The clinical efficiency and safety of 60W superpulse thulium fiber laser in retrograde intrarenal surgery

Chandra Mohan Vaddi, Paidakula Ramakrishna, Soundarya Ganeshan*, Siddalinga Swamy, Hemnath Anandan, Manas Babu, Rakesh Panda
Department of Urology, Preeti Urology and Kidney Hospital, Remedy Hospital LN, Hyderabad, Telangana, India
*E-mail: drsoundarya.ganesan@gmail.com

INTRODUCTION

Flexible ureteroscopy with laser lithotripsy is an attractive minimally invasive options for the management of urolithiasis, with low morbidity and high treatment efficacy.[1-3] For over three decades, Holmium YAG (Ho: YAG) laser has been considered the gold standard for laser lithotripsy.[1,4,5] The HoYAG laser is versatile in that it can ablate stone of any composition and also has soft-tissue applications. Having an excellent safety profile, this has been considered the most successful laser so far.[1,4,5] However, it has some technical limitations. The wavelength of the HoYAG laser does not match the water absorption peak.[5] The multimodal beam profile limits the compatibility of HoYAG to larger diameter fibers (>200 μm), which in turn impairs the scope deflectability and irrigation flow.[5] Pulse energy of the HoYAG laser cannot be increased without an increase in retropulsion and an inefficient pumping scheme that limits the pulse frequency (<5–80 Hz). The HoYAG lasers are big and heavy that require high power outlets and water-cooling system.[5]

Conversely, the Thulium fiber laser (TFL) wavelength (1940 nm) is closer to the water absorption peak, which results in four-fold higher absorption than HoYAG.[6] The higher absorption in water translates into lower

ABSTRACT

**Introduction:** Our aim is to evaluate the clinical efficiency and safety of 60W Thulium fiber laser (TFL) during retrograde intrarenal surgery (RIRS). The performance of the TFL across different ranges of stone volumes and stone densities is assessed.

**Materials and Methods:** Between October 2019 and August 2020, a prospective study was done on 135 patients with <20 mm renal stones, who underwent RIRS using TFL. Stone parameters, total laser time, total energy delivered (kJ), and fiber burn-back were recorded. Laser efficacy (J/mm³) and ablation speed (mm³/s) were calculated.

**Results:** Data of 126 of 135 patients included in the study were analyzed. The mean patient age was 45.04 ± 12.30 years. Mean stone size was 15.19 ± 4.52 mm, and mean stone volume was 1061.85 ± 806.81 mm³. Mean laser time was 19.78 ± 12.32 min. At higher stone volume (>1000 mm³), J/mm³ decreased significantly from 16.18 ± 5.90 to 10.92 ± 3.21 (P < 0.001) and the ablation speed increased significantly (0.77 ± 0.28–1.04 ± 0.28 mm³/s [P < 0.001]). Stone density did not have a significant influence on the laser efficacy [B = -0.31 (-2.45 to 1.82, p=0.771)] or on the ablation speed [B = -0.06 (-0.17 to 0.05, p=0.278)]. Overall SFR was 93.6%. The complication rate was 16.6% (21/126). Out of the 21, 12 patients had hematuria and 9 had fever, which were of Clavien grades 1–2.

**Conclusion:** Superpulse TFL is efficient and safe. The work efficiency increases for larger volume stones. The work efficiency remains the same across different stone densities. No complication more than Clavien grade 2 was encountered.
ablation threshold, with the requirement of lesser energy to achieve same ablation volumes.\textsuperscript{6,9} The uniform beam profile enables coupling with smaller diameter fibers (50–150 μm core).\textsuperscript{3} The diode-pumped laser enables very high pulse frequencies (up to 2200 Hz) and very low pulse energies (as low as 0.025J).\textsuperscript{5,6} These allow a more flexible choice of laser parameters, combined with less retro expulsion and less fiber burn back. The TFL machines are lighter, portable and require a simple air-cooling system.\textsuperscript{3,5,9,10}

TFL requires lower energy settings than HoYAG laser to achieve the same ablation rates, because of the more efficient water absorption\textsuperscript{6} and “micro-explosion” mechanism.\textsuperscript{7} The ablation rates are two-fold higher than Ho YAG laser from the reports of \textit{in vitro} studies\textsuperscript{8–10} and ablation volume is 2.2, 2.0, and 1.6 times higher than short pulse, long pulse, and Moses modes of Ho YAG laser.\textsuperscript{11} The preclinical studies propose that TFL enables achieve faster and finer “Dust,”\textsuperscript{12} as very low pulse energy and very high frequency is possible.\textsuperscript{6} Claimed to have so many advantages, this study assessed the application of TFL in a clinical scenario.

