (0.58–3.9)	4.85 (1.74–10.1)
	Median Lasing Time (s)	372 (182–826)	493 (193–1020)	241 (127–413)	607 (271–972)
	Surgery Length (min)	48 (32–66)	51 (34–67)	40 (28–60)	55.5 (42–96)
	Median Stone Ablation Efficacy (joule/mm^3)	18.5 (8.8–37.9)	21.76 (11.6–43.7)	11.47 (5.3–28.5)	19 (8.4–34.4)
	Median Stone Ablation Speed (mm^3/s)	0.6 (0.3–1.4)	0.7 (0.3–1.5)	0.5 (0.3–0.9)	0.5 (0.2–0.7)
	Median Energy per Minute (kJ/Min)	0.9 (0.4–1.2)	1.08 (0.7–1.2)	0.33 (0.18–0.8)	0.5 (0.3–0.8)
	Basket Used, Yes	189 (44.7%)	109 (40.2%)	58 (48.7%)	22 (64.7%)
	UAS Used, Yes	167 (39.5%)	132 (48.7%)	24 (20.3%)	11 (32.4%)
	Pre-stented, Yes	132 (31.2%)	79 (29.2%)	40 (33.9%)	13 (38.2%)
	Stent placement (post), Yes	360 (85.9%)	232 (86.6%)	99 (84.6%)	29 (85.3%)
Re-interventions	1 Month				
	ESWL	0.00% (0)	0.00% (0)	0.00% (0)	0.00% (0)
	PCNL	0.00% (0)	0.00% (0)	0.00% (0)	0.00% (0)
	Ureteroscopy	2.13% (9)	1.85% (5)	1.69% (2)	5.88% (2)
	Open renal surgery	0.00% (0)	0.00% (0)	0.00% (0)	0.00% (0)
	Stent insertion	0.47% (2)	0.00% (0)	0.85% (1)	2.94% (1)*
	Total unique patients	2.36% (10)	1.85% (5)	2.54% (3)	5.88% (2)
	3 Months				
	ESWL	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
	PCNL	0.5% (2)	0.7% (2)	0.0% (0)	0.0% (0)
	Ureteroscopy	2.8% (12)	2.2% (6)	5.1% (6)	0.0% (0)
	Open renal surgery	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
	Stent insertion	0.5% (2)	0.0% (0)	1.7% (2) *	0.0% (0)
	Total unique patients	3.3% (14)	2.9% (8)	5.1% (6)	0.0% (0)
	0–3 Months				
	Total unique patients	5.2% (22)	4.4% (12)	6.8% (8)	5.9% (2)

NB “Kidney and Ureter” = patients with stones in both locations

1. At 1 month follow-up, ten patients had a total of 11 re-intervention entries. One subject had both ureteroscopy and stent insertion re-interventions

2. At 3 months follow-up, fourteen patients had a total of 16 re-intervention entries. Two subjects had both ureteroscopy and stent insertion

3. Overall, 22 subjects had re-intervention within 3 months after TFL lithotripsy. Two subjects had ureteroscopy re-intervention at both 1 month and 3 months follow-ups

