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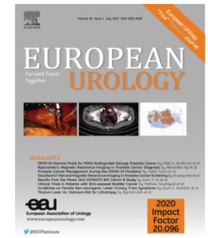

European Association of Urology

Platinum Priority – Stone Disease

Editorial by Dima Raskolnikov, Jonathan D. Harper on pp. 80–81 of this issue

Thulium Fibre Laser *versus* Holmium:YAG for Ureteroscopic Lithotripsy: Outcomes from a Prospective Randomised Clinical Trial

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Abstract

Background: Holmium:yttrium-aluminium-garnet (Ho:YAG) laser is the gold standard for ureterorenoscopic (URS) lithotripsy. Thulium fibre laser (TFL) has recently been introduced as a new technology and may challenge Ho:YAG as the preferred laser owing to favourable properties as demonstrated in preclinical studies.
Objective: To evaluate and compare outcomes after URS lithotripsy with Ho:YAG and TFL.
Design, setting, and participants: In a prospective randomised trial, patients aged ≥18 yr with ureteral and/or renal stones (≥5 mm) scheduled to undergo day-case URS lithotripsy were invited to participate. In total, 120 consecutively admitted patients with signed consent were included for randomisation.
Intervention: URS lithotripsy with Ho:YAG or TFL.
Outcome measurements and statistical analysis: The primary outcome was the stone-free rate (SFR) assessed on noncontrast computed tomography at 3-mo follow-up. Secondary outcomes were the operative time and complications. Outcomes were compared between the groups using the *t* test and χ^2 test.
Results and limitations: After a single session, the SFR was 67% in the Ho:YAG group and 92% in the TFL group, $p = 0.001$. For ureteral stones, the SFR was 100% in both groups, and for renal stones; 49% (Ho:YAG) and 86% (TFL), $p = 0.001$. Operative time was shorter using TFL (49 min) compared to Ho:YAG (57 min), $p = 0.008$. Bleeding that impaired the endoscopic view was the most frequent intraoperative adverse event and occurred in 13 patients (22%) in the Ho:YAG group and three (5%) in the TFL group, $p = 0.014$.
Conclusions: In this study, significantly more patients with renal stones achieved stone-free status and fewer experienced intraoperative complications using TFL compared to Ho:YAG. TFL is the emerging laser of choice for stone lithotripsy.
Patient summary: We compared outcomes after ureterorenoscopic treatment of kidney and ureteral stones using two different lasers. Our results show that the new thulium fibre laser technology is superior to the current standard laser (holmium:YAG) in clearing kidney stones and reducing operative complications.

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1. Introduction

Holmium:yttrium-aluminum-garnet (Ho:YAG) laser has served as the gold standard for ureterorenoscopic (URS) lithotripsy in recent decades. Thulium fibre laser (TFL) has recently been introduced as a new technology and may challenge Ho:YAG as the laser of choice owing to a number of advantageous properties. Emitting pulsed infrared light at a wavelength of 1940 nm, which is close to the water absorption peak, a fourfold higher absorption coefficient is achieved with TFL compared to Ho:YAG. This corresponds to a low threshold for tissue ablation and stone lithotripsy [1]. Cavitation bubble dynamics also differ from Ho:YAG, and TFL produces a stream of bubbles smaller than those seen with Ho:YAG use [2]. TFL is therefore expected to be very efficient at disintegrating stones in clinical practice. Previous laboratory studies have predicted that TFL lithotripsy may be up to four times faster than with Ho:YAG when the same energy settings are applied [3].

Compared to Ho:YAG, TFL has the ability to function at very low energies and extremely high frequencies. However, urolithiasis treatment with TFL may be more efficient when using moderately lower energy settings similar to those commonly used with Ho:YAG.

Although TFL has been extensively studied in the laboratory setting, few clinical studies have been reported [4–6]. The question of whether the clinical reality for TFL meets the high expectations of this early research therefore remains. Only one randomised trial comparing Ho:YAG and TFL has been published, which found that the latter was associated with significantly shorter operative and lasering times, but was limited to the treatment of ureteral stones [7].