The aim of this study was to evaluate the clinical efficiency and the safety of TFL during retrograde intrarenal surgery (RIRS). The clinical efficiency of the laser was analyzed in terms of ablation speed (time required for ablation of 1 mm\textsuperscript{3} volume of stone, mm\textsuperscript{3}/sec) and laser efficacy (energy required for ablation of 1 mm\textsuperscript{3} volume of stone, J/mm\textsuperscript{3}).\textsuperscript{13} The performance of 60W TFL across different ranges of stone volumes and stone densities was assessed.

**MATERIALS AND METHODS**

**Study design**

Between October 2019 and August 2020, a prospective study was done on 135 cases of RIRS, using 60W Superpulse Thulium fiber laser (Urolase SP+, IPG Photonics, Oxford, Massachusetts, United States). Informed consent was obtained from all the patients enrolled and Institutional Ethics Committee approval was obtained (ECR/255/INST/AP/AUGUST 22, 2019). Inclusion criteria were: renal and proximal ureteric stones <20 mm in size. Exclusion criteria were: patients on anticoagulants/bleeding diathesis, previously operated genitourinary tracts with modified anatomy (reimplanted ureters, conduits, posttransplant), anomalous kidneys, patients requiring concomitant surgical intervention, pediatric cases (<12 years of age), and pregnant patients.

All patients included in the study underwent basic blood investigations, urine culture and noncontrast computed tomography (NCCT) kidney, ureter, and bladder (KUB), for the assessment of the stone size and density. Stone volume was calculated using automated software (GE, General Electronics, version 4.4, Chicago, Illinois, United States).

**Surgical technique**

Flexible ureterorenoscopy (FURS) was done using P7 (Olympus, Shinjuku, Tokyo) or Flex X2s (Karl Storz, Tuttingen, Germany) scopes. A 9.5/11.5 Fr, 28 cm (Cook Flexor) ureteral access sheath (UAS) was used. In cases where UAS insertion failed, double-J stents were inserted and RIRS was performed 10–14 days later. A 200 μ laser fiber was used in all cases.

All procedures were done by a single surgeon. Initially, contact lithotripsy was done in either dusting mode or fragmentation mode. This was followed by noncontact lithotripsy (popcorning), until fine dust, small enough to pass spontaneously, was formed.\textsuperscript{12} Thus, popcorning is common in both modes, at the end, to obtain fine dust. No stone retrieval was done after fragmentation mode. Nitinol basket (N-circle 2.2Fr, Cook Urological or Dakota 1.9Fr, Boston Scientific) was used for relocation of lower pole stones.

The settings used were 0.1–0.2J, 100–150 Hz (10–30W) in Dusting mode, 1–2J, 10–20 Hz (10–40W) in Fragmentation mode and 0.1–0.2J, 200 Hz (20–40 W) in Popcorning mode. Irrigation was done manually using a 50 ml syringe. A 3.5 Fr D (Indovasive, Biorad Medisys, Pune, India) stent was placed in all the cases, which was removed after 2 weeks.

**Outcome measures**

Total FURS time was the time between flexible ureteroscope insertion and removal from access sheath. Total laser time was the total time the laser was in use, recorded from the laser machine. Laser efficacy was calculated as the total energy delivered, divided by the stone volume (J/mm\textsuperscript{3}).\textsuperscript{13} Ablation speed was estimated as the stone volume divided by the total laser time (mm\textsuperscript{3}/s).\textsuperscript{13} The laser fiber was measured for the burn-back after each case using digital micrometer (Mitutoyo, Tokyo, Japan). Complications were classified according to the modified Clavien-Dindo grading and the stone-free rate was calculated by NCCT KUB at the end of 3 months. Residual stones more than 2 mm were considered significant. After initial NCCT KUB at 3 months, patients were followed up with serial ultrasonography KUB three monthly and if they developed flank pain or hydrourteronephrosis, computed tomography urogram was done to look for any ureteric sticture.

