

Adoption of thulium fiber laser for lithotripsy: A scoping review and bibliometric analysis

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ABSTRACT

Introduction: While Holmium:YAG for laser lithotripsy remains the gold standard, the thulium fibre laser (TFL) has gained traction as a tool in urolithiasis management. The objective of this study was to review its adoption and use as a clinically effective laser lithotrite.

Methods: We performed a scoping review for articles on TFL for lithotripsy according to Preferred Reporting Items for Systematic reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR). Available clinical outcomes and pre-clinical processes from studies were

KEY MESSAGES

- This review and bibliometric analysis integrates 107 studies (38 clinical, 69 pre-clinical) from 16 countries, mapping the bench-to-bedside trajectory of TFL and documenting a sharp post-2019 surge and global uptake.
- TFL is used mainly in fURS with short laser-on times, high but variably defined SFRs, acceptable complication rates, and rare ureteral/urothelial injury. This is supported by a strong proportion of prospective designs (26% RCTs; 37% prospective cohorts).
- Research gaps include standardizing outcomes/reporting, pragmatic head-to-head trials vs. other modern laser systems with cost-effectiveness analyses and advancing translational safety through more clinically realistic benchtop models with thermal studies.

extracted. A bibliometric analysis was performed to outline and visualize publication trends overall and between clinical vs. pre-clinical studies. The review was registered in the International Prospective Register of Systematic Review (CRD42022300788).

Results: We identified a total of 107 studies using TFL for lithotripsy, 38 of which were clinical including 2803 patients, and 69 pre-clinical. Of the clinical studies, 26 (68%) were prospective and 29 (76%) involved ureteroscopic management of stones compared to 11 (29%) percutaneous nephrolithotomy. Complications rates remained acceptable between 0–32% and stone-free rates varied from 61–100%. Tissue damage from TFL varied from 0–8%. Bibliometric analyses showed a rise in publications after 2020 in both clinical and pre-clinical work, with the U.S. (34%) then Russia (12%) as the leading countries, and the *Journal of Endourology* (24%) then *World Journal of Urology* (23%) being the leading venues.

Conclusions: By unifying clinical outcomes and pre-clinical insights, this review showed the maturation of TFL into an effective, versatile lithotripsy modality with accelerating global uptake. Further evidence is required to better characterize remaining clinical variability, lack of standardized outcome definitions, and cost-effectiveness analyses.

INTRODUCTION

Urolithiasis is a common and increasingly prevalent urological disease, placing a considerable burden on healthcare systems worldwide. Up to 10–20% of patients with urinary stones will require surgical intervention (1). The most common and versatile procedure is flexible ureteroscopy (fURS) (2). In this realm, laser lithotripsy is ubiquitous. While the Holmium:YAG (Ho:YAG) laser has remained the industry standard since the 1990s (3), the Thulium fiber laser (TFL) is a promising candidate for efficacious lithotripsy based on recent benchtop and clinical investigations (4).

TFL offers potential advantages that have spurred extensive research into its applications. It operates at a wavelength of 1940 nm (vs. Ho:YAG's 2120 nm), resulting in a higher water absorption coefficient, more efficient stone dusting, and reduced retro-pulsion (5). TFL's specific modulated pulse properties may allow for more versatile fragmentation settings, while compatibility with smaller laser fibers ($\leq 150\mu\text{m}$) may enhance irrigation and deflection in fURS. This new laser continues to garner increasing attention from the global scientific community, as evident by multiple reviews on its technical evolution (6,7) and clinical outcomes (8–11). However, existing syntheses remain fragmented and do not integrate preclinical insights, clinical translation findings, and global trends.

As such, there is a need for an updated scoping review to consolidate clinical outcomes and preclinical innovations in TFL lithotripsy. To additionally provide insights into research publications associated with TFL, we performed a bibliometric analysis of current works.

METHODS

This work was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42023464849). We followed the Cochrane Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) guidelines (12).