On the basis of the hypothesis that TFL yields superior outcomes, we conducted a clinical prospective randomised trial with the primary aim of comparing stone-free rates (SFRs) following URS lithotripsy with Ho:YAG and TFL for both ureteral and renal stones. Secondary aims were to compare the results of the two lasers in terms of operative time, complications, and the rate of postendoscopic ureteral stenting.

2. Patients and methods

2.1. *Study design, setting, and study population*

In this prospective, single-centre, randomised trial, all patients aged ≥18 yr scheduled to undergo elective day-case URS lithotripsy were invited to participate in the study. Consecutive patients with ureteral and/or renal stones (≥5 mm), confirmed on preoperative noncontrast computed tomography (NCCT) and for which conservative treatment had failed, were assessed for possible recruitment. Eligible patients received both oral and written information about the study at a dedicated consultation 1 wk before surgery. Exclusion criteria included inability to give informed consent, untreated urinary infection, known anatomic abnormality (eg, urinary diversion or ureteral stricture), urothelial tumour (s), negative URS, direct extraction of the stone(s) without needing laser lithotripsy, and failure to reach the stone in the upper urinary tract with the ureteroscope. Adherence to the trial protocol was upheld for all study participants and no deviations from the original protocol occurred.

2.2. *Ureteroscopy, randomisation, and laser settings*

All cases were carried out under general anaesthesia at the Haukeland University Hospital (HUH) day surgery unit. The procedures were performed using a standardised technique as previously described [8]. Therefore, with the exception of the laser modality, all other steps were the same. After initial cystoscopy, the ureter was cannulated with either a semirigid (8/9.8CH; Richard Wolf Medical Instruments, Vernon Hills, IL, USA) or a flexible ureteroscope (URF-V3 or P7; Olympus, Tokyo, Japan) depending on the stone location. A safety guidewire and ureteric access sheath (UAS) are not routinely used during URS at HUH [9].

When the stone was reached, laser lithotripsy was performed if the stone was considered too large for direct extraction with a grasper or an NGage basket (Cook Medical, Bloomington, IN, USA). Only patients for whom laser lithotripsy was deemed necessary were included. At the time of laser lithotripsy, the patients were randomised to undergo treatment with either Ho:YAG laser (Medilas H Solvo 30 W; Dornier MedTech, Weßling, Germany) or TFL (Soltive Premium 60 W; Olympus, USA).

Randomisation sequence generation was performed electronically and before patient participation. To ensure equal numbers of patients with ureteral and renal stones in each group, patients were stratified according to stone location (ureteral or renal) and stone density (above or below 1000 Hounsfield units measured centrally in the stone in bone-window mode on NCCT by the reporting radiologist). Randomisation to each of the four strata was then performed in blocks of four. Random sequence allocation and concealment were implemented using consecutively numbered, sealed envelopes. At the time of laser lithotripsy, the envelope was opened by a designated nurse and the assigned laser machine could then be used. At the end of the procedure, automatically registered laser data were collected by this same person.

The start-up laser settings were 0.4 J at 6 Hz for both Ho:YAG and TFL. These settings were selected on the basis of previous experience with the lasers [4,6]. Energy was only increased if disintegration was considered ineffective by the surgeon. The maximum setting was limited to 0.4 J at 6 Hz in the ureter and 0.8 J at 20 Hz in the renal pelvis. The laser fibre used was 270 μm for Ho:YAG and 200 μm for TFL. Dusting was the preferred strategy for stones in the renal pelvis and, if considered necessary, small residual fragments were extracted afterwards. Fragmentation and retrieval was the preferred strategy for ureteral stones. Ureteral stents were inserted according to the European Association of Urology criteria [10]. If a stent was inserted, it was removed within 2 wk. Participants remained blinded to their allocated intervention throughout the study.

2.3. *Outcomes*

The primary outcome measure was SFR as determined on NCCT at 3-mo follow-up. Two different definitions of SFR were used based on the radiological findings: (1) zero residual fragments and (2) no residual fragments ≥3 mm. These definitions were based on SFR criteria available in the contemporary literature [11,12]. Stone-free status was assessed using NCCT in bone window mode. The outcome adjudicator was an experienced urologist blinded to the patients' allocated intervention.