**Statistical analysis**

Data were coded and recorded in the MS Excel spreadsheet program. SPSSv23 (IBM Corp., USA) was used for data analysis. Descriptive statistics were elaborated in the form of means/standard deviations and medians/interquartile range for continuous variables, and frequencies and percentages for categorical variables. Data were presented graphically wherever appropriate for data visualization using histograms/box-and-whisker plots/column charts for continuous data and bar charts/pie charts for categorical data.
Group comparisons for continuously distributed data were made using the independent sample t-test when comparing two groups, and one-way ANOVA when comparing more than two groups. Post hoc pairwise analysis was performed using Tukey’s honestly significant difference test in the case of one-way ANOVA to control for alpha inflation. If data were found to be non-normally distributed, appropriate nonparametric tests in the form of Wilcoxon test/Kruskal–Wallis test were used for these comparisons. Chi-squared test was used for group comparisons for categorical data. In case the expected frequency in the contingency tables was found to be <5 for >25% of the cells, Fisher’s exact test was used instead.

Linear correlation between two continuous variables was explored using Pearson’s correlation (if the data were normally distributed) and Spearman’s correlation (for non-normally distributed data). Receiver operating characteristic (ROC) curves were plotted for determining the diagnostic performance and the best cut-off for continuous variables in predicting a dichotomous outcome. Binary logistic regression was conducted to ascertain the significant predictors of dichotomous outcomes. Linear regression was conducted to ascertain the significant predictors of continuous outcomes. First, univariable regression was performed to find out the individual coefficients/odds ratios and significance for each of the variables. Then, the backward stepwise variable selection was used to choose the best set of predictor variables. Finally, multivariable linear/ordinal/logistic regression was performed to get the final model. Statistical significance was kept at P < 0.05.

RESULTS

Laser efficiency outcomes

Data of 126 of 135 patients included in the study were analyzed, 9 had lost follow-up and were excluded. Demographic data are described in Table 1. Laser efficiency parameters are described in Table 2. An increase in stone size (>10 mm) and volume (>1000 mm³) significantly increased the laser time (13.56 ± 7.21–31.42 ± 11.46 min [P < 0.001]). At higher stone volume (>1000 mm³), the energy required for ablation of 1 mm³ of stone (Laser efficacy, J/mm³) decreased significantly from 16.18 ± 5.90 to 10.92 ± 3.21 (P < 0.001) and the ablation speed increased significantly (0.77 ± 0.28 to –1.04 ± 0.28 mm/s [P < 0.001]) [Figure 1a and b].

At higher stone density (>1000HU), the laser time significantly increased from 14.25 ± 10.35 to 26.08 ± 11.39 min (P < 0.001). However, multivariate analysis revealed, stone density did not have a significant influence on the laser efficacy [B = -0.31 (-2.45 to 1.82, p=0.771)] or on the ablation speed [B = -0.06 (-0.17 to 0.05, p=0.278)].

From the above results, for larger stone volume, the work efficiency of the laser increases (energy required for ablation of 1 mm³ of stone decreases). Furthermore, the stone fragmentation rate (ablation speed) increases for larger volume stones.

Stone density did not have a significant influence on the laser efficacy or on ablation speed. The work efficiency remains the same across different stone densities. Subgroup analysis was performed between dusting and fragmentation modes after controlling for parameters such as stone size, volume, and density [Table 3]. Regression analysis revealed ablation speed was significantly higher in fragmentation mode (0.95 ± 0.28 mm/s) as compared to dusting mode (0.76 ± 0.25 mm/s), P = 0.008. Fiber burn-back was significantly higher with fragmentation mode than in dusting mode (2.43 ± 3.53 mm vs. 0.43 ± 0.67 mm, P < 0.001). In fragmentation mode, fiber burn-back >1 mm occurred when power settings of ≥16W was used (P < 0.001, area under ROC curve-0.855) [Figure 2a]. Fiber burn-back >5 mm occurred

