Detailed instructions are included for each section. All instructions must be removed, and all sections completed. "Not Applicable" is an acceptable response if the section does not apply to the research.

1. STUDY TITLE

Prospective single-center study comparing Thulium fiber laser to pulsed Thulium:YAG laser in the ureteroscopic treatment of nephrolithiasis

2. PRINCIPAL INVESTIGATOR

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3. STUDY RATIONALE

To our knowledge no large-scale study has examined the outcomes of p-Tm:YAG compared to TFL for the treatment of kidney stones which warrants an investigation giving the promising results previously reported.

4. SPECIFIC AIMS/HYPOTHESES

Our primary objective is to assess stone dusting ablation efficiency (Joules/stone volume ablated) between both laser systems in vivo for ureteroscopic stone treatment (Ventimiglia et al., 2021, 2023; Corrales and Traxer, 2022). Secondary objectives include assessing stone dusting ablation speed (stone volume ablated/lasing time), stone-related clinical outcomes, effect of hard stones (>1000HU) on ablation efficiency, and safety/complication profile of both laser systems.

We hypothesize that dusting ablation efficiency and speed of the p-Tm:YAG laser will be non-inferior to TFL for the treatment of renal stones totaling 7-20 mm in diameter with similar clinical and safety/complication outcomes.

5. BACKGROUND AND SIGNIFICANCE

Ureteroscopic stone treatment is a minimally invasive procedure commonly performed for kidney stones. Recently, the thulium fiber laser (TFL) has demonstrated effectiveness in this procedure. A new laser system developed by Dornier, the Thulio pulsed Thulium:YAG (p-Tm:YAG) is beginning to be studied in vitro (Huusmann et al., 2021; Petzold et al., 2021a, 2021b, 2021c, 2021d; Kraft et al., 2022a, 2022c; Kwok et al., 2023) and in vivo (Panthier et al., 2023). Dornier Thulio p-Tm:YAG may represent an attractive new laser platform, with comparable properties to TFL including decreased retropulsion, (Petzold et al., 2021b) smaller dust, (Petzold et al., 2021a) and improved ablation efficiency relative to Ho:YAG. (Petzold et al., 2021a; Kraft et al., 2022a; Solano et al., 2023) Moreover, the p-Tm:YAG laser has been shown to be effective in treating a wide range of human stone types. (Kwok et al., 2023). The Dornier Thulio p-Tm:YAG laser has been tested clinically in a limited fashion via pilot studies in URS (Panthier et al., 2023) and the RevoLix Hybrid Thulium Laset (HTL) was studied in mini-PCNL (Bergmann et al., 2023). However, limited research has directly compared its efficacy and safety and no prospective comparative trials have been published. This study aims to investigate whether Dornier Thulio p-Tm:YAG laser is non-inferior to TFL in terms of dusting ablation efficiency (J/mm3) and dusting ablation speed (mm3/s) for ureteroscopic stone treatment.

6. RESEARCH DESIGN AND METHODS

Patients will be identified based on operating room schedule, clinic visits or hospital admission. All patients will be counseled on standard treatment options – extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL) and ureteroscopy (URS). The discussion regarding treatment options and subsequent care will not deviate from routine care. Those selecting URS will be enrolled to have data collected prospectively. Patients will be consented prior to surgery for collection of demographics, disease, perioperative, and postoperative data. Abdominopelvic computed tomography (CT) will be used to delineate pre-operative stone size, with measurements

captured in greatest axial and coronal dimensions. A preoperative abdominopelvic CT will be obtained if one is not available as suggested by American Urological Association guidelines. Urinalysis or urine culture will be obtained preoperatively as required in the guidelines. (Assimos et al., 2016) Preoperative alpha blocker will be used at surgeon discretion.

Patients will have flexible URS performed in standard fashion, without deviation from the standard of care. The patient will be brought to the operating room and given general or regional anesthesia per anesthesia and patient preference. The patient will be placed in lithotomy position and prepared and draped in standard fashion. Rigid cystoscopy will be performed and a flexible guidewire will be placed through the ipsilateral ureter to the kidney under fluoroscopic guidance. Any existing ureteral stent will be removed (if present). A second wire will be placed at the discretion of the surgeon. Ureteral dilation will be performed at the discretion of the surgeon. An access sheath will be placed (size and length per surgeon discretion). If sheath cannot be placed patient will be excluded from the study and remainder of the case completed at physician discretion. Flexible URS and laser lithotripsy will be performed using a dusting technique until the surgeon feels it is necessary to switch to fragmentation mode. The surgeon will report the estimated % of the case that was completed by dusting at the conclusion of the case. A 270 micron Thulium laser fiber will be utilized for patients in the TFL group and also a 272 micron p-Tm:YAG laser fiber will be utilized for patients in the p-Tm:YAG group.