Secondary outcome measures included operative time (measured from initial insertion of the cystoscope to bladder emptying at the end of the procedure), intraoperative complications, and rates of postendoscopic ureteral stenting. These were recorded at the time of surgery, while postoperative complications during hospitalisation and following discharge were registered during the hospital stay and at 3-mo follow-up, respectively.

2.4. Statistical analysis and approval

The trial design was set to identify the possible superiority of TFL on the basis of our experience. In an earlier study, we found that the SFR after Ho:YAG laser URS lithotripsy was 54.2% at 3-mo follow-up using the stricter definition of zero residual fragments detected on NCCT [9].

SFRs were compared between the laser devices using a χ^2 test. *R* version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria) was used for power analysis. The total sample size was calculated as 102 for an estimated SFR of 80% for TFL and 54.2% for Ho:YAG, using an α error probability of 0.05 and power ($1 - \beta$ error probability) of 0.8. To compensate for possible nonevaluable patients, a total of 120 patients (60 patients in each group) were planned for inclusion.

Independent-sample *t* tests were used to compare continuous variables between the two randomised groups. Exact χ^2 test and Fisher's exact test were used to compare categorical variables. Logistic regression adjusting for stratification factors have been applied for primary and secondary outcomes (SFR, operative time, intraoperative complications, and rate of postendoscopic stenting) [13]. Statistical analyses were performed using IBM SPSS Statistics 27 (IBM Corp., Armonk, NY, USA). Statistical significance was set at $p < 0.05$.

The study was registered on ClinicalTrials.gov (NCT04668586, protocol ID 170907) and the hospital's database for science (e-Protocol, project ID 2024), and was approved by the Norwegian Regional Ethical Committee (REC-170907). Informed consent including a signed form was obtained from each participant.

3. Results

Between January 14 and June 30, 2021, a total of 149 consecutive patients scheduled to undergo a total of 153 day-case URS lithotripsies at HUH were eligible for enrolment in the study. Of these, 17 declined to participate and a further 16 were excluded as they did not satisfy the eligibility criteria. In total, 120 URS procedures were performed in the remaining 116 patients included in the study. One patient underwent bilateral URS, while three patients had two consecutive procedures. Fig. 1 shows the case flow through each stage of the study in a Consolidated Standards of Reporting Trials (CONSORT) diagram [14]. No exclusions after randomisation occurred. However, one patient in the TFL group was lost to follow-up regarding SFR and refused to attend imaging, but follow-up consultation regarding complications was carried out.

Table 1 lists the baseline demographics for each group. There were no significant differences between the study arms. Data for the procedures in the two groups are presented in Table 2. UAS was not used in any case. The operative time was significantly shorter with TFL (49 min, interquartile range 32–63) than with Ho:YAG (57 min, interquartile range 45–70), $p = 0.008$. The frequency of postendoscopic ureteral stenting did not differ between the TFL and Ho:YAG groups (37% vs 52%, respectively), $p = 0.09$. Surgeons performing the procedures included three faculty urologists and six residents.

Table 3 lists SFR results for both ureteral and renal stones for the Ho:YAG and TFL groups. For ureteral stones, the SFR was 100% for both lasers (ie, no residual fragments in the ureter or kidney). For renal stones, the SFR was significantly higher after TFL than after Ho:YAG, regardless of the SFR definition.

No procedures were discontinued because of intraoperative complications. Minor adverse events occurred significantly more often in the Ho:YAG group (n = 16, 27%) than in the TFL group (n = 5, 8%), $p = 0.011$. Most patients in whom intraoperative bleeding impaired endoscopic vision during laser activation were still rendered stone-free (eight in the Ho:YAG group and two in the TFL group). Table 4 compares intraoperative complications between the two groups. Ureteral wall injuries were classified according to Traxer and Thomas [15].

Early postoperative complications occurring before hospital discharge were recorded for two patients in the TFL group and two in the Ho:YAG group, $p = 1$. All of these early complications were classified as Clavien-Dindo grade 1.

In total, 55 patients in the TFL group (92%) and 50 in the Ho:YAG group (83%) were discharged from hospital on the same day as their surgery, $p = 0.3$. The remainder were discharged on the next day.