Eligibility criteria

Primary studies on the topic of TFL for lithotripsy were included. Clinical studies were included if they reported efficacy or safety. Pre-clinical studies were included if they incorporated a Thulium-based laser upon calculi or calculi phantoms if *in vitro*, or to be *ex vivo* or *in vivo*, to be included. Exclusion criteria fewer than 5 patients for clinical studies, or pre-clinical studies on TFL without incorporation of calculi or calculi phantoms (laser-alone studies) if *in vitro*, as well as conference abstracts, and literature reviews. Of note, work on the pulsed Thulium:YAG lithotrite was included as well for comprehensiveness owing to their shared origin, despite different laser mechanisms.

Screening process

Multiple reviewers (IA, RD, & ALN) independently screened the results of electronic literature searches based on the pre-defined eligibility criteria from inception until September 14th of 2024. Articles after this date were not considered due to known lag-time effects for citations and bibliometrics. The databases were Medical Literature Analysis and Retrieval System Online (MEDLINE), Excerpta Medica dataBASE (EMBASE), Scopus, and Web of Science. English was applied as a language restriction. Bibliographies from included studies were also parsed to identify missed relevant citations. All articles were uploaded to Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) for screening. A comprehensive record of database-specific screening strategies is presented in Tables S1-S4 in Appendix S1.

Data synthesis

Extracted data from included studies was tabulated by two independent reviewers (IA & RD), categorized by either clinical or pre-clinical study type. Discrepancies were resolved through discussion.

For the bibliometric analysis, bibliometric data included year of publication, journal, country of lead author, citations from Scopus, field-weighted citation impact (FWCI) from Scopus, and citations per year were extracted. FWCI is a metric that describes the ratio of total citations received by an article compared to the total citations that would be expected based on the average of the subject field (13). Meaning a high FWCI article is high-performing in its field regardless of exact citation count. Type of TFL system used was also recorded from all studies. For clinical studies, patient outcomes including demographics, complications, and stone free

rates (SFR) were outlined. Complications were described with endourology-adjusted Clavien-Dindo classification system grades (14). For pre-clinical studies, based on an a priori focus on experimental methodologies, we outlined study design, set-up, and relevant objectives.

Quality and risk of bias assessment

Clinical studies were assessed for quality and bias using design-specific Cochrane tools by two independent reviewers (IA & RD), with discrepancies resolved through discussion.

Randomized controlled studies were evaluated using the risk of bias in randomized trials (RoB 2) tool (15). Non-randomized cohort studies were evaluated using the risk of bias in non-randomized studies of interventions (ROBINS-I) tool (16). Pre-clinical studies were evaluated qualitatively in this regard due to a lack of prevalent validated tools.

Bibliometric and statistical analyses

All analyses were conducted using R, version 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria). For all studies, descriptive statistics were outlined as appropriate. Citation counts, FWCI, and citations per year were summarized overall and compared between clinical vs. pre-clinical studies using Mann-Whitney U test. Choropleth maps were generated to compare counts for country of lead overall and between clinical vs. pre-clinical studies. Journal counts were visualized overall and between clinical vs. pre-clinical studies. Publication trends were visualized per year and cumulatively over time, overall and between clinical vs. pre-clinical studies.

RESULTS

Included studies

As per PRISMA guidelines, from 2016 records, 1257 underwent initial screening, and 172 full articles were retrieved to identify a total of 107 studies for inclusion (Figure 1). Clinical studies represented 38 (36%) articles from 2020-2024; while pre-clinical studies represented 69 (64%) articles from 2005-2024. Across all studies, 16 countries for study lead were represented (Figure 2A), with the top 3 countries being USA (34%) by a large margin, then Russia (12%), and India (10%). These studies were published across 30 different journals (Figure 2B), with the top 3 journals being Journal of Endourology (24%), World Journal of Urology (23%), then a drop to the Journal of Biomedical Optics (9%). Visualizing publication trends over time (Figure 2C & 2D), it is evident that counts were slowly rising for pre-clinical works from 2005-2019, until sharply increasing for both pre-clinical and clinical works from 2020 onwards. Comparing median citation metrics between clinical and pre-clinical studies (Table S6), pre-clinical studies received significantly more total citations with 19 (IQR 7, 35) vs. 14 (IQR 2.5, 22.5) ($p=0.045$). But as FWCI (2.3 vs. 2.7 respectively) and citations per year (5 vs. 4.5 respectively) were similar between groups ($p=0.847$ and $p=0.174$ respectively), this difference can be attributed to the lag-

time between pre-clinical and clinical topics. Comprehensive bibliometric data for all 107 studies is available in Table S5 & S6 in Appendix S1.