Laser settings will be adjusted at the surgeons' discretion but begin at 0.3 J and 10 Hz (long pulse mode for Thulio and short pulse for TFL). (Petzold et al., 2021a) At the surgeon discretion the joules and/or frequencies can be increased by smallest increments available. If possible, a stone fragment will be removed and sent for stone analysis. An additional fragment may be sent for culture at the discretion of the surgeon. Adequacy of dusting will be defined as stone fragments smaller than the laser fiber diameter. A ureteral stent will be placed at the conclusion of the surgery. A string will be left on the stent at the discretion of the surgeon. Post-operative medical therapy will be an alpha receptor blocker to induce ureteral relaxation if not contraindicated for allergy, cataracts, or history of adverse reaction. Additionally, standard postoperative pain medications will be prescribed at the discretion of the treating surgeon.

The stent will be maintained for 2 to 21 days after surgery. Low-dose CT abdomen/pelvis will be performed at 6 weeks postoperatively to assess for stone-free rate, development or persistence of hydronephrosis/obstruction, and need for ancillary procedures. Telephone calls at 2, 4, and 6 weeks will be placed by the CRC to determine any unreported AEs. First clinic follow-up after stent removal will be performed at 8 weeks after stent removal. Telephone call at 2, 4 and 6 weeks will be made by CRC to determine any unreported AE's.

Lasing time (s), laser energy expended (J), and estimated % of the case completed with dusting will be recorded at the conclusion of the case from the laser data log.

All study procedures are standard of care expect for the randomization aspect, which will randomly assign a patient to one of two laser groups, and data collection.

Demographic fields that will be obtained preoperatively include age, gender, ASA (American Society of Anesthesiologists) score (for comorbidity assessment), height, weight, body mass index (BMI), and primary or recurrent stone, prior stone composition(s). Disease fields that will be obtained include stone volume (calculated with maximal axial and coronal dimensions), average stone Hounsfield units, degree of hydronephrosis (mild/moderate/severe), and prior ureteral stenting or nephrostomy tube placement.

Perioperative fields will include total operative time, presence of preoperative alpha blockers, procedure time, laser time, setting of lithotripsy that was used most frequently during the case, total laser energy used, use of active fragment extraction (# of fragments beyond that for analysis/culture), 1st assist skill level (PGY level), use and size of ureteral access sheath, intra-operative complications, and treatment on any anticoagulation.

Postoperative fields will include length of hospitalization, postoperative complications, stone composition, need for ancillary procedures, stent duration, and stone-free status on postoperative low-dose CT imaging (axial slices 2.5mm and sagittal/coronal 3mm) using residual stone ABC grading (0 fragments, <2mm fragments, 2-4mm fragments) as recently recommended by Journal of Endourology. (Stern et al., 2023).

The trial will be a prospective, study of patients with renal stones 7-20 mm in size located at or above the level of the ureteropelvic junction. Total enrollment will be limited to 100 patients (50 ureteral and 50 renal) for the study with goal of 50 patients (25 ureteral and 25 renal) in each arm. This goal recruitment number is based on a power analysis for a noninferiority study utilizing a pre-determined non-inferiority margin of 20%, and was calculated to provide 90% power with a one-sided significance level of 0.025.

Table 1, adapted from (Solano et al., 2023), was constructed using results from recently published studies reporting ablation efficiency (J/mm3). The median ablation efficiency for TFL in the table was of 5.6 J/mm3 (Enikeev et al., 2021) with IQR 3-9.9. Assuming a normal distribution, the median and IQR values were used to estimate mean of 6.2 J/mm3 and standard deviation of 5.2 J/mm3. (Wan et al., 2014; Luo et al., 2018) Non-inferiority margin was set at 20% (6.2-1.2=5.0 J/mm3). Estimated mean difference between TFL and Tm:YAG ablation efficiencies was 0 based on a recent systematic review by an international expert in the field (Solano et al., 2023). Data was input into a validated sample size calculator https://app.sampsize.org.uk/ as previously described. (Flight and Julious, 2016; Negida, 2020) A sample size of 24 participants per group (n=48 total) was found to provide 90% power to detect a non-inferiority margin of 20% with a one-sided significance level of 0.025.

In a separate power calculation using data from the only published in-vitro direct comparison of TFL to Tm:YAG revealed an average ablated weights across all laser configurations to be 0.61g (SD= 0.44 g) for p-Tm:YAG and 0.76g (SD= 0.51 g) for TFL. (Kraft et al., 2022b) Using a mean difference of 0.16g and a non-inferiority margin of 20% (0.76g-0.15g=0.61g) with a population SD of 0.47g, data was input into a validated sample size calculator https://app.sampsize.org.uk/ as previously described. (Flight and Julious, 2016; Negida, 2020) A sample size of 24 participants per group (n=48 total) was found to provide 90% power to detect a non-inferiority margin of 20% with a one-sided significance level of 0.025.