Data for postoperative complications leading to readmission are presented in Table 5. There was no difference in the number of readmissions between the groups, with seven (12%) in the TFL group and eight (13%) in the Ho:YAG group, $p = 1$. No ureteral strictures or persistent hydronephrosis were identified on follow-up NCCT at 3 mo.

4. Discussion

In this study, we have compared outcomes after URS lithotripsy using Ho:YAG or TFL. Significantly more patients were rendered stone-free after a single session with TFL use compared to Ho:YAG (92% vs 67%; $p = 0.001$). When analysed further according to stone location, the SFR was 100% for ureteral stones in both groups. For renal stones, the SFR was 86% for TFL and 49% for Ho:YAG, $p = 0.001$. Considering that more than 60% of the renal stones were located in the lower calyx, an SFR close to 90% for TFL is higher than previously reports in the literature for clearance of lower-pole stones with URS [16–18]. In comparison, the 49% SFR for Ho:YAG may seem disappointing, but this still represents an improvement on a previous report from HUH [9].

In the present study, we also applied the SFR definition of zero residual fragments detected on NCCT as recommended by Ghani and Wolf [11]. Even when using this stricter definition, the SFR after treatment of ureteral stones was still 100% in both groups. However, the SFRs for renal stones were considerably lower using this definition, although still significantly better for TFL compared to Ho:YAG. This is also superior to the mean rate of 51% (range 35–60%) reported for renal stones using Ho:YAG [11]. Reporting the zero-fragment SFR is important for more accurate comparisons between studies. However, we appreciate that universal consensus is lacking regarding SFR criteria, including use of <3 mm as the cutoff for the residual fragment size [19].

While no procedures were discontinued because of intraoperative complications, bleeding that impaired