---

Table 1: Characteristics of the study population

| Parameters of study population | Study population n=126 |
|-------------------------------|------------------------|
| Age (years), mean±SD          | 45.04±12.30            |
| Sex, n (%)                    |                        |
| Male                          | 76 (60.3)              |
| Female                        | 50 (39.6)              |
| Side, n (%)                   |                        |
| Right                         | 74 (58.7)              |
| Left                          | 52 (41.2)              |
| Location, n (%)               |                        |
| Single                        | 97 (76.9)              |
| Multiple                      | 29 (23.0)              |
| Upper calyx                   | 18 (14.2)              |
| Middle calyx                  | 14 (11.1)              |
| Lower calyx                   | 23 (18.2)              |
| Pelvis                        | 14 (14.2)              |
| Proximal ureter               | 24 (19.04)             |
| Multiple locations            | 29 (23.0)              |
| Preoperative stent, n(%)      | 44 (34.9)              |
| Ureteral access sheath usage, n(%) | 117 (92.8)  |
| Relook RIRS (required), n (%) | 11 (8.7)               |
| Follow-up (months), mean (SD) | 16.95 (0.98)           |
| Stone free, n (%)             | 118/126 (93.6)         |

SD = Standard deviation, RIRS = Retrograde intrarenal surgery

Table 2: Laser efficiency outcomes

| Parameters of the study population | Mean±SD |
|-----------------------------------|---------|
| Stone size (mm), mean±SD          | 15.19±4.52 |
| Stone volume (cu.mm), mean±SD     | 1061.85±806.81 |
| Stone density (HU), mean±SD       | 985.82±302.57 |
| Total laser time (min), mean±SD   | 19.78±13.12 |
| Total FURS time (min), mean±SD    | 33.21±16.05 |
| Mode of operation, n (%)          |         |
| Fragmentation                     | 65 (51.6)                |
| Dusting                           | 61 (48.4)                |
| Average power (Watts), mean±SD    | 18.50±11.26              |
| Total energy consumed (KiloJoules), mean±SD | 13.06±1.93 |
| Laser efficacy (J/mm³), mean±SD   | 14.35±5.70               |
| Ablation speed (mm²/s), mean±SD   | 0.86±0.31                |

FURS = Flexible ureterorenoscopy, SD = Standard deviation, HU = Hounsfield units
when power settings of ≥22.5W was used ($P = 0.001$, area under ROC curve 0.901) [Figure 2b]

**Clinical outcomes**

The follow-up ranged from 15 to 18 months, with the mean (standard deviation) duration being 16.95 (0.98) months. The stone-free rate was 93.6% (118 out of 126 patients). Postoperative complications occurred in 16.6%, (21/126), which were mostly of Clavien Grades 1–2. Twelve patients had hematuria, out of whom 11 were of Grade 1 and one was of Grade 2, requiring irrigation for 48 h. Nine patients had fever, who required a change to a higher generation antibiotic (Clavien Grade 2). No complication > Grade 2 was seen.
DISCUSSION

There are enough preclinical studies to suggest that TFL is efficient in lithotripsy by virtue of fast ablation and high ablation volumes. There are only a few clinical studies focussing on the efficiency of TFL till date. The performance of the TFL across different ranges of stone volumes and stone densities is assessed in our study, using the parameters of laser efficacy (J/mm³) and ablation speed (mm³/s), as a measure of lithotripsy efficiency. This is the first clinical study on TFL, highlighting the relation of the above parameters with stone volume and density.

The usage of TFL in the clinical setting has been reported from a few centers worldwide. Corrales and Traxer in their series of 50 cases, found TFL a safe and effective modality with minimal complications.

In our study, a mean FURS time of 33.21 ± 16.05 min and mean laser time of 19.78 ± 12.32 min was required for a mean stone size of 15.19 ± 4.52 mm and mean stone volume of 1061.85 ± 806.81 mm³. Mean ablation speed was 0.86 ± 0.31 mm/s and the mean laser efficacy was 14.35 ± 5.70 J/mm³. Previous studies with HoYAG lithotripsy suggest much longer operating times for similar sized stones. Sabinis et al. reported a mean operating time of 50.63 min for a mean stone size of 14.2 mm (0.34), with 30W HoYAG laser at 15W setting. Resorlu et al. reported a mean operating time of 43.2 min for a mean stone size of 15.6 mm.