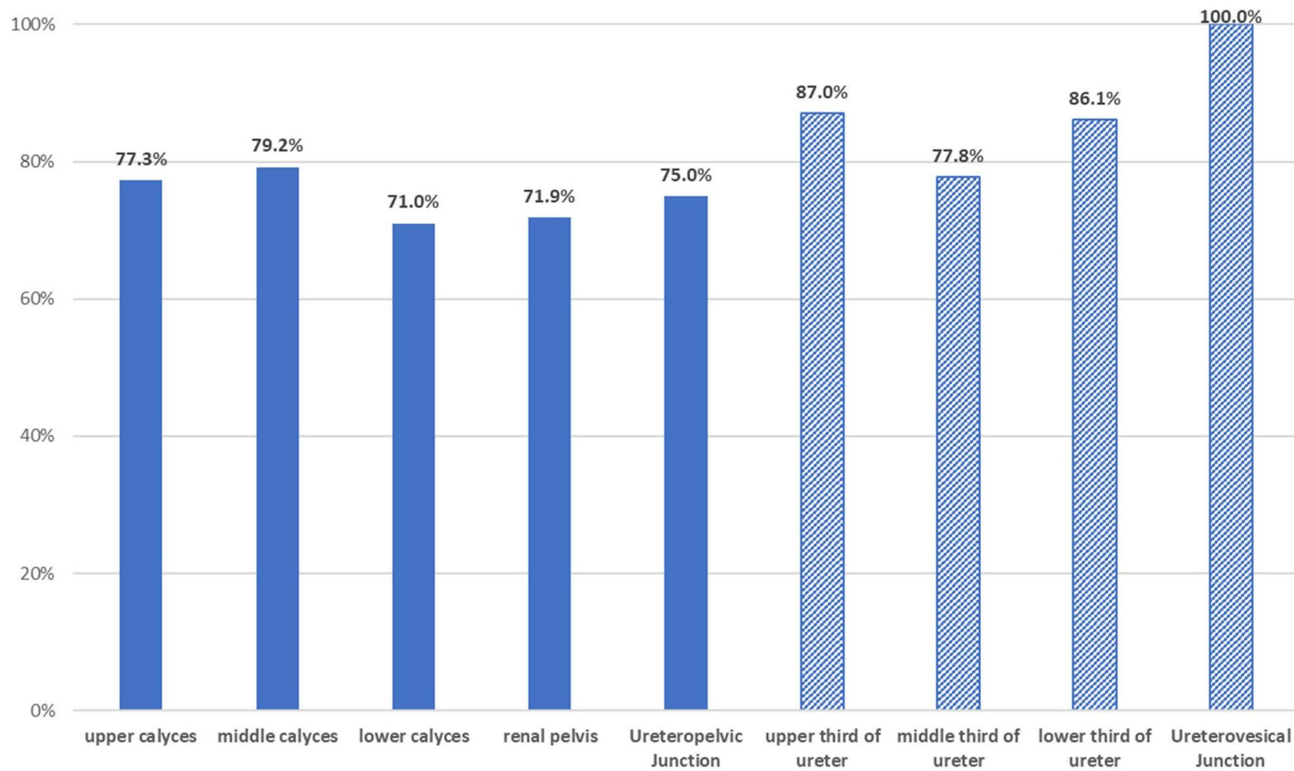


Fig. 1 3 month stone-free rate by stone location

metrics with maximal diameter, total stone volume, and stone density amongst all stones treated, only strong correlations ($r > 0.5$) were found between total laser energy and maximal diameter or total stone volume ($r = 0.59$, $p < 0.0001$, $r = 0.65$, $p < 0.0001$).

Adverse events and re-intervention

Rate of serious adverse events (SAEs) related to the TFL, or index procedures was 1.89% (8/423). 31 SAEs occurred, with eight [8] being related and 23 being unrelated to the URS procedure (Table 6). UTI was the most common SAE (3.54%) and is a known complication post-procedure and not specific to the laser used. One patient experienced acute kidney injury, and two had post-operative ureteral strictures. The patients with strictures recovered without sequelae after treatment, and upon further clinical and radiologic investigation, these incidents were associated with an impacted stone and not TFL lithotripsy. No thermal tissue damage was observed in any cases.

Re-treatment was required in 5.2% of all patients within three months following URS with TFL lithotripsy (0–1 Month: 2.4%, 1–3 Months 3.3%). Repeat URS was the most common salvage procedure (Table 2).

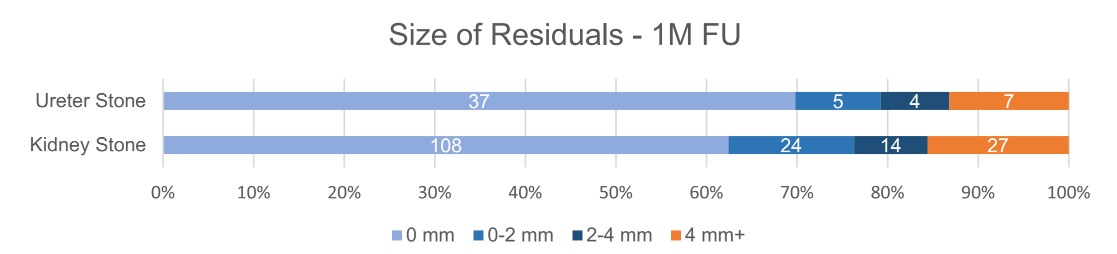
Discussion

This is the largest international prospective cohort study to date evaluating the real-world safety, performance, and patient outcomes of the SOLTIVE™ SuperPulsed TFL System used in URS. Our study showed TFL to be efficacious and safe for stone ablation regardless of stone location, burden, or density. No significant differences were observed in ablation speed and efficacy, lasing time consumption, or total energy used across all stone densities meaning it was effective against all stone types. Our study demonstrates TFL to be comparable to previously reported SFRs, stone ablation metrics, SAE and re-intervention rates to other currently available laser systems [12, 13].