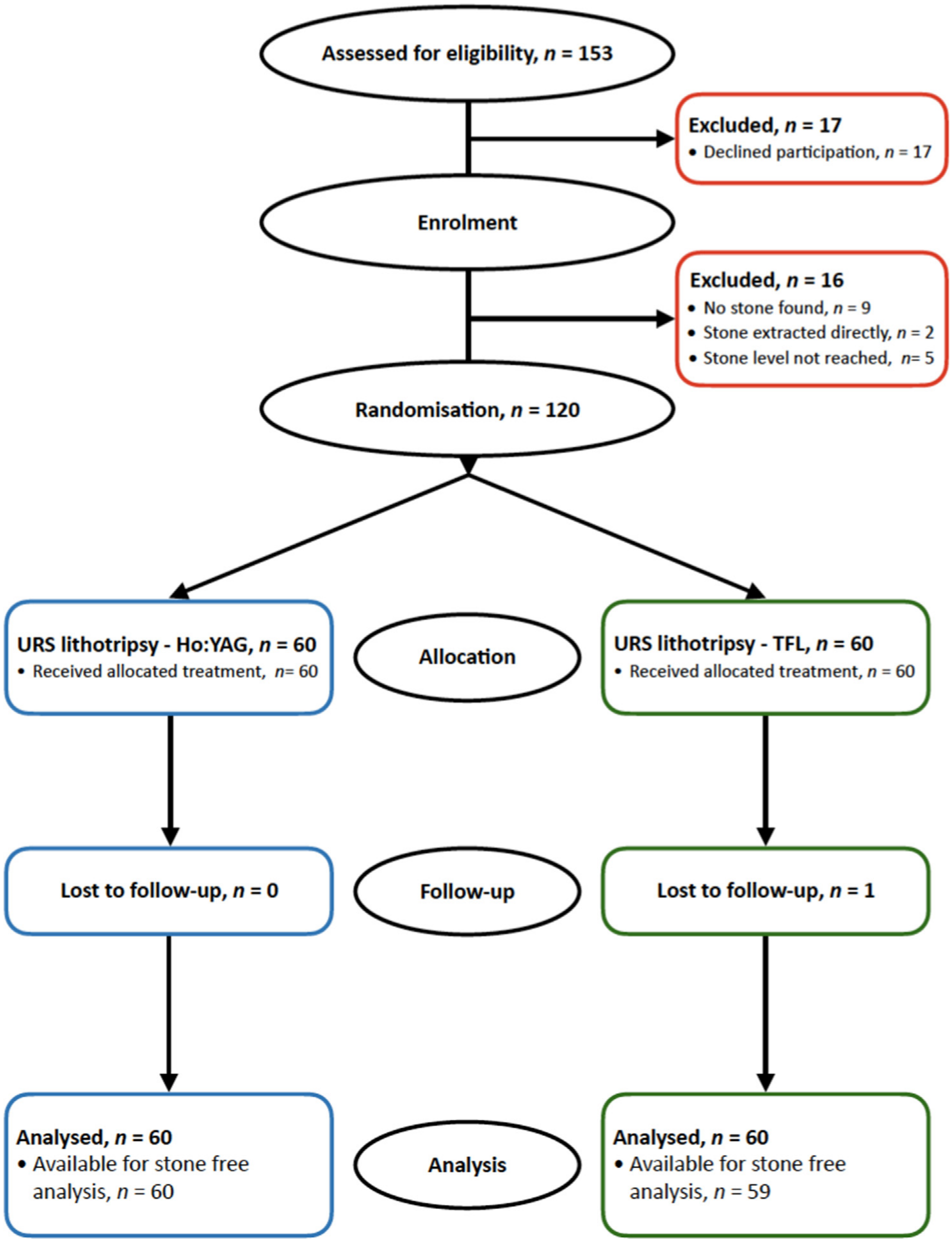

Fig. 1 – Consolidated Standards of Reporting Trials (CONSORT) diagram of case flow through the study phases. Ho:YAG = holmium:yttrium-aluminum-garnet laser; TFL = thulium fibre laser; URS = ureterorenoscopy.

endoscopic vision occurred significantly more often with Ho:YAG (22%) than with TFL (5%), $p = 0.014$. A similar result was reported by Martov et al. [7] when comparing the clarity of the endoscopic view after stone lithotripsy using TFL and Ho:YAG, with a clear view maintained in 87% and 64% of cases, respectively, $p < 0.05$. The lower rate of bleeding in the TFL group is probably related to its higher energy absorption by water and lower threshold for tissue ablation [1].

Although laser operating time (LOT) was similar in the two groups, the overall operative time was significantly shorter in the TFL group (49 min) than in the Ho:YAG group (57 min), $p = 0.008$. The most reasonable explanation is that superior endoscopic vision was maintained during laser activity with TFL. Because of this, fewer breaks and less time were needed to optimise the view in the TFL group. Reduced retropulsion associated with TFL in comparison to Ho:YAG lithotripsy has been demonstrated in several preclinical studies [1,20]. Theoretically, this may also have influenced the operative time in the present study.

Total laser energy and LOT did not differ significantly between the study groups. Laser energy and LOT may depend on several factors, such as stone burden, density, and composition, as well as operator experience. However, none of these factors differed between the groups. Calculation of the actual laser power used revealed that only a slight elevation from the initial setting was utilised in both groups. The use of low power is important considering the risk of thermal injuries such as stricture formation, although other factors (eg, proximity of the fibre to the

Table 1 – Baseline demographics

Characteristic	Holmium group	Thulium group
Sex, *n* (%)		
Female	21 (35)	22 (37)
Male	39 (65)	38 (63)
Mean age, yr (IQR)	54 (45–64)	53 (38–68)
American Society of Anesthesiologists score, *n* (%)		
I	18 (30)	18 (30)
II	37 (62)	32 (53)
III	5 (8)	10 (17)
Side, *n* (%)		
Right	26 (43)	23 (38)
Left	34 (57)	37 (62)
Mean stone density, Hounsfield units (IQR)	911 (620–1200)	896 (600–1257)
Renal stones		
Median/mean stone burden, mm (IQR)[a]	12/15 (8–18)	12/13 (7–16)
Number of stones, *n* (%)		
1 stone	24 (61)	18 (50)
2 stones	8 (21)	10 (28)
3 stones	1 (3)	2 (5)
>3 stones	6 (15)	6 (17)
Location, *n* (%)[b]		
Lower calyx	25 (64)	22 (61)
Renal pelvis, upper and mid calyx	14 (36)	14 (39)
Ureteral stones		
Median/mean stone burden, mm (IQR)[a]	7/9 (6–10)	8/9 (6–11)
Number of stones, *n* (%)		
1 stone	19 (90)	21 (88)
2 stones	1 (5)	2 (8)
3 stones	–	–
>3 stones	1 (5)	1 (4)
Location, *n* (%)[c]		
Upper	11 (52)	6 (25)
Middle	1 (5)	2 (8)
Lower	9 (43)	16 (67)
Preoperative dilatation of the upper tract, *n* (%)	23 (38)	17 (28)
Prestented, *n* (%)[d]	5 (8)	7 (12)