Clinical studies on TFL for lithotripsy

The current clinical usage for this technology showcases its efficacy and versatility. From 38 clinical articles encompassing 2803 patients managed with TFL for lithotripsy, 10 (26%) were randomized controlled trials (RCTs) (17–26), 2 (5%) were non-randomized comparative prospective cohorts (27,28), 5 (13%) were comparative retrospective cohorts (29–33), 14 (37%) were prospective cohorts (34–47), and 7 (18%) were retrospective cohorts (48–54). Of note, 3 (8%) included studies (34,35,41) showcased clinical use of the pulsed Thulium:YAG. Majority of these clinical studies involved use of TFL during fURS (29, 76%) while 11 (29%) involved utilization of TFL during percutaneous nephrolithotomy (PCNL) or mini-PCNL. Almost 80% of studies (30) included patients with renal stones, 20 (53%) of patients had ureteric stones, and 5 (13%) had bladder stones. Laser-on-time ranged from 1.2-35 minutes, complication rates ranged from 0-32%, and SFR ranged from 61-100% at a follow-up ranging from 24 hours to 3 months. SFR definitions for each study varied and are available in Table S8 of Appendix S1. Specific complication reports included primarily hematuria, urinary tract infections (UTI), and post-operative fevers. Urothelial or ureteric damage was rarely reported at a range of 0-8% over studies. For studies that reported urothelial or ureteric damage, 2 (29%) used a ureteral access sheath (22,33), 2 (29%) did not use a sheath (30,37), and 3 (43%) did not report sheath use for these cases (21,25,31). A single study described tissue injury during laser-on fragmentation (22), a single study described this with the laser off (37), and the rest did not describe this granularity. Detailed study methodologies and findings including laser types, laser settings, stone characteristics, all complications with Clavien-Dindo grades, SFR definitions, and outcomes are available in Table S7 & S8 in Appendix S1. All studies described initial laser studies, which varied substantially between studies. While some studies described changes in settings for fragmentation, popcorning, or dusting (Table S7), no studies described settings between different stone composition types. Bibliometric sub-group analyses for clinical studies are available in Figure S3B & S4B.

Detailed domain-specific and overall plots for risk of bias assessment are presented in Figure S1 & S2 in Appendix S1. All 10 randomized studies were assessed as having some concerns overall (17–26). For all other cohort studies, 13 (46%) were assessed as having overall serious risk of bias (34–37,41,43–45,49–53) and 15 (54%) as moderate risk of bias (27,29–33,38–40,42,46–48,54,55).

Pre-clinical studies on TFL for lithotripsy

A complete reference list of 69 identified pre-clinical studies is available in Appendix S1. We found 57 articles (83%) were in vitro studies with isolated stone samples, 9 (13%) were ex vivo studies with mostly porcine specimens, and 3 (4%) were in vivo studies with porcine models.

These had high variability with earlier works focusing on establishing feasibility (56,57), later works on fine-tuning efficacious laser settings (58–60), and recent works investigating its extended safety profile (e.g., temperature effects, tissue damage) (61–65). Detailed study processes including laser types and experimental aims are available in Table S9 in Appendix S1. Bibliometric sub-group analyses for pre-clinical studies are available in Figure S3A & S4A.

DISCUSSION

This scoping review and bibliometric analysis maps the bench-to bedside arc of TFL in lithotripsy and clarifies where the strongest evidence lies. A total of 107 studies spanning 16 countries and 30 journals were assessed. With extensive pre-clinical work (2005-2019) laying the groundwork for rapid translation, we observed a sharp inflection in output after 2019 that was coincident with international (Russian/North American/European) regulatory approvals (66). Clinically, across 2,803 patients, TFL was used predominantly in fURS with a substantial minority in (mini-)PCNL, displaying short laser-on-times and promising SFRs. Safety signals were consistent with contemporary endourology procedures, dominated by UTI, hematuria, and low rates of tissue injury.