TFL is described as being capable of superior dusting compared to Ho:YAG due to the longer pulse width that results in less stone retropulsion and also finer stone debris ("dust") across all stone types [12–14]. Theoretically, the wavelength of TFL is closer to water (compared to Ho:YAG) resulting in improved stone fragmentation and dusting without resulting in increased temperatures in the stone [15]. Bench testing showed this difference in wavelength to result in faster stone ablation rates compared to Ho:YAG with Moses pulse modulation [16]. In our study,

Table 3 Stone free rates and residual fragments (RFs)

Completely Stone-free	**Overall**	**Kidney**	**Ureter**	**Kidney & Ureter**
Patients (Total N)	423	271	118	34
1 month	158/232 **(68.1%)**	108/162 **(66.7%)**	37/50 **(74.0%)**	13/20 **(65.0%)**
3 months	248/324 **(76.5%)**	157/215 **(73.0%)**	72/84 **(85.7%)**	19/25 **(76.0%)**
Fragments <= 4mm	**Overall**	**Kidney**	**Ureter**	**Kidney & Ureter**
Patients (Total N)	423	271	118	34
1 month	208/246 **(84.6%)**	146/173 **(84.4%)**	46/53 **(86.8%)**	16/20 **(80.0%)**
3 months	300/348 **(86.2%)**	195/231 **(84.4%)**	82/90 **(91.1%)**	23/27 **(85.2%)**
Fragments <= 2mm	**Overall**	**Kidney**	**Ureter**	**Kidney & Ureter**
Patients (Total N)	423	271	118	34
1 month	188/244 **(77.1%)**	132/171 **(77.2%)**	42/53 **(79.3%)**	14/20 **(70.0%)**
3 months	273/340 **(80.3%)**	177/227 **(78.0%)**	76/87 **(87.4%)**	20/26 **(76.9%)**



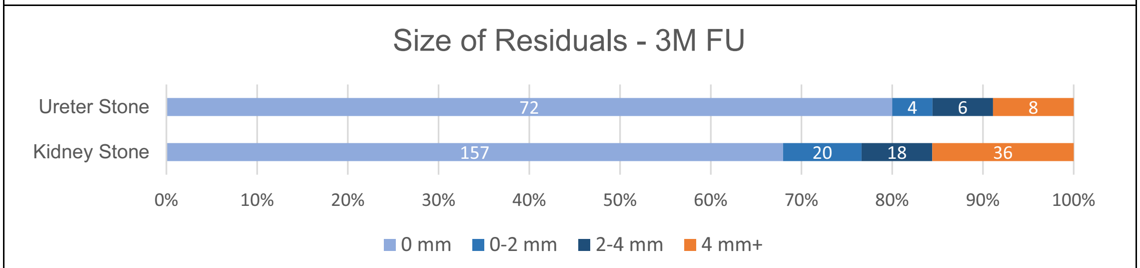


Table 4 Stone volume quartiles and stone-free rate

Kidney Stone volume by quartile (mm^3)	N	Median (mm^3)	Mean (mm^3)	3 M SFR %
18–124	54	56.6	62.1	85%
125–286	52	188.0	189.9	73%
287–675	54	478.1	457.7	69%
676 +	45	1190.0	2175.7	60%
Stone volume by quartile (mm^3)	**Odds ratio estimate**	**Lower 95% CI**	**Upper 95% CI**	**Pr > Chi-Square**
	0.7	0.5	0.9	0.0054*
Ureter Stone volume by quartile (mm^3)	N	Median (mm^3)	Mean (mm^3)	3 M SFR %
6.5–67	22	32.9	32.0	86%
68–111	19	78.3	82.4	95%
112–230	20	163.9	169.4	75%
231 +	17	400.1	843.3	82%
Stone volume by quartile (mm^3)	**Odds ratio estimate**	**Lower 95% CI**	**Upper 95% CI**	**Pr > Chi-Square**
	0.8	0.4	1.4	0.3894