Ibrahim et al. compared regular and Moses modes of high power HoYAG laser (120W) and reported that total laser time of 21.1 ± 15.1 min and operating time of 50.9 ± 27.9 min was required for a mean stone size of 1.4 ± 0.97 cm with regular mode. With Moses mode, laser time of 14.2 ± 12.3 min and operating time of 41.1 ± 21.1 min was required for a mean stone size of 1.7 ± 1.5 cm. They used 32W and 10W settings for dusting and fragmentation, respectively, while we used up to 40W settings. Comparing with the results from this study, it was observed that the operating time with SP TFL is shorter than the regular mode of High power HoYAG (33.21 ± 16.05 min vs. 50.9 ± 27.9 min, respectively).

Ventimiglia et al. used 35W HoYAG for a mean stone volume of 1599 mm³ and reported the laser efficacy as 19 J/mm³ and ablation speed as 0.7 mm/s. Majdalany et al. used Moses Technology, P120 laser for a mean stone volume of 290 mm³ and found the laser efficacy to be 38.2 J/mm³ and the ablation speed to be 0.9 mm³/s. In this study, 60W TFL was used for a mean stone volume of 1061.85 mm³, and found the laser efficacy was 14.35 J/mm³ and the ablation speed was 0.86 mm³/s.

Laser efficacy is the energy required for the ablation of 1 mm³ of stone. A lesser J/mm³ indicates higher work efficiency. Higher ablation speeds (mm³/s) imply better work efficiency. Ventimiglia et al. reported that more energy was required to ablate 1 mm³ of stone, for bigger volume stones, using 35W HoYAG laser. On the contrary, with 60W TFL, we found that less energy was required to ablate 1 mm³ of stone, for bigger volume stones (>1000 mm³) [Figure 1b]. The ablation speed increased significantly with increasing size (>10 mm) and volume (>1000 mm³) of the stone [Figure 1a]. Therefore, this implies, bigger the stone, lesser the energy required per mm³ of stone (better work efficiency) and faster the rate of ablation.

Ventimiglia et al. reported that more J/mm³ was required for stones with density >1000HU, with 35W HoYAG. In our study, we found that stone density did not have a significant influence on the laser efficacy [B = -0.31 (-2.45 to 1.82, p = 0.771)] or on the ablation speed [B = -0.06 (-0.17 to 0.05, p = 0.278)]. This implies that TFL works efficiently across different stone densities.

Recently, Enikeev et al. compared 15W (30 Hz, 0.5J) and 30W (200 Hz, 0.15J) settings, in dusting mode using SuperPulsed Thulium-fiber laser (NTO IRE-Polus, Russia) peak/average power of 500/50 W. They found that ablation efficacy and speed were higher in 30W mode as compared to 15W mode (2.7 vs. 3.8 J/mm³ and 5.5 vs. 8.0 mm³/s, respectively). We used Fragmentation mode (average power 24.82 ± 10.52W) and Dusting mode (average power 10.84 ± 3.82 W). We found that ablation speed was significantly higher in fragmentation mode (0.95 ± 0.28 mm³/s) as compared to the dusting mode (0.76 ± 0.25 mm³/s), P = 0.008. Further multicentric randomized controlled studies, using these different modes of lithotripsy are needed, before we draw conclusions.

Andreeva et al. reported a fiber burn of 1.4 mm with 50W setting in his preclinical study using Superpulse TFL (IPG Photonics, Oxford, MA), maximum average power of 50W. We found fiber burn-back was quite high in the fragmentation mode, as compared to the dusting mode. In the fragmentation mode, fiber burn-back >1 mm occurred when average power settings of ≥16W were used. Fiber burn-back >5 mm occurred when average power settings ≥22.5W were used [Figure 2a, b]. In the dusting mode, the fiber burn-back was very low (mean 0.43 ± 0.67 mm), P < 0.001.

Complications were of Clavien grades 1–2. There was no case of significant bleeding requiring transfusion, urine leak, stricture and no significant change in serum creatinine postoperatively (1.13 ± 0.29 vs. 1.01 ± 0.17, P = 0.85). Despite using up to 40W power settings, we did not find any high grade (more than Clavien Grade 2) complications, in the given follow-up period.