The clinical corpus that we identified builds on the growing and strong evidence that TFL has established a role in urolithiasis treatment. The large proportion of prospective designs (26% RCTs and 37% prospective cohorts) likely contributes to clinicians' attitudes and confidence in this technology. These findings align with growing enthusiasm for TFL reported in contemporary surveys of endourologists and practice-pattern reports. For example, Canadian surgeons indicated a preference for TFL when available (67) in their practices, despite only a reported 59% availability in non-academic centres. The immediate clinical agenda should prioritize harmonizing outcome definitions (e.g. SFR thresholds pertaining to imaging modality and timing), head-to-head RCTs against modern high-power, pulse-modulated (MOSES) Ho:YAG platforms, and cost-effectiveness analyses that include equipment varieties and operating time. Although this is not unique to TFL, the field of lithotripsy in general may benefit from these additions. Another gap with no featured work yet in this context would be the role of TFL versus other lasers in the new adjunctive uses of suction and steerable devices in URS. The growing use of adjunctive suction or steerable devices in URS Future trials should also capture patient-centered and safety-adjacent endpoints that are sparse in current TFL reports like post-operative pain, ED visits, readmissions, and intraoperative temperature management strategies. There is growing literature about unsafe settings associated with TFL, but investigations in this regard are continuing both clinically and in the lab. Future guideline committees will need to address the question of TFL for lithotripsy and provide recommendations beyond SFR alone.

Even in the era of regulatory approval for TFL, pre-clinical work remains indispensable for parameter discovery and safety investigations. Our identified pre-clinical experiments converged on features that are instrumental to clinical use: dusting efficiency at low energy/high frequency, reduced retropulsion, and the ergonomic advantages of $\leq 150 \mu\text{m}$ fibers for TFL. The

possible thermal risks of this technology have also been spotlighted, with recent investigations into mitigation by flow and duty-cycle control (64,68). Our temporal analyses show that after clinical use expanded in 2020, both pre-clinical and clinical publications surged. This bidirectional reinforcement between laboratory and clinical work is a unique strength of the TFL literature thus far. However, as rightly noted by Kim and Ghani (2022) and reinforced by our findings, most experimental TFL work has been performed in idealized *in vitro* settings with continuous laser contact (69). Certainly, the possibility of irreconcilable differences in a real-world setting exists, considering the lack of more realistic *ex/in vivo* work. The next benchtop priorities seem clear: adopting standardized experimental designs that are accurate with clinical use, further quantifying thermal effects under clinically relevant dwell times, and establishing *a priori* protocols in collaboration with regulatory boards to ease further translation for future human trials.

Notwithstanding the robust and rapidly expanding body of literature, this scoping review has illuminated several critical knowledge gaps that must guide future widespread adoption of TFL for lithotripsy. Primarily, there is a deficit in long-term clinical data and real-world effectiveness studies beyond specialized and academic centers, leaving the durability of TFL's outcomes and its performance across a broader surgical setting uncertain. The field also lacks comprehensive economic analyses comparing TFL to advanced Ho:YAG platforms, a key determinant for widespread adoption across the globe. In the same light, practical considerations including noise pollution, differences in energy ports, and size constraints between the two have received relatively shallow investigations. For TFL, while thermal risks have been identified pre-clinically, their clinical correlation and optimal mitigation strategies during prolonged procedures remain inadequately explored. For this, developing better high-fidelity pre-clinical models in realistic experiments will be a crucial consideration. Finally, patient-centered outcomes, including convalescence metrics and health-related quality of life, are virtually absent from the current evidence base. Therefore, the next generation of studies must prioritize pragmatic trials with longer follow-up, rigorous cost-effectiveness evaluations, protocols for intraoperative safety monitoring, and the inclusion of patient-reported outcome measures to fully define TFL's role in modern endourology.