Statistically significant values are in bold

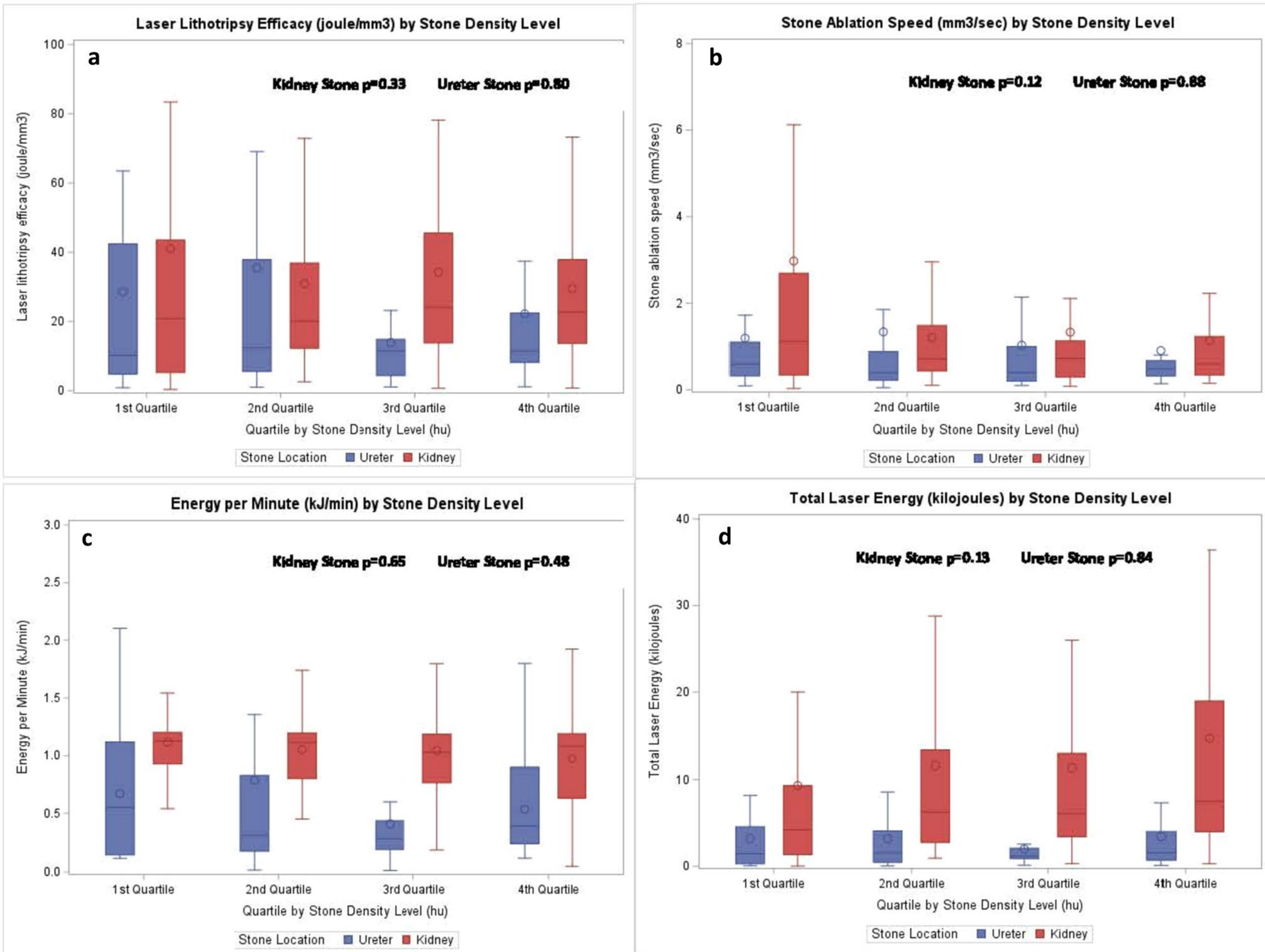


Fig. 2 Median stone density quartiles and ablation metrics. No differences were found in parameters for stone density (except total laser energy and surgery length in the all stones category). For ureteral stones, bigger stone sizes showed a faster technique of—ablation speed is faster (technique dependent)—need to explain this difference in technique. R-0.21. (− 1 to 1). Closer to 0 means no correlation. Weak but significant correlation, strength is weak

dusting was the lithotripsy technique of choice supporting previous claims that this laser is suited to the dusting technique. Previous prospective studies have shown no significant differences in clinical outcomes between patients who underwent dusting versus basketing during URS, even at 5-years post-URS [17].