Laser	Reference	N	Stone size (mm^3)	Stone density (HU)	Laser on time (min)	Ablation speed (mm^3/s)	Ablation efficacy (J/mm^3)
TFL	(Enikeev et al., 2021)	149	179 (94–357)	985 ± 60	1.2 (0.5–2.7)	2.33 (1.33-4.65)	5.6 (3–9.9)
	(Haas et al., 2023)	56	288 (77-371)	990 (726-1203)	5.1 (1.7-7.3)	8.05 (4.55-11.53)	2.4 (1.1-3.2)
	(Korolev et al., 2021)	125	2386 (1083 - 4202)	900 (625–1275)	5.31 (3.3-9.6)	6.8 (4.6-12.5)	3.38 (1.68; 5.36)
			1186 (905–2317)	1100 (750–1350)	5.2 (1.95-8.8)	5.1 (3-8.7)	4.89 (2.77-7.44)
			1337 (878–3665)	1170 (636–1300)	5.9 (3.55-10.53)	4.4 (3.4-7.6)	4.21 (3.3-6.12)
	(Sierra et al., 2022)	50	346 (147–1800)	900 (400-1500)	17.4 (13.2–-24.4)	0.3 (0.2–1.3)	8.7 (4.8–65.2)
			1125 (294-4000)	950 (725-1125)	26.38 (17–57.1)	0.7 (0.4–1.2)	14.3 (7.8–24.7)
	(Taratkin et al., 2022)	153	279.6 (139.4–615.8)	1,020 ± 382 (250–1,900)	2.7 (1.6–6.6)	1.7 (1.0–2.8)	13.3 (7.3–20.9)
	(Vaddi et al., 2022)	126	1061.85 ± 806.81	985.82 ± 302.57	19.78 ± 12.32	0.86 ± 0.31	14.35 ± 5.70
Ho: YAG	(Haas et al., 2023)	52	319 (59-521)	1028 (808-1286)	4.8 (1.2-6.7)	10.46 (3.41-14.46)	1.6 (0.7-2.2)
	(Ventimiglia et al., 2021)	30	1599 (630–3502)	1040 (753–1275)	-	0.7 (0.4–0.9)	19 (14–24)
	(Patil et al., 2022)	51	2770.54 ± 1977.06	1211.68 ± 259.81	11.30 ± 8.23	4.64 ± 2.07	9 ± 5
	(Azilgareeva et al., 2022)	25	508.9 (293.2-628.3)	1124.0 ± 329.0	15.0 (11.2-18.3)	0.6 (0.5-0.9)	30.8 (22.8-41.2)

The electronic data will be stored in the REDCap (Research Electronic Data Capture) application (16,17). REDCap is a stand-alone system with no interaction or connectivity to other systems, and the database is located behind the UCSD firewall. Users must have a UCSD provided ID/password to connect to REDCap and their ID must be specifically

authorized in order to access an individual study's data. All changes to the data, and each "record viewed" is logged back to the individual ID with a timestamp. When the case report forms are configured, each field has an attribute that can be set to flag it as an “identifier”. This “identifier” is used by REDCap to control certain actions related to the field. REDCap also has several built-in functions to control the exporting of identifying information. Individual users are each granted specific export rights, including – None, De-Identified, and Full. Additional export de-identification options include removing identifiers and dates, hashing IDs and date shifting.

Demographic data, pre-operative, and post-operative data will be summarized using mean, median and quartiles (continuous variables) and frequency and percent (categorical variable).

Intention-to-treat analysis will be performed. Non-inferiority analysis will be conducted for the primary endpoints, with a pre-specified non-inferiority margin of 20%.

Secondary endpoints will be compared using appropriate statistical tests (e.g., t-test, chi-square test).
All analyses will be performed using a statistical software package (e.g., SPSS).

7. RESEARCH PARTICIPANTS

We plan to enroll 100 participants in this study at the University of California, San Diego.