This review must be interpreted considering its limitations. First, our search was restricted to English, so non-English reports and gray literature may be underrepresented. Second, clinical studies were highly heterogeneous in laser platforms, settings (pulse energy/frequency, pulse modulation, fiber caliber), stone location, and SFR definitions. This precluded pooled estimates or dose–response analyses which would be beneficial in understanding the real-world usage of this technology. Third, risk of bias was frequently moderate-serious for clinical studies, tempering the certainty of data synthesis from this review. Fourth, TFL's pre-clinical corpus is dominated by *in vitro* work using incongruent phantoms, irrigation conditions, and surrogates for ablation/retropulsion; ergo, the overall clinical

translatability of these studies remains difficult to assess. Fifth, bibliometric comparisons relied on Scopus-derived counts and FWCI, which remain susceptible to platform and time-lag effects despite citations-per-year adjustment.

CONCLUSIONS

This study integrates clinical and pre-clinical evidence on TFL lithotripsy, delineating its bench-to-bedside trajectory. Across 107 studies encompassing 2,803 patients, TFL was predominantly used for fURS and PCNL with short laser-on-times, high (albeit variably defined) SFRs, and acceptable complication rates. Bibliometrics showed global adoption and a post-2019 publication surge mirroring regulatory approvals. These findings support TFL as an effective and versatile modality. We identified key areas for future research, including standardizing outcomes, cost-effectiveness analyses, and translational safety work on thermal management.