The SFRs in this study were comparable to previous TFL, Ho:YAG and Ho:YAG with MOSES studies [12, 14, 18–21]. In a review of seven TFL studies, qualitative synthesis revealed SFRs (RF < 2 mm) of 85 to 100% [22]. Despite the similar results, radiologic imaging post-URS in our study were performed according to each urologist's standard practice, which may affect the SFRs depending on modality. Comparatively, our cohort encompassed a greater range of maximal stone diameters, burden, and densities. Statistical analysis showed a significant inverse relationship between SFRs and stone burden in renal stone patients in our cohort. Greater stone volumes are associated with lower SFRs as they typically necessitate greater quantities of laser energy. We hypothesize that SFRs may be higher in longer-term follow-up as TFL effectively renders stones to dust which may require time for clearance and may still be reported as residual fragments. Newer suction ureteral access sheaths may further help improve stone-free rates [23].

The TFL re-intervention (5.2%) and adverse event rate (1.9%, 8/423) during URS was low. Our study documented only a single occurrence of pyelonephritis; however, it occurred between the one-to-3-month period post-URS, therefore unlikely to be related to URS. In a study by Martov et al., pyelonephritis was reported in 15.9% of TFL cases [19]. Our data shows TFL to be safe with re-intervention and complication rates comparable to those reported using Ho:YAG (± MOSES) studies [12, 14].

Table 5 Correlation between laser metrics vs. stone diameter, volume, and density

	Statistic	Total laser energy (kJ)	Surgery length (Min)	Total laser time (Min)	Stone ablation speed (mm^3/s)	Laser lithotripsy efficacy (joule/ mm^3)	Energy per minute (kJ/Min)
All stones							
Maximal stone diameter (mm) N = 388	r (p)	**0.594 (< .0001)***	0.389 (< .0001)	**0.54372 (< .0001)***	0.318 (< .0001)	– 0.105 0.0385	0.257 (< .0001)
Consolidated stone volume (mm^3) N = 402	r (p)	**0.652 (< .0001)***	0.413 (< .0001	**0.5924 (< .0001)***	0.486 (< .0001)	– 0.243 (< .0001)	0.313 (< .0001)
Stone density in bone window (HU) N = 385	r (p)	0.176 (0.0005)	0.102 (0.046)	0.22293 (< .0001)	– 0.033 (0.524)	0.042 (0.415)	– 0.007 (0.877)
Renal stones							
Maximal stone diameter (mm) N = 248	r (p)	**0.640 (< .001)***	0.398 (< .0001)	**0.581 (< .0001)***	0.284 (< .0001)	– 0.218 (< 0.001)	0.166 (0.0088)
Consolidated stone volume (mm^3) N = 258	r (p)	**0.686 (< .0001)***	0.428 (< .0001)	**0.626 (< .0001)***	0.455 (< .0001)	– 0.394 (< .0001)	0.210 (0.0007)
Stone density in bone window (HU) N = 246	r (p)	0.203 (0.001)	0.101 (0.115)	0.244 (< .0001)	– 0.113 (0.076)	0.067 (0.297)	– 0.047 (0.461)
Ureteral stones							
Maximal stone diameter (mm) N = 105	r (p)	0.331 (0.001)	0.365 (0.0001)	0.343 (0.0003)	0.354 (0.0002)	– 0.173 (0.077)	0.107 (0.278)
Consolidated stone volume (mm^3) N = 108	r (p)	0.437 (< .0001)	0.377 (< .0001)	0.462 (< .0001)	0.495 (< .0001)	– 0.291 (0.002)	0.160 (0.098)
Stone density in bone window (HU) N = 103	r (p)	0.054 (0.588)	0.053 (0.594)	0.157 (0.114)	– 0.009 (0.924)	– 0.014 (0.891)	– 0.032 (0.750)

Spearman Correlation Coefficient (nonparametric measure of association) is calculated, since the data distribution is non-normal