IQR = interquartile range.
[a] Stone burden was defined as the widest diameter of the stone. If multiple stones were present, the stone burden was calculated as the sum of the widest diameters.
[b] Some patients had stones in multiple locations. If one or more stones were located in the lower calyx, this was registered as a lower calyx stone even though the rest of the stones may be located in other locations (renal pelvis, upper or middle calyx).
[c] If multiple stones were located at different levels of the ureter, the most proximal location was registered.
[d] Patients underwent prestenting for obstruction and/or infection at acute admission several weeks before inclusion in the study (five ureteral stones in the holmium group, three ureteral and four renal stones in the thulium group).

urothelium and the temperature of the irrigation fluid) can contribute [21]. Liang et al. [22] found that high frequency can lead to a more pronounced rise in temperature compared to low-frequency settings at equal power. This is especially important for TFL, which is capable of dusting at very high frequencies. However, dusting at high frequency as well as high-energy fragmentation comes at a cost of impaired vision due to a snowstorm effect and retropulsion, which in turn may result in longer operative times and potentially lower SFRs [6]. The results reported here clearly illustrate the efficacy of using low energy at low frequency. These findings are therefore a useful contribution to recommendations for TFL laser settings, although further clinical studies are needed to gain consensus on optimal settings for this laser device.

The current study does have certain limitations, including the single-centre setting. While the initial laser settings were the same in both groups, any increase in power was at the surgeon's discretion. Although registration of energy consumption revealed that the actual power exceeded the initial setting of 2.4 W, there was no difference in total laser

Table 2 – Characteristics related to the ureterorenoscopic procedure

Characteristic	Holmium group	Thulium group	*p* value
Surgical experience, *n* (%)			0.9
Resident[a]	22 (37)	20 (33)	
Urologist	38 (63)	40 (67)	
Ureteral balloon dilatation, *n* (%)	7 (12)	7 (12)	1
Endoscope used, *n* (%)			0.9
Semirigid	10 (17)	13 (22)	
Flexible	3 (5)	3 (5)	
Both semirigid and flexible	47 (78)	44 (73)	
Safety guidewire, *n* (%)	2 (3%)	–	0.5
Impacted stone, *n* (%)	11 (18)	7 (12)	0.4
Median/mean total laser energy, kJ (IQR)	2/4.2 (0.8–6)	1.9/3.5 (0.9–5.1)	0.4
Median/mean laser operating time, min (IQR)	8/13 (4–19)	10/13 (6–17)	0.9
Median/mean surgical time, min (IQR)	60/57 (45–70)	49/49 (32–63)	0.008 [b]
Postendoscopic stenting, *n* (%)	31 (52)	22 (37)	0.09 [b]
Day-case treatment, *n* (%)	50 (83)	55 (92)	0.3
Stone composition, *n* (%)			0.4
Calcium oxalate monohydrate	33 (65)	41 (77)	
Calcium oxalate dihydrate	13 (25)	8 (15)	
Other	5 (10)	4 (8)	

IQR = interquartile range.
[a] Residents' experience ranged from 6 mo to almost 4 yr of training. A faculty urologist always supervised the procedure. The resident was registered as the main surgeon if they performed the main part of the procedure.
[b] Adjusted for four-category stratification group.