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FIGURES AND TABLES

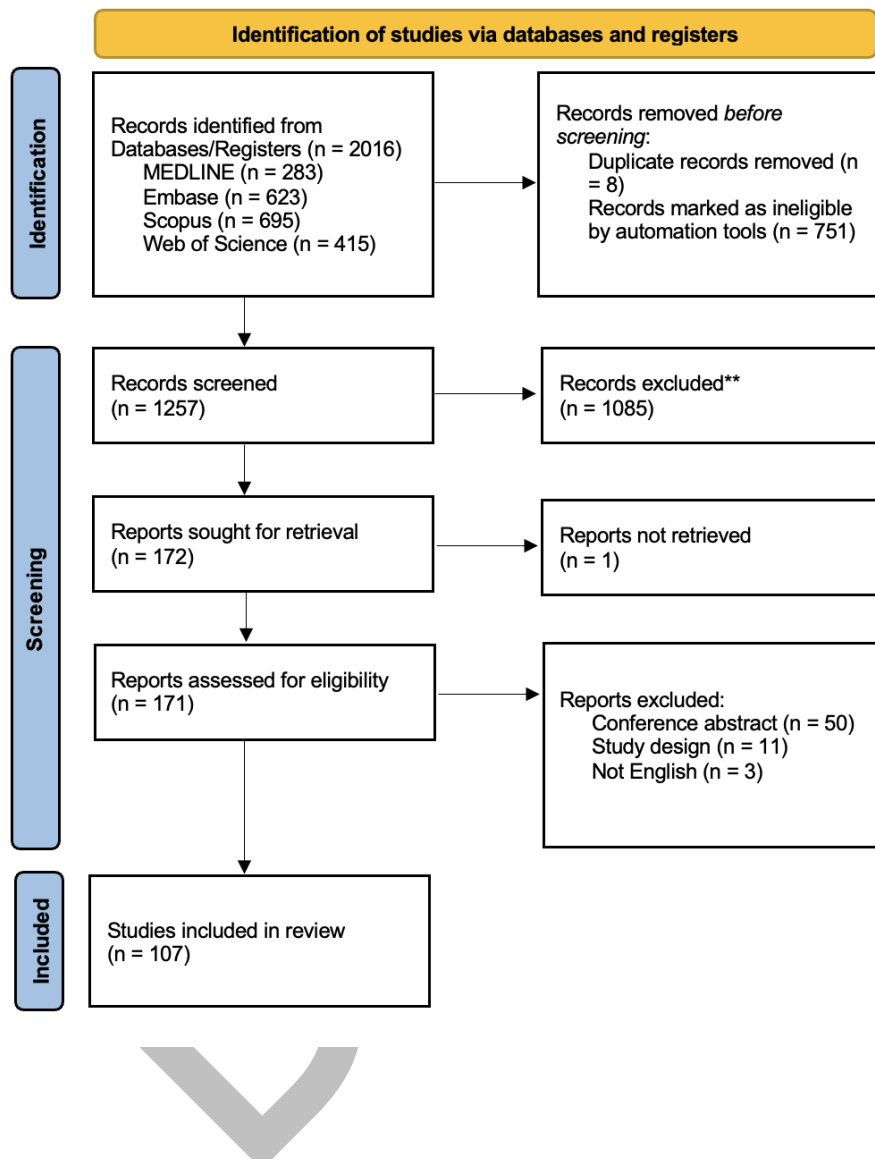
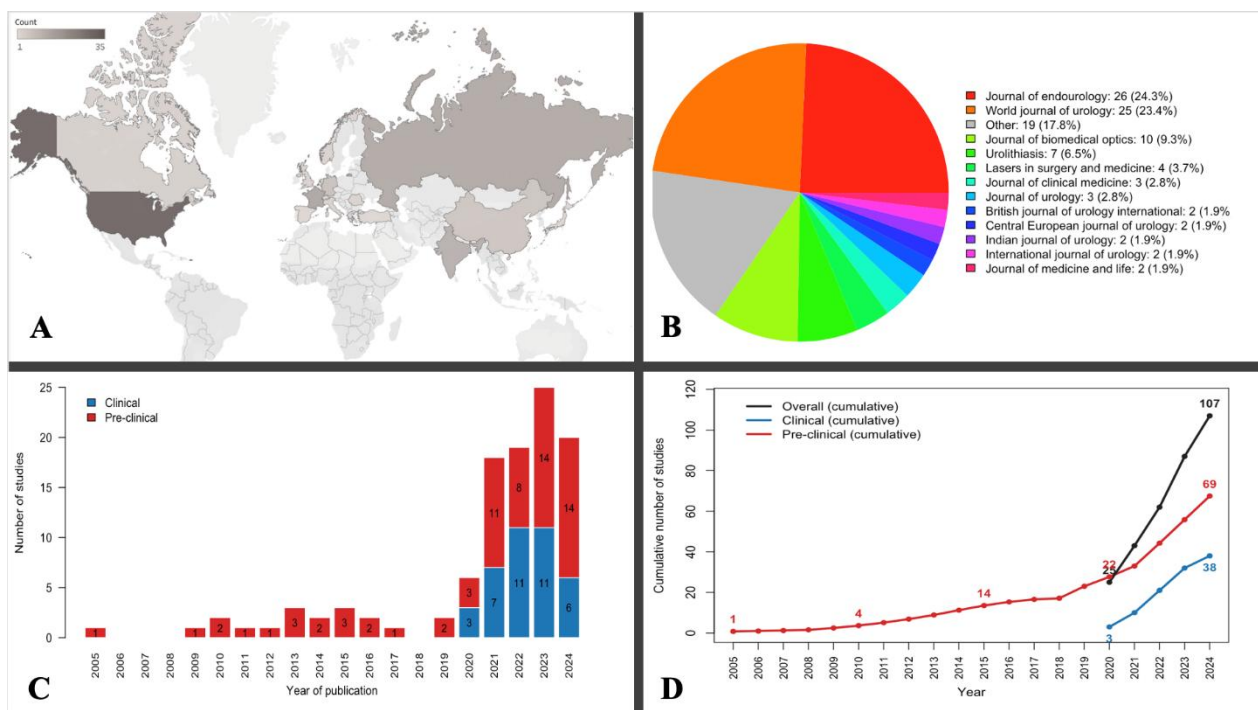
Figure 1. PRISMA (Preferred reporting items for systematic reviews and meta-analyses) diagram for thulium fibre laser studies in lithotripsy.

Figure 2. Bibliometric analyses for thulium fiber laser studies in lithotripsy, including (A) an overall country of lead choropleth map; (B) overall journal distribution where singleton journal entries were counted under Other; (C) number of clinical/pre-clinical studies published per year; and (D) clinical/pre-clinical cumulative studies per year.



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