*r ≥ 0.50

Statistically significant values are in bold

Due to the abundance of possible laser setting options with TFL, optimal laser settings have yet to be determined. Manufacturer preset laser parameters may not be appropriate for all patients and are guidelines only for initial settings which may require adjustment depending on different situations. Understanding the properties of laser heat generation may enhance the safety of ureteroscopic laser lithotripsy [24–26]. In 47% of the kidney stone cases and 61% of the ureteral stone cases, the investigators changed from the initial study laser settings after one minute of laser time as per the study protocol. Even when using these power settings, SFR and ablation metrics were similar to previously published studies [22]. No thermal-related urothelial injuries occurred in our study with mean energy delivery of ~ 1.0 kJ/min (kidney) and ~ 0.6 kJ/min (ureter). Other factors can help mitigate temperature rise and intrarenal pressure such as using cooled irrigation fluid, providing a constant irrigation flow, periodically pausing laser emissions, and using a ureteral access sheath (with or without suction). The performance of TFL is independent of stone characteristics outside of stone size. Larger stones required more laser energy and time to ablate, however surgery length, ablation speed, efficacy, and energy consumption used per minute only had very weak correlation with stone density (Table 5). Results from our study emphasize using conservative laser settings with TFL. High average power settings may not improve outcomes and may increase complication rates. Historically,

Table 6 Serious adverse events

Adverse event (Clavien Dindo classification)	Adverse event related to study device or procedure?		
	Unrelated	Related	Total
Grade 1			
UTI	10	5	15
Pyelonephritis	7	1	8
Fever	1	1	2
Grade 2			
Sepsis	3	0	3
Acute kidney injury	0	1	1
Grade 3a	0	0	0
Grade 3b			
Stricture	2	0	2
Grade 4	0	0	0
Grade 5	0	0	0
Total cases	23	8	31
Total patients	22	7	29

irrigation flow was often turned off to reduce retropulsion from Ho:YAG lasers, particularly in the ureter. However, the longer pulse width of TFL reduces stone retropulsion, enabling more continuous laser emission. This could lead to higher irrigation temperatures due to the principles of thermodynamics. Previous studies have documented no differences in irrigant temperature change comparing TFL to Ho:YAG systems [16, 27, 28]. Keeping the power below 20W in the kidney (and 10W in the ureter), using constantly flowing cooled irrigation (< 37.0 C), and a UAS may help minimize temperature increases in addition to intrarenal pressure [29].

Our study is the first to demonstrate the effectiveness of TFL in stone ablation independent of stone density. Ablation speeds and efficacy remain the same throughout the stone density quartiles analyzed. Median ablation speed and energy to ablate 1mm^3 of stone volume with TFL were comparable to both low- or high-power Ho:YAG systems reported previously [30]. Our findings were not congruent with early TFL studies, where ablation speeds with TFL were found to be two-to-five times higher than Ho:YAG under similar conditions [22]. Moreover, in a meta-analysis by Chua et al., TFL had significantly higher ablation speeds and efficacy than Ho:YAG, and was similar to Ho:YAG with MOSES [14]. Despite our TFL laser efficiency metrics not being as high as previously reported, SFRs and patient outcomes in our study were comparable to those previously reported [12, 14, 22, 30]. Lastly, our clinical experience with TFL suggests that at the same laser settings or wattage, TFL and Ho:YAG are not equivalent due to differences in laser physics between the two (wavelength, peak power and pulse-width). The higher ablation speeds in the kidney are likely due to ablation techniques as renal stones tend to ablate into fine dust. In contrast, ureteral stones can be broken up where they can be basketed or flushed out.

Conclusion

Overall, the SOLTIVE™ SuperPulsed Laser TFL System is a safe and effective in laser lithotripsy with low complication and re-intervention rates. Stone ablation speeds and laser efficacy were similar across all stone densities. Stone-free rates were comparable to previously reported TFL and Ho:YAG studies. The performance of TFL is independent of stone characteristics outside of stone size, and utilizing high average power settings may not improve outcomes. Due to the abundance of possible laser setting options with TFL, future studies are necessary to determine optimal laser settings.

Author contribution BC —Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved. VW—Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Accuracy or integrity of any part of the work investigated and resolved. MH— Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved. WM— Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved. BK— Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved. MG— Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved. DB— Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved. PK—Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved. PO— Substantial contributions to the conception or design of the work;

or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved. OT—Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; Drafting the work or revising it critically for important intellectual content; Final approval of the version to be published; Accuracy or integrity of any part of the work investigated and resolved.

Data availability Data is provided within the manuscript or supplementary information files.

Declarations

Conflict of interest The authors declare no competing interests.

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