Table 3 – Stone-free rates at 3 mo

Definition and location	Holmium group (*n* = 60)	Thulium group (*n* = 59)	*p* value[a]
No residual fragments ≥3 mm			
Overall, % (*n*)	67 (40)	92 (54)	0.001
Renal stones, % (*n*)	49 (19)	86 (30)	0.001
Ureteral stones, % (*n*)	100 (21)	100 (24)	–
Zero fragments			
Overall, % (*n*)	57 (34)	80 (47)	0.006
Renal stones, % (*n*)	33 (13)	66 (23)	0.005
Ureteral stones, % (*n*)	100 (21)	100 (24)	–

[a] Adjusted for four-category stratification group.

Table 4 – Intraoperative complications

Complication	Holmium group	Thulium group	*p* value
Total adverse events, *n* (%)[a]	16 (27)	5 (8)	0.011 [b]
Bleeding impairing vision, *n* (%)	13 (22)	3 (5)	0.014
Perforation, *n* (%)[c]	1 (2)	0 (0)	1
Mucosal abrasion, *n* (%)[d]	6 (10)	2 (3)	0.3

[a] Some patients had more than one adverse event. There were no ureteral avulsions. No procedures were discontinued because of to adverse events.
[b] Adjusted for four-category stratification group.
[c] Perforation was assessed endoscopically or as contrast leakage on a retrograde pyelogram.
[d] Only mucosal abrasion of grade 1 or 2 was registered according to the classification of ureteral wall injuries presented by Traxer and Thomas [15].

Table 5 – Postoperative complications leading to readmission

Complication	Holmium group	Thulium group	*p* value
Total readmissions, *n* (%)[a]	8 (13)	7 (12)	1
Infection, *n* (%)	6 (10)	4 (7)	0.7
Obstruction, *n* (%)[b]	2 (3)	4 (7)	0.7
Other, *n* (%)[c]	1 (2)	1 (2)	1

[a] Some patients had more than one cause of readmission. All complications were classified as Clavien-Dindo grade 2 except for one patient in the thulium group needing a ureteral stent, which was classified as Clavien-Dindo grade 3.
[b] Obstruction leading to dilatation of the upper urinary tract detected on noncontrast computed tomography or pain.
[c] Discomfort related to a ureteral stent or voiding difficulties.

energy between the two groups. It is likely that the results were therefore not influenced by this modest increase in power from the initial laser setting. Furthermore, the laser fibres differed in size between the two groups, which introduces bias and impacts irrigation rates. Although the difference in irrigation between the two groups was limited, this may have influenced the endoscopic view. A further limitation is that no validated tool was used to grade visibility [23]. Most of the stones in this study were <2 cm and future studies are required to assess outcomes with TFL in treating larger stone burdens. No UAS was used in any of the procedures, so UAS did not influence the comparison between Ho:YAG and TFL in the present study. Arguably, UAS omission could have influenced the SFRs, although a recent study showed that UAS yielded no benefit with respect to the SFRs when results from 22 centres and 5316 URS procedures were evaluated [24].

Further studies with larger sample sizes are warranted to validate our findings. While NCCT is considered the gold standard for assessing stone-free status, it is less accurate than contrast studies in detecting stricture formation, which also may not be detectable until a follow-up period beyond 3 mo.

5. Conclusions

Significantly higher SFRs were achieved after single-session URS lithotripsy for renal stones using TFL compared to Ho:YAG. In addition, operative time was significantly shorter and there were significantly fewer intraoperative complications associated with TFL use. The results of this randomised trial support the movement towards TFL as the laser of choice for endoscopic renal stone lithotripsy.

Author contributions: Øyvind Ulvik 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: Ulvik.
Acquisition of data: Ulvik, Æsøy, Juliebø-Jones, Gjengstø, Beisland.
Analysis and interpretation of data: Ulvik, Æsøy, Juliebø-Jones, Beisland.
Drafting of the manuscript: Ulvik, Æsøy, Juliebø-Jones.
Critical revision of the manuscript for important intellectual content: Ulvik, Æsøy, Juliebø-Jones, Gjengstø, Beisland.
Statistical analysis: Ulvik.
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Supervision: Ulvik, Beisland.
Other: None.

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Peer Review Summary

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