The SFR in this study was 93.6% which is higher than the results obtained with high power HoYAG laser.
systems in lithotripsy. Nat Rev Urol 2018;15:563-73.
6. Kronenberg P, Traxer O. The laser of the future: Reality and expectations about the new thulium fiber laser – A systematic review. Transl Androl Urol 2019;8:529-817.
7. Hardy LA, Vinnichenko V, Fried NM. High power holmium: YAG versus thulium fiber laser treatment of kidney stones in dusting mode: Ablation rate and fragment size studies. Lasers Surg Med 2019;51:522-30.
8. Andreeva V, Vinarov A, Yaroslavsky I, Kovalenko A, Vybornov A, Rapoport L, et al. Preclinical comparison of superpulse thulium fiber laser and a holmium: YAG laser for lithotripsy. World J Urol 2020;38:497-503.
9. Panthier F, Doizi S, Lapouge P, Chausain C, Kogane N, Berthe L, et al. Comparison of the ablation rates, fissures and fragments produced with 150 μm and 272 μm fiber lasers with superpulsed thulium fiber laser: An in vitro study. World J Urol 2021;39:1683-91.
10. De Coninck V, Keller EX, Kovalenko A, Vinnichenko V, Traxer O. MP03-20 dusting efficiency comparison between Moses technology of Ho: YAG laser and superpulse thulium fiber laser. J Urol 2019;201 Suppl 4:e28-9.
11. Traxer O, De Coninck V, Keller E, Kovalenko A, Andreeva V, Doizi S. Comparing short, long, and Moses regimes of Ho: YAG laser vs. Super Pulse™ fiber laser in vivo: Ablation speed and retropulsion effect. Eur Urol Suppl 2019;18:e501-2.
12. Keller EX, De Coninck V, Doizi S, Daudon M, Traxer O. What is the exact definition of stone dust? An in vitro evaluation. World J Urol 2021;39:187-94.
13. Ventimiglia E, Pauchard F, Gorgen AR, Panthier F, Doizi S, Traxer O. How do we assess the efficacy of Ho: YAG low-power laser lithotripsy for the treatment of upper tract urinary stones? Introducing the Joules’ mm³ and laser activity concepts. World J Urol 2021;39:891-6.
14. Corrales M, Traxer O. Initial clinical experience with the new thulium fiber laser: First 50 cases. World J Urol 2021;39:3945-50.
15. Enikeev D, Taratkin M, Klimer R, Inoyatov J, Azilgareeva C, Ali S, et al. Superpulsed thulium fiber laser for stone dusting: In search of a perfect ablation regimen – A prospective single-center study. J Endourol 2020;34:1175-9.
16. Taratkin M, Azilgareeva C, Korolev D, Barghouthy Y, Tsarichenko D, Akopyan G, et al. Prospective single-center study of SuperPulsed thulium fiber laser in retrograde intrarenal surgery: Initial clinical data. Urol Int 2022;106:404-10.
17. Sabnis RB, Jagtap J, Mishra S, Desai M. Treating renal calculi 1-2 cm in diameter with minipercutaneous or retrograde intrarenal surgery: A prospective comparative study. BJU Int 2012;110:E346-9.
18. Resoru B, Ulsen A, Ziyapak T, Diri A, Atis G, Guven S, et al. Comparison of retrograde intrarenal surgery, shockwave lithotripsy, and percutaneous nephrolithotomy for treatment of medium-sized radiolucent renal stones. World J Urol 2013;31:1581-6.
19. Ibrahim A, Elhilali MM, Fahmy N, Carrier S, Andonian F. Double-blinded prospective randomized clinical trial comparing regular and Moses modes of holmium laser lithotripsy. J Endourol 2020;34:624-8.
20. Majdalany SE, Levine BA, Ghanir K. The efficiency of Moses technology holmium laser for treating renal stones during flexible ureteroscopy: Relationship between stone volume, time, and energy. J Endourol 2021;35:S14-21.

How to cite this article: Vaddi CM, Ramakrishna P, Ganesan S, Swamy S, Andanan H, Babu M, et al. The clinical efficiency and safety of 60W superpulse thulium fiber laser in retrograde intrarenal surgery. Indian J Urol 2022;38:191-6.