Inclusion criteria:

- Solitary renal stone 7 to 20 mm in size or in the case of multiple stones the conglomerate diameter (additive maximal diameter of all stones on axial imaging of computed tomography) of 7-20 mm is required
- Must be a suitable operative candidate for flexible ureteroscopy per American Urological Association guidelines
- Must be 18 years or older
- Must be able to give consent
- Bilateral ureteroscopy will be permitted but only the first side (per surgeon discretion) will be included in the study
- Surgeons participating in the study must be urological attending surgeons or fellows with subspecialty training in Endourology

Exclusion criteria:

- Concomitant stones in the ureter
- Prior ipsilateral upper urinary tract reconstructive procedures or history of ipsilateral ureteral stricture
- Prior radiotherapy to the abdomen or pelvis
- Neurogenic bladder or spinal cord injury
- Pregnancy
- Untreated UTI

8. RECRUITMENT

Ureteroscopic treatment of renal calculi is the standard of care treatment approach, and thus no treatments will be performed that are not considered standard of care.

Patients will be identified based on operating room schedule, clinic visits or hospital admission. They will be approached in person by study personnel.

Using block randomization, participants will be randomized in a 1:1 ratio to receive either p-Tm:YAG or TFL treatment. Surgeons will be blinded to the assigned laser treatment until in the operating room.

Project subjects will be chosen from the pool of patients presenting in a UCSD Urology clinic with kidney stone disease who have chosen to undergo flexible ureteroscopy with holmium laser lithotripsy. Females of childbearing age are given a pregnancy test prior to the procedure. No person shall be excluded from being offered the trial except those based on the above inclusion/exclusion criteria. Vulnerable groups such as pregnant women, fetuses; neonates; prisoners; children; groups with known cognitive impairment; or institutionalized individuals will not be involved in this project. This project has neither direct benefit to individual participants nor monetary compensation, and as such is less likely to lead to coercion of patient populations.

This project will be requesting a partial waiver of HIPAA authorization to be granted. Identifiers will be protected from improper use by having access restricted to project personnel which is limited to the PI and project coordinator. Identifiers will be destroyed 4 years after the project initiation or 2 years after data collection is complete. Project recruitment could not be possible without access to medical chart information which includes PHI. This access to PHI poses minimal risk as it is not used for reasons other than identifying potential participants. No PHI will be used as part of data collection for the project except name on the Informed Consent Form.

9. INFORMED CONSENT

The treating physician, also a project team member, will first determine if potential project subjects, who are candidates for ureteroscopy with holmium laser lithotripsy, are interested in participating in the research project, and upon agreement, a project team member or project coordinator will introduce the project details and initiate the consent interview. All project subjects will be asked to review, understand, and sign an Informed Consent Form and HIPAA form before enrolling in this project. Consent will be performed by either the treating physician, also a project team member, or the project coordinator in a private examine room or other private space where confidentiality and privacy of the consenting process can be maintained. Those obtaining consent will use lay language to ensure participants understand fully. There will be no exculpatory language used in the consenting process. Project subjects will only be recruited from patients presenting at the UCSD Urology Clinic seeking Standard of Care treatment for their kidney stone disease that meet all inclusion and exclusion criteria. Students or employees will only be invited to join the project only if they fall into the above group and will be reminded that their participation is strictly voluntary. Unintended coercion will be avoided by ensuring that all potential candidates are informed their participation is voluntary and their decision will in no way effect the care they receive. Potential subjects who agree to consider participation will be asked to verbalize that they are finished considering their participation. This will ensure that each potential subject is provided the amount of time they require to consider participation

We will make use of a document translated into the participant's primary language, the use of an "official" translator, and continued, qualified interpretive services will be offered to the participant throughout the duration of the study.

10. BANKING OF INFORMATION/BIOSPECIMENS FOR FUTURE USES

N/A

11. MINIMIZATION OF RISK

As part of standard of care, coinciding with this research project, participants will be exposed to radiation from scheduled CT scan of the abdomen and pelvis. The total exposure resulting from these imaging studies is calculated to be approximately 9.15 mSv – 9.65mSv. This amount is more than one would receive from one year of natural exposure in the San Diego area, which is approximately 1.6 mSv—but is what would be expected from standard of care imaging that kidney stone patients receive during routine care. Cumulative exposure from radiation may increase one's risk of developing certain types of cancer in the future.

The principal investigator for this research project has determined and verified that all imaging scans prescribed for this project would typically be performed as part of the standard medical care required to adequately monitor the participant's current illness. If they are especially concerned with radiation exposure, or they have had a lot of x-rays or imaging scans already, they should discuss this with the principal investigator for this project, Dr. Sur, or their regular doctor.

We have taken multiple steps to protect the privacy and confidentiality of each subject, specifically data collection using a HIPAA compliant database (REDCap), and ensuring that any data analysis will be without identifiers.

Subjects in this project will not directly benefit in this project from the information gained but will contribute overall to medical knowledge. It is already common practice in clinical medicine to perform ureteroscopy/lithotripsy for renal stones with intra-renal pressure measurements, but the influence of intra-renal pressure on surgical outcomes has not been defined. The results of this project would have significant impact on the greater kidney stone community.

12